Comparison of Clinical Outcomes of Silver-modified Atraumatic Restorative Technique vs Atraumatic Restorative Technique in Primary Teeth: A Randomized Controlled Trial

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ABSTRACT

Aim: To compare the clinical outcomes of silver-modified atraumatic restorative technique (SMART) vs atraumatic restorative technique (ART) in primary teeth.

Materials and methods: This study was a randomized clinical trial conducted on 30 children. The study was split-mouth design, so each group was consisted of 30 children. Children aged 3–6 years old of both genders. Communication with the children was established. Gross debris from cavitation was removed. Carious dentin on walls was excavated using spoon excavator and low-speed contra with round or fissure bur. The areas to be treated were isolated with cotton rolls. For ART, glass ionomer cement (GIC) was applied according to the manufacturer's instructions. For silver-modified atraumatic restorative technique (SMART), a protective coating was applied to the lips and skin to prevent a temporary tattoo. Silver diamine fluoride (SDF) was applied carefully using bended microsponge brush. It was applied directly to only the affected tooth surface. The lesion was dried for 15 seconds with gentle flow of compressed air. After 1 week, GIC was applied according to the manufacturer's instructions. Clinical evaluation was done for all teeth at 6 and 12 months. The data were collected and then statistically analyzed using the Chi-square test to show the difference between groups.

Results: The restoration of the first primary molar with ART restoration alone showed a lower success rate when compared with the restoration with a combination of SDF and ART (SMART technique), with percentages of 70% and 76.67% and 53.33% and 60% after 6 months and 12 months of follow-up, respectively.

Conclusion: Silver diamine fluoride is successful in arresting dentin caries and can be used to increase the efficacy of the ART technique in primary teeth.

Clinical significance: It is recommended to use SDF as a noninvasive approach to control dentin caries with the ART technique.

Keywords: Atraumatic restorative technique, Randomized clinical trial, Silver diamine fluoride, Silver-modified atraumatic restorative technique.

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INTRODUCTION

A study published in 2019 reported an early childhood caries (ECC) prevalence (69.2%) among the 3–6-year-old Egyptian preschool children.¹ Assessing methods to provide timely, cost-effective, and culturally accepted services are challenges for the implementation in preschool children with high caries prevalence.²

A high number of untreated carious lesions presented in preschool children compared with other age-groups.^{3,4} The overall health of children from low-income countries as well as their learning activities in school are affected by untreated dental caries. The inadequate resources, insignificant access to primary oral care, and the higher expenses for restorative dentistry are causes for healthcare loss.⁵ As reported by parents, dental fear, economic confines, scheduling difficulties, and conveyance issues are among the obstacles to dental care for children.⁶

Conventionally, in children, the management of the carious lesions through surgical removal of the carious tissue and the replacement with a suitable restorative material can be challenging for the young child, the family, and the dental team.⁷ So, minimal

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Informed consent: The children were recruited to this study after their parents were assigned informed written consent.

Statement of human rights: This study was ethically conducted in accordance with the Declaration of Helsinki. This study was approved by the ethical committee of scientific research of Faculty of Dentistry (Mansoura University) with the code number: A 04030919.

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invasive dentistry (MID), which aims at maintenance of the sound tooth structure using noninvasive techniques, has replaced the conventional techniques of ⁸ MID such as ART,⁹ SDF,¹⁰ and SMART.¹¹

The ART had a very good success rate in treating dentine caries in young children because preschool children are too young to cope with long conventional dental treatment.⁹ Due to its effectiveness in delaying the cycle of restoration and feasibility, the ART is now receiving support to be a vital component in dental public health services for young children and the children with special needs.¹²

Atraumatic restorative technique showed high rate of success with highly viscous glass ionomer cement (HVGIC) in primary teeth. This is recorded by a systematic review and meta-analysis on the quality of ART. The result was 93% and 62% over 2 years for single-and multiple-surface ART, respectively.¹³

Modified ART techniques include opening the enamel to access the dentin with a high-speed headpiece, applying SDF to arrest caries, and then use materials such as resin-modified glass ionomer, this technique is called silver-modified atraumatic restorative treatment (SMART) technique.¹⁰

Application of SDF can be done either immediately before placing a restoration or waiting for a few days or weeks until the carious lesions have arrested, sensitivity has resolved, or the patient has become familiar to the dental environment. Using SDF before restoration placement may reduce carious lesion progressing and decrease irreversible pulpitis. However, there are currently no randomized control trials investigating effectiveness of SMART technique compared with other restorative options.^{14–16}

The advantages of SDF are that it is efficient and can be applied with minimum training in less than 1 minute by health professionals in various health and communities. It is favorable for pediatric patients due to its ease of application, so it meets the instant needs of a child in one treatment session as it is minimally invasive and painless.¹⁷ The main disadvantage of SDF is the presence of silver compounds leads to the black staining of the carious lesions.¹⁵

dos Santos et al.¹⁸ applied a randomized controlled study to compare the effect of ART with 30% SDF in 91 children. *Results:* After 12 months, SDF treatment was more effective than intermediate restorative treatment (IRT) for arresting of caries. Their conclusion was that the SDF treatment showed better effects than IRT arresting of caries in deciduous teeth, indicating its use for underdeveloped countries.

MATERIALS AND METHODS

Ethics

This study was confirmed by the Ethical Committee of Scientific Research of Faculty of Dentistry (Mansoura University) with the code number: A 04030919. The children recruit to this study after their parent assigned an informed written consent.

Study Model

The protocol followed the recommendations of the Consort Statement (Flowchart 1). This was a randomized controlled clinical trial. ClinicalTrials.gov Identifier: NCT05438381. The design of the study was a split-mouth design to decrease variability and decrease the number of participants.

Sample-size Calculation

Based on the results of dos Santos et al.,¹⁸ for the evaluation of the effectiveness of the treatments for arrest of decay, the percentage of SDF success after 6 months was 84.7%, while for IRT was 53.1%. For this study, a sample size of 30 was obtained using unpaired two-sample two-tail *z*-test. The effect size (dz = 2.813) and the required sample size were calculated for $\alpha = 0.05$ and a confidence power of 0.8039, assuming a normal distribution.

Patient Selection

This study was conducted on 13 children selected from Pediatric Dental Clinic, Faculty of Dentistry, Mansoura University.

Inclusion Criteria

The children included in the study were aged 3–6 years old of both genders, apparently healthy and free from any systemic diseases or chronic conditions, have bilateral restorable carious cavitated lower first primary molars asymptomatic, or have reversible pulpitis.

Flowchart 1: Evaluation, enrollment, randomization, dropout, and completion of participants (the CONSORT flowchart)



Exclusion Criteria

The children were excluded if they have chronic systemic conditions or have irreversible pulpitis.

Randomization

The study was split-mouth design. The right side of all participants was done ART and the left side was SMART.

Clinical Procedures

- Communication with the children was established.
- Gross debris from cavitation was removed.
- Carious dentin on walls was excavated using spoon excavator and low-speed contra with round or fissure bur.
- · Areas to be treated were isolated with cotton rolls.
- Dryness of the lesion with gentle flow of compressed air was done.

Control Group: Right Side of the Patient (ART Technique) (Group I) (D1)¹⁹

 GIC FujiTM II capsule (GC, USA) was applied according to the manufacturer's instructions.

Experimental Group: Left Side of the Patient (SMART Technique) (Group II) (D2)

- A protective coating was applied to the lips and skin to prevent a temporary henna-appearing tattoo that can occur if soft tissues come into contact with SDF.
- Silver diamine fluoride (38%) from Kids-e-Dental Company was applied carefully using bended microsponge brush. The brush was dipped into SDF and dabbed on the side of the plastic dish to remove excess liquid before application.
- Silver diamine fluoride was applied directly to only the affected tooth surface of the lower first primary molar.
- Excess SDF was removed with gauze, cotton roll, or cotton pellet to minimize systemic absorption.
- Application time was at least 1 minute. No more than one drop of SDF was used for the entire appointment.
- The lesion was dried for 15 seconds with gentle flow of compressed air.
- After 1 week, GIC Fuji[™] II capsule (GC, USA) was applied according to the manufacturer's instructions.

Evaluation

All primary molars were evaluated clinically at 6 months and 12 months of the follow-up period. The following are the evaluation criteria:

• Recurrent caries (catch with probe), pain (spontaneous, with eating, with percussion), clinical abscess, and mobility.

Statistical Analysis

The data were collected, tabulated, and statistically analyzed using SPSS program software, version 20. The results were considered statistically significant at p < 0.05.

• Chi-square test was performed to compare the significance between the groups in clinical evaluation.

RESULTS

This study was a randomized controlled clinical trial using a splitmouth design. The selected children were randomly allocated to two treatment groups: ART restoration using either HVGIC (GC FujiTM II) or SDF-HVGIC (GC FujiTM II).

The clinical evaluation of the involved teeth among the studied groups was compared regarding success/failure after 6 months of follow-up of the different restorative treatment techniques and represented as number and percentages, and then was statistically analyzed using Chi-square test.

Clinical Evaluation after 6 Months

The clinical evaluation of the involved teeth among the studied groups was compared regarding success/failure after 6 months of follow-up of the different restorative treatment techniques and represented as number and percentages, and then was statistically analyzed using Chi-square test, these are summarized in Table 1.

After 6 months of follow-up in a group of children treated with conventional ART, only 9 teeth of the 1st molar tooth (D1) scored failed clinically with a percentage of 30%. Meanwhile, a total of 21 teeth of the 1st molar teeth (D1) scored success clinically with a percentage of 70%. While after 6-months of follow-up in a group of children treated with SMART technique, only 7 teeth of the 1st molar tooth (D2) scored failed clinically with percentage of 23.33%, and a total of 23 teeth of the 1st molar tooth (D2) scored success clinically with a percentage of 76.67%. The results of Chi-square test showed no statistical significant difference in the success and failure rate among the different studied restorative techniques with *p*-value of 0.5593 and Chi-square value of 0.3409.

Clinical Evaluation after 12 Months

Along the study period and at the end of 12-month follow-up in a group of children treated with conventional atraumatic restorative technique, only 14 teeth of the 1st molar tooth (D1) scored failed clinically with a percentage of 46.67%. Meanwhile, a total of 16 teeth of the 1st molar tooth (D1) scored success clinically with a percentage of 53.33%, these are summarized in Table 2 and Figure 1. While, at the end of 12-month follow-up in a group of children treated with SMART technique, only 12 teeth of the 1st molar tooth (D2) scored failed clinically with a percentage of 40%, and a total of 18 teeth of the 1st molar tooth (D2) scored success clinically with a percentage of 60%. The results of Chi-square test showed a statistical significant difference in the success and failure rate among the different studied restorative techniques with a *p*-value of 0.96938 and Chi-square value of 0.0015.

After 12 months of follow-up, the result showed that the restoration of the first primary molar with ART restoration alone

Table 1: Comparison of clinical evaluation follow-up results after 6 months among the studied groups

		Group I	Group II		
Variable		1st molar (D1)	1st molar (D2)	Chi-square	p-value
Clinical evaluation	Success; n (%)	21 (70%)	23 (76.67%)	0.3409	0.5593 ^{ns}
	Failure; <i>n</i> (%)	9 (30%)	7 (23.33%)		

ns, nonsignificant



Table 2. Companson of clinical evaluation follow-up results after 12 months among the studied groups								
		Group I	Group II					
Variable		1st molar (D1)	1st molar (D2)	Chi-square	P-value			
Clinical evaluation	Success; n (%)	16 (53.33%)	18 (60%)	0.0015	0.96938 ^{ns}			
	Failure; <i>n</i> (%)	14 (46.67%)	12 (40%)					

Table 2: Comparison of clinical evaluation follow-up results after 12 months among the studied groups

ns, nonsignificant



Fig. 1: Shows success of both techniques (ART technique and SMART technique) in lower first primary molars (12 months follow-up)

showed lower success rate when compared with the restoration with a combination of SDF and ART (SMART technique).

DISCUSSION

Early childhood caries is a global health problem that causes pain and infection to many children.²⁰ Studies have shown that ECC is more prevalent among preschool children groups in low socio-economic countries. Mostly, the carious cavitated lesions in preschool children are mostly left untreated.²¹

The study was split-mouth designed to decrease intersubject variability, increase study accuracy, and decrease the number of participants, as each patient was his own control.²² The atraumatic restorative technique was selected in the present study because it is a part of MID concept.²³ It is an alternative approach for surgical management of dental caries which involves the removal of soft, decayed tissue using hand instruments, then application of adhesive material to the cavity.²⁴ Additionally, ART can be considered as an economical, effective method for controlling caries progression in underdeveloped populations.²⁵

Highly viscous glass ionomer cement was chosen as restorative material in this study because it has been accepted in the treatment of primary molars.²⁶ It has been the material of choice for ART technique because of its excellent properties for restoration,^{23,27} including fluoride release, high compressive strength, chemical bond to tooth structures, and thermal expansion coefficient similar to that of the tooth.²⁸ Also, it prevents food trapping and provides an occlusal area for mastication.²¹

However, the major disadvantage of ART is the residual cariogenic bacteria which remain under the restorations.²⁹ As well as the presence of carious lesions in the margins of restorations remains the major reason for the replacement of restorative materials.³⁰

Therefore, SDF was selected in this study as a test material because it is one of the methods available to arrest caries by modifying the bacterial action on the tissue and enhancing remineraliztion. As the fluoride component of SDF strengthens the tooth structure and decreases its solubility against the attack by the acid products of bacterial metabolism,³¹ also, the silver of SD interferes with biofilm formation, so that it kills cariogenic bacteria.³²

In the present study, SDF is used as part of a restorative process by placement of restoration following use of SDF, which is known as SMART restoration.^{33,34} SDF and ART come under the MID concept and aimed to maximum conservation of the tooth structure with the least psychological impact on the child.²¹ It was found that the use of SDF with GIC can improve antibacterial action and the physical properties of the GIC as well as provided the best esthetic profile without deteriorating the GIC fluoride-releasing pattern.³⁵

MID further becomes clinically relevant in the ongoing COVID-19 pandemic, in which minimally invasive procedures have been emphasized for decreasing the burden of dental caries in children.²¹ Moreover, the results of the present study showed that the restoration of the first primary molar with ART restoration alone showed higher failure rate when compared with the restoration with a combination of SDF and ART (SMART technique) after 6 months and 12 months of follow-up. This may be because of the loss of the GIC-filling material, which left open cavities in which carries progression occurred before replacement of the GIC sealant.¹⁸ Moreover, the caries prevention effect of GIC on dentin caries is claimed to be a result of its adhesive property to hard dental structures, so, its ability to seal cavities and prevent marginal linkage of the restoration, isolating the cavity from the external environment and reducing bacterial growth.³⁶

Also, the use of SMART technique that resulted in high success rate after 12 months of follow-up in this study may be explained by using SDF before restoration placement that reduces carious lesion progression and irreversible pulpitis.¹⁵ Moreover, regarding Tantbirojn et al.,³⁷ the fluoride released by GIC would only be effective in preventing the progression of incipient carious lesions, which does not apply to lesions involving dentine. However, the presence of SDF under ART restoration in SMART technique improves the antibacterial activity and remineralization of GIC and helps in enhancing the ability of ART to resist the caries progression.³⁵ This result is in accordance with the results of dos Santos et al.,¹⁸ which reported that after 12 months, treatment with SDF was more effective than GIC for the arrest of caries. Also, Fung et al.³⁸ found that application of SDF has higher success rate of 90.0% in arresting of carious lesions in children.

Limitations of The Study

From the clinical observation during the present study, it was noticed that the GIC restoration in teeth treated with SMART technique has unesthetic black staining due to silver ion release from SDF, which may act as a barrier for acceptance in many children and parents.²¹ Also, the loss of GIC restoration due to wear or solubility was observed.¹⁸ Further investigation of SDF and SMART technique is necessary using esthetic crowns to overcome the color of SDF.

CONCLUSION

Using 38% SDF may be a good method of choice for arresting of caries and increases clinical efficacy of ART technique.

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