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A 24-MONTH CLINICAL ASSESSMENT OF ACTIVE DENTIN CARIES ARRESTING BY SILVER DIAMINE FLUORIDE IN PRIMARY MOLARS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Introduction: Atraumatic restorative technique (ART) has succeeded to gain enormous global attention. Silver Diamine Fluoride (SDF) helps in controlling active carious lesions and aids in prevention of further advancement of caries.

Aim of the study: To clinically assess and compare the efficiency of conventional glass ionomer cement (Fuji IX) and SDF in arresting active dentin caries in primary molars.

Methods: A 25 children aged from 4-7 years with sixty primary molars, affected by active dentin carious lesion (scores 4 or 5) according to ICDAS II were recruited in the current study. All primary molars treated with modified ART. The treated primary molars divided into two groups regarding restorative material: group I restored with Fuji IX while group II with 38% SDF and Fuji IX. Treated primary molars assessed clinically for certain parameters and followed up for 3, 6, 9, 12 and 24 months.

Results: Regarding comparison of assessed clinical aspects (spontaneous pain, mobility, sensitivity to percussion and sinus or swelling) a statistically significant decreasing success rate in both group I (*P*-value <0.001, effect size = 0.364) and group II (*P*-value <0.001, effect size = 0.187) was found. Regarding Kaplan-Meier survival analysis the mean survival time for group I was 18.5 months and for group II was 22.1 months. No statistically significant difference between survival of both groups (*P*-value = 0.082).

Conclusion: A 38% SDF provides easy and efficacious substitutional method for treatment of early childhood caries in children versus conventional restorative treatment with higher longevity, treatment results and prognosis.

KEYWORDS: Silver diamine fluoride (SDF), active dentin caries, primary molars, non-invasive treatment, minimally invasive treatment.

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INTRODUCTION

Dental caries considered a global general public health problem particularly amongst school age children. Unlike other infectious disease, it has agreed to be non-self-limiting condition, where if begins and left without treatment its progression is fast which can possess a negative impact on children's quality of life specially toddlers if suffer from caries at early phase may have higher susceptibility in both dentitions. (1)

The atraumatic restorative treatment (ART) become a worldwide interesting technique specially in developing states due its ease of application as it is believed to be a painless restorative approach which includes no local nor drilling. The ART comprises the use of hand instrument in removing of dental caries and restoring it by extremely viscid glass ionomer cement that adheres chemically to the surface of the tooth and providing the release of fluoride at the same time, it considered a biocompatible material. In addition, it has used to seal adjacent pits and fissures through insertion by using finger pressure. (2)

The Glass ionomer cements exhibit many likable qualities as antibacterial abilities; release of fluoride, its coefficient of thermal expansion mimics the tooth structure and superior marginal seal due to physiochemical bonding to tooth structure. (3)

However, the poor physical properties of glass ionomer as its tendency to demonstrate surface grazing, lower resistance to fracture and poor aesthetics aid in the limitation of its use, which in turns increase the demand for restorative material development for children throughout the past decades.(4)

The innovation of a new types of glass ionomer GC Fuji IX GP has gained popularity in pediatric dentistry. It possesses some advantages as fluoride release, tooth structure adhesion without requiring extra aid from bonding system, sufficient strength and ability for finishing and polishing in single visit.(5)

Lately some various non-operative procedures that is efficient and reasonable are adopted in treating caries in children. These comprises brushing teeth with fluoridated toothpaste and utilizing several fluoride agents for retarding the advancement of the caries process as SDF which become popular because of excellent abilities in dentine caries arrest. (6)

Silver Diamine Fluoride (SDF) become accepted as a clinical therapy that is applicable in controlling active carious lesion and assist in further prevention of the dentine caries. Its usage safe, easy, non-invasive and reasonable. Despite its disadvantage, which is staining the carious lesion darkly during its arrest, it supplies clinicians by an additive means for treating carious lesions, when aesthetics is not a major interest. (7)

Many researchers studied the effect of SDF on active dentine caries arrest in children for 12-months follow up, but rare studies follow up its effect for 24-months. Therefore, the aim of this study is clinical assessment of arresting active dentine caries by SDF in primary molars for 24-months.

SUBJECTS AND METHODS

Study settings and design

A randomized clinical trial. The participants in the study were chosen from the children visiting the outpatient clinic of Pediatric Dentistry Department, Faculty of Dentistry, Suez Canal University, Egypt where, treatment and follow up of patients was done after 3 months, 6 months, 9 months, 12 months and 24 months was performed. Ethical approval was obtained from the Research Ethical Committee (47/2017).

Sample size calculation

The power of the sample was calculated using the G-Power 3.13 power analysis software. The minimum required sample for the one-way ANOVA and post –hoc test, with alpha of 0.05, will be 30

samples in each group. Thus, a total of 60 teeth were divided into 2 groups for the purpose of this study.

Study population

Sixty deciduous molars in 25 children that fulfilled the inclusion criteria of the study were selected. They aged from 4-7 years showing 2 deciduous molars at least with active dentin caries (scores 4 or 5) depending on the International Caries Detection and Assessment System (ICDAS II) [8]

Eligibility criteria

Inclusion criteria:

1. Both genders.
2. Apparently healthy and medically free.
3. Range of age (4-7 years).
4. At least two bilaterally deciduous molars having active dentin caries (scores 4 or 5).
5. Negatively rating (2) uncooperative child patients depending on Frankel's behavior rating scale.
6. No evidence of clinical pulpal exposure or degradation. [9]
    - Absence of spontaneous pain or pain not alleviated by painkiller.
    - Absence of pain on percussion.
    - Absence of prematurely mobile primary teeth.
    - Absence existent abscess or a sinus.
7. Neither internal or external resorption of the root nor periapical and/or inter-radicular radiolucency proved by preoperatively periapical radiograph.

Exclusion criteria:

1. Children allergic to silver confirmed after recording history and implementing skin test.
2. Children suffering from ulcerative gingivitis.

After finishing the personal data, medical and dental histories, examination of the children clinically and radiographically was done. The preoperative digital x-ray films were recorded in the child file on the personal computer.

Before any clinical operative procedures, the clinical examinations for all patients were performed. Random assignment of the eligible consented participants to either right or left side was done. Equal division of the selected teeth into 30 molars for the control group and 30 molars for the intervention group done depending on the sequence created on the Microsoft Excel sheet, in which simple randomization of the control group (I) and the experimental group (II) were done in a simple way.

Conventional glass ionomer (Fuji IX GP FAST) was used in restoration of the control group **(I),** while 38% silver diamine fluoride was used in treatment of the experimental group **(II)** followed by restoration by conventional glass ionomer (Fuji IX GP FAST). Removal of the softly carious superficially infected dentin layers on the walls of the cavity was done utilizing the atraumatic restorative technique by means of sharp spoon excavator. Water spray was used for thorough cleaning of the prepared cavities then air-dried.

Follow up of patients carried out after 3 months, 6 months, 9 months, 12 months and 24 months. During each follow up visit, the teeth were assessed for the next clinical features: spontaneous pain (absence or presence), tooth mobility (absence or presence), sensitivity to percussion (absence or presence), and examination of any muco-buccal folds changes. Any tooth showed any of the previous clinical features, the treatment and restoration were counted as failure (F); and anything else was regarded as clinical success (S). (Figure 1)

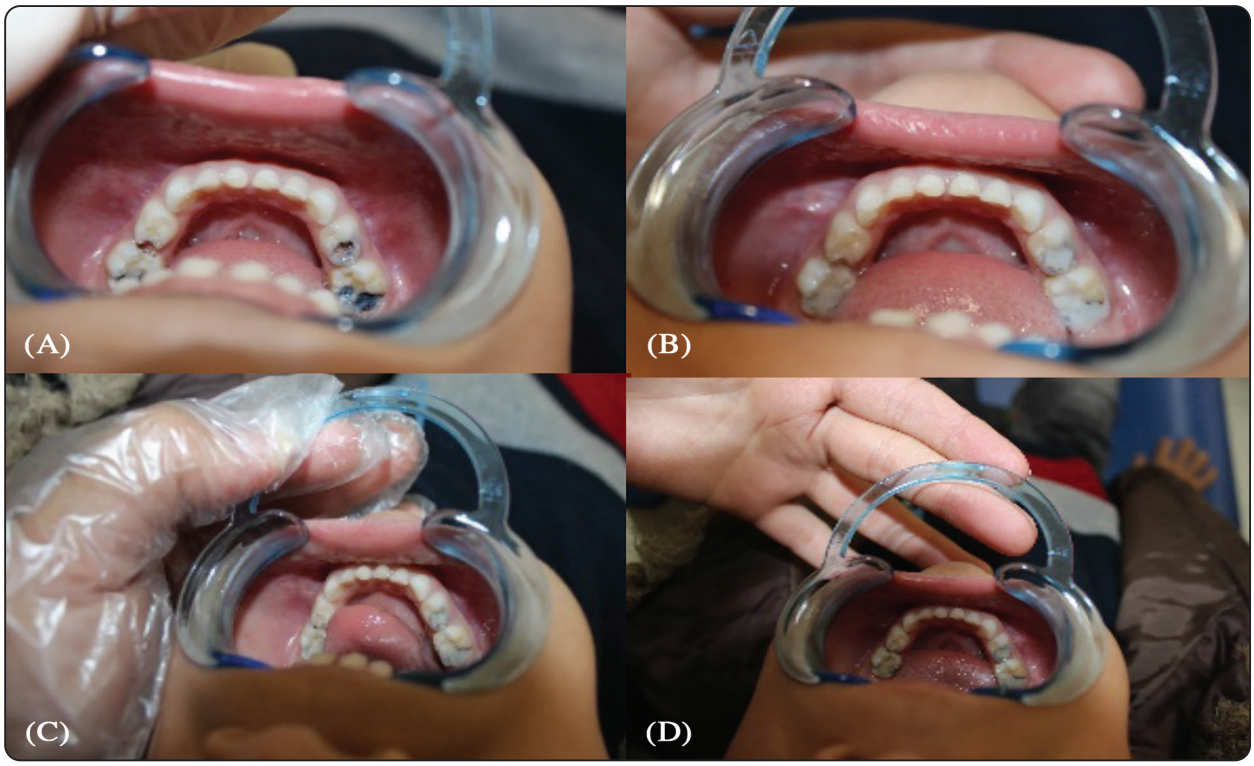

Fig. (1) Follow up intervals, A) preoperative, B) 3 months, C) 9 months, D) 24 months.

STATISTICAL ANALYSIS

Qualitative data were presented as frequencies and percentages. Since the study is a split-mouth design, Wilcoxon signed-rank test used to compare between the two groups. Friedman's test used to study the changes by time within each group. Kaplan-Meier survival curve constructed to calculate the mean survival estimates of the two groups. Comparison between survival times performed using Log rank test. The significance level was set at $P \leq 0.05$. Statistical analysis performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS

I. Demographic data:

The current study was done on 25 patients: 16 boys (64%) and 9 girls (36%). For age the mean values (Standard deviation) were 4.9 (0.9) years with 4 years old minimum and 7 years old maximum.

The study used 60 deciduous molars: 14 first deciduous molars (23.3%) and 46 second deciduous molars (76.7%). The upper deciduous molars were 12 (20%) and the lower deciduous molars were 48 (80%).

II. Clinical evaluation:

1. Spontaneous pain: (Table 1)

At base line, all cases in the two groups were successful. After 3 as well as 6 months, Fuji IX group showed statistically significantly lower success than Fuji IX + Silver Diamine Fluoride group. Absolute risk reduction values were 17.8% and 19.7%, respectively denoting that the risk of pain is reduced by17.8% after 3 months and 19.7% after 6 months when receiving Fuji IX + Silver Diamine Fluoride. After 9, 12 as well as 24 months; no statistically significant difference between both groups was found.

Regarding the changes, there was a statistically significant change in success rate within each group. In both groups, there was a decrease in success rate after 3 months, from 3 to 6 as well as 6 to 9 months. No change in success rate from 9 to 12 months. From 12 to 24 months, there was a decrease in success rate and increase in dropouts in Fuji group while in Fuji IX + Silver Diamine Fluoride group there was a decrease in failure rate and an increase in dropouts.

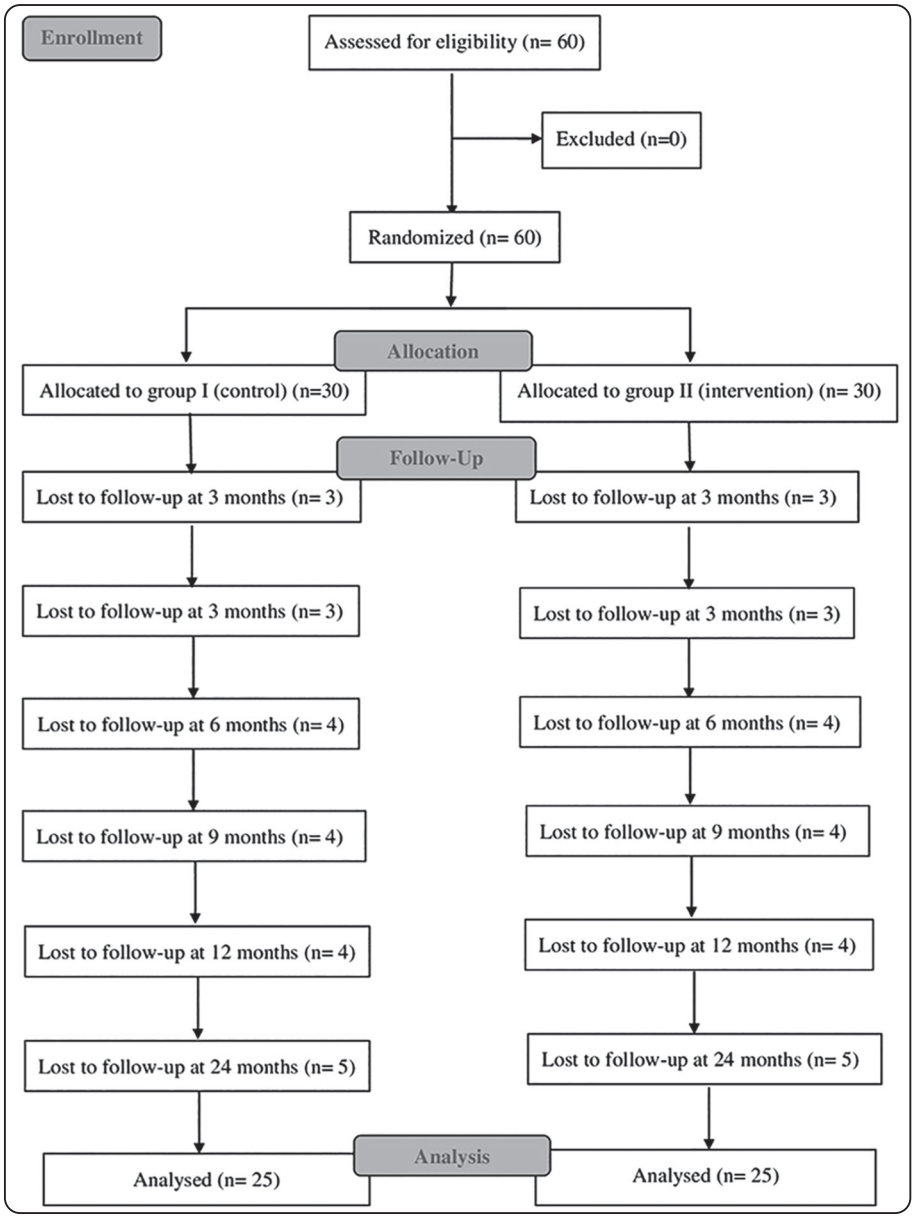

Fig. (2) Shows the number of cases involved in the two groups at different study periods.

TABLE (1) Descriptive statistics and results of Wilcoxon signed-rank test for comparison between spontaneous pain in the two groups and Friedman's test for the changes in spontaneous pain within each group

Time	Fuji IX (n = 30)		Fuji IX + Silver Diamine Fluoride (n = 30)		*P*-value	*Absolute Risk reduction*
	n	%	n	%		
Base line:					1.000	-
Success (No pain)	30	100	30	100		
3 months:					0.034*	17.8%
Success (No pain)	20	66.7	26	86.7		
Failure (pain)	7	23.3	1	3.3		
Drop-out	3	10	3	10		
6 months:					0.035*	19.7%
Success (No pain)	17	56.7	24	80		
Failure (pain)	9	30	2	6.7		
Drop-out	4	13.3	4	13.3		
9 months:					0.109	16.9%
Success (No pain)	16	53.3	22	73.3		
Failure (pain)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
12 months:					0.109	16.9%
Success (No pain)	16	53.3	22	73.3		
Failure (pain)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
24 months:					0.052	18.7%
Success (No pain)	15	50	22	73.3		
Failure (pain)	10	33.3	3	10		
Drop-out	5	16.7	5	16.7		
***P*-value**	<0.001*		<0.001*			
Effect size (w)	0.364		0.187			

: Significant at P ≤ 0.05

2. Tooth mobility: (Table 2)

At base line, all cases in the two groups were successful. After 3 months, no statistically significant difference between both groups was found. After 6 months, Fuji IX group showed statistically significantly lower success than Fuji IX + Silver Diamine Fluoride group. Absolute risk reduction value was 14.1% denoting that the risk of tooth mobility is reduced by 14.1% after 6 months when receiving Fuji IX + Silver Diamine Fluoride. After 9, 12 as well as 24 months; there was no statistically significant difference between both groups.

Regarding the changes, there was a statistically significant change in success rate within each group. In both groups, there was a decrease in success rate after 3 months, from 3 to 6 as well as 6 to 9 months. No change in success rate from 9 to 12 months. From 12 to 24 months, there was a decrease in success rate and increase in dropouts in Fuji group while in Fuji IX + Silver Diamine Fluoride group there was a decrease in failure rate and an increase in dropouts.

TABLE (2) Descriptive statistics and results of Wilcoxon signed-rank test for comparison between tooth mobility in the two groups and Friedman's test for the changes within each group

Time	Fuji IX (n = 30)		Fuji IX + Silver Diamine Fluoride (n = 30)		*P*-value	*Absolute Risk reduction*
	n	%	n	%		
Base line:						
Success (No mobility)	30	100	30	100	1.000	-
3 months:						
Success (No mobility)	22	73.3	26	86.7		
Failure (Mobility)	5	16.7	1	3.3	0.102	11.9%
Drop-out	3	10	3	10		
6 months:						
Success (No mobility)	17	56.7	24	80	0.035*	14.1%
Failure (Mobility)	9	30	2	6.7		
Drop-out	4	13.3	4	13.3		
9 months:						
Success (No mobility)	16	53.3	22	73.3	0.109	16.9%
Failure (Mobility)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
12 months:						
Success (No mobility)	16	53.3	22	73.3	0.109	16.9%
Failure (Mobility)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
24 months:						
Success (No mobility)	15	50	22	73.3	0.052	18.7%
Failure (Mobility)	10	33.3	3	10		
Drop-out	5	16.7	5	16.7		
***P*-value**	<0.001*		<0.001*			
Effect size (w)	0.364		0.187			

: Significant at P ≤ 0.05

3. Change in muco-buccal fold: (Table 3)

At base line, all cases in the two groups were successful. After 3 months, no statistically significant difference between both groups was found. After 6 months, Fuji IX group showed statistically significantly lower success than Fuji IX + Silver Diamine Fluoride group. Absolute risk reduction value was 19.7% denoting that the risk of change in muco-buccal fold is reduced by 19.7% after 6 months when receiving Fuji IX + Silver Diamine Fluoride. After 9, 12 as well as 24 months; there was no statistically significant difference between both groups.

Regarding the changes, there was a statistically significant change in success rate within each group. In both groups, there was a decrease in success rate after 3 months, from 3 to 6 as well as 6 to 9 months. No change in success rate from 9 to 12 months. From 12 to 24 months, there was a decrease in success rate and increase in dropouts in Fuji group while in Fuji IX + Silver Diamine Fluoride group there was a decrease in failure rate and an increase in dropouts.

TABLE (3) Descriptive statistics and results of Wilcoxon signed-rank test for comparison between change in muco-buccal fold in the two groups and Friedman's test for the changes within each group

Time	Fuji IX (n = 30)		Fuji IX + Silver Diamine Fluoride (n = 30)		*P*-value	*Absolute Risk Reduction*
	n	%	n	%		
Base line:						
Success (No change)	30	100	30	100	1.000	-
3 months:						
Success (No change)	23	76.7	26	86.7	0.180	8.9%
Failure (Change)	4	13.3	1	3.3		
Drop-out	3	10	3	10		
6 months:						
Success (No change)	17	56.7	24	80	0.035*	19.7%
Failure (Change)	9	30	2	6.7		
Drop-out	4	13.3	4	13.3		
9 months:						
Success (No change)	16	53.3	22	73.3	0.109	16.9%
Failure (Change)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
12 months:						
Success (No change)	16	53.3	22	73.3	0.109	16.9%
Failure (Change)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
24 months:						
Success (No change)	15	50	22	73.3	0.052	18.7%
Failure (Change)	10	33.3	3	10		
Drop-out	5	16.7	5	16.7		
***P*-value**	<0.001*		<0.001*			
Effect size (w)	0.359		0.190			

: Significant at P ≤ 0.05

4. Sensitivity to percussion: (Table 4)

At base line, all cases in the two groups were successful. After 3 months, no statistically significant difference between both groups was found. After 6 months, Fuji IX group showed statistically significantly lower success than Fuji IX + Silver Diamine Fluoride group. Absolute risk reduction value was 19.7% denoting that the risk of sensitivity to percussion is reduced by 19.7% after 6 months when receiving Fuji IX + Silver Diamine Fluoride. After 9, 12 as well as 24 months; there was no statistically significant difference between both groups.

Regarding the changes, there was a statistically significant change in success rate within each group. In both groups, there was a decrease in success rate after 3 months, from 3 to 6 as well as 6 to 9 months. No change in success rate from 9 to 12 months. From 12 to 24 months, there was a decrease in success rate and increase in dropouts in Fuji group while in Fuji IX + Silver Diamine Fluoride group there was a decrease in failure rate and an increase in dropouts.

TABLE (4) Descriptive statistics and results of Wilcoxon signed-rank test for comparison between sensitivity to percussion in the two groups and Friedman's test for the changes in within each group

Time	Fuji IX (n = 30)		Fuji IX + Silver Diamine Fluoride (n = 30)		*P*-value	*Absolute Risk Reduction*
	n	%	n	%		
Base line:						
Success (No sensitivity)	30	100	30	100	1.000	-
3 months:						
Success (No sensitivity)	23	76.7	26	86.7	0.180	8.9%
Failure (Sensitivity)	4	13.3	1	3.3		
Drop-out	3	10	3	10		
6 months:						
Success (No sensitivity)	17	56.7	24	80	0.035*	19.7%
Failure (Sensitivity)	9	30	2	6.7		
Drop-out	4	13.3	4	13.3		
9 months:						
Success (No sensitivity)	16	53.3	22	73.3	0.109	16.9%
Failure (Sensitivity)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
12 months:						
Success (No sensitivity)	16	53.3	22	73.3	0.109	16.9%
Failure (Sensitivity)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
24 months:						
Success (No sensitivity)	16	53.3	22	73.3	0.052	18.7%
Failure (Sensitivity)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
***P*-value**	<0.001*		<0.001*			
Effect size (w)	0.355		0.187			

: Significant at P ≤ 0.05

III. Survival analysis: (Figure 3)

As regards to Kaplan-Meier survival analysis, the mean survival time for Fuji IX was 18.5 months with 95% Confidence Interval (15.3 – 21.8) months. Survival time mean for Fuji IX + Silver Diamine Fluoride was 22.1 months with 95% Confidence Interval (20.1 – 24.1) months. No statistically significant difference between survival of both groups was found (*P*-value = 0.082).

TABLE (5) Mean survival time (months), 95% Confidence Interval (95% CI) and results of comparison between survival of the two materials using Kaplan-Meier survival analysis

Fuji IX (n = 30)		Fuji IX + Silver Diamine Fluoride (n = 30)		*P*-value
Mean survival	95% CI	Mean survival	95% CI	
18.5	15.3 – 21.8	22.1	20.1 – 24.1	0.082

: Significant at P ≤ 0.05

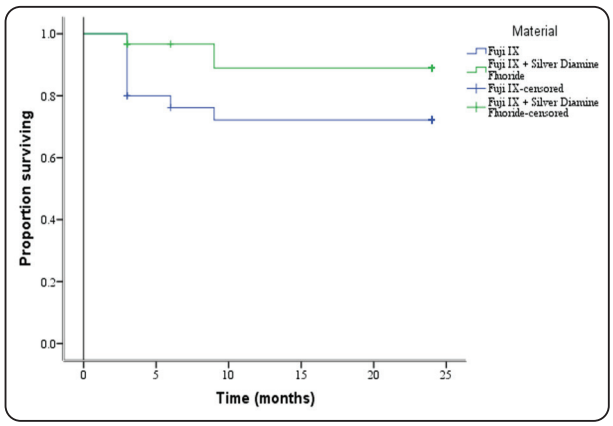

Fig. (3) Flow chart showing the number of cases involved in the two groups at different study periods.

DISCUSSION

Early childhood caries (ECC) is highly prevalent in children globally and is rapidly progressed due to improper removal of dental plaque or poor oral hygiene. Several processes for prevention and caries arresting among children adopted fluoride products[1] but recently SDF gain popularity in treatment of caries due to its low cost and easiness in application. [5]

Atraumatic restorative technique (ART) comprises removal of the superficial soft infected dentine caries by using spoon excavator and leaving the hard-discoloured dentine, which considered as a mechanical form of selective caries removal. [10] The clinical advantage of using this technique is its short time span, which is useful during treatment of children especially who are uncooperative. Furthermore, the clinician will be less fatigued and less stressed during removal of caries that in turns aids in behaviour management of the child. [11]

GIC Fuji IX was selected as a final restoration of the primary teeth treated by ART because it exhibits some properties as chemical adhesion to tooth structure, biocompatibility, acceptable aesthetics, finishing and polishing in single visit, fluoride release, and the similarity of its coefficient of thermal expansion to the tooth. [10,12]

These results might be attributed to the fluoride release ability of the SDF, which aid in silver phosphate deposition resulting in restoration of the mineral content that allowing for tooth structure re-hardening. This may be attributed to the ability of SDF released fluoride penetrate in dentine better than enamel due to the higher content of protein substrate, carbonates, and phosphates available for reaction in dentine. [13] Also, the fluoride release from GIC Fuji IX as stated by Dos Santos and Shahid et al [10,12] may aid in the success rate after follow up for 24-month.

Either application of SDF solution or highly fluoride-releasing glass ionomer annually results in arrest of active carious dentine in deciduous teeth as stated by Zhao et al. [14] In addition, they recommended the increase of application frequency to be on 6 months' basis in order to elevate the caries-arresting rate after application of SDF. Many in vitro studies concluded that the fluoride release from GIC can results in retardation of the caries process progression in the neighbouring teeth surfaces but needs more studies clinically, which may be consistent with the results of the current studies. [9]

As regards clinical results a statistically significant decrease in success rate was found in

group I in comparison to group II concerning the clinical parameters examined (spontaneous pain, mobility, percussion sensitivity and swelling/sinus) proving that dental caries progress towards the pulp. It was clear that a broad extent of carious lesion arrest exists, referring to a proportion (changes according to the study) of carious lesion will not be subjected to arrest.

The findings of the current study were in consistence with those revealed by Niederman et al [15] who stated that using single application of 38% SDF for reducing caries results in 96% caries reduction in primary teeth compared to 55.6% reduction in recently erupted permanent teeth.

Many systematic reviews stated showed successful caries arrest in children after using SDF. Application of SDF showed approximately 89% (from 49 to 138%) higher caries arrest efficiency in deciduous teeth in comparison to other clinical procedures or placebo. [16-18]

The results of the current study agreed with a study done by M. Jiang, et al. who stated that most of the carious lesions treated by SDF had become hard and arrested during probing prior to placement of ART restorative material. He suggested that for young patients' application of SDF firstly to arrest the carious lesion is a good choice. ART approach can restore the primary tooth later for the improvement of aesthetics, function and morphology when the child grows older. [11]

As regards the results of survival rate for both groups, the mean survival time for Fuji IX was 18.5 months with 95% confidence interval (15.3 – 21.8) months while the mean survival time for Fuji IX + Silver Diamine Fluoride was 22.1 months with 95% confidence interval (20.1 – 24.1) months. We can conclude that the restorative material utilized in group II showed better prognosis and treatment outcomes than that utilized in group II, which proves that group II (SDF and Fuji IX) showed higher long life and prognosis than group II (Fuji IX) provided that ART clinical approach was adopted.

Within the limitations of this study, a 24-month follow-up was adopted, but dental restorations believed to serve for a longer time than that, so it would be desirable for the future studies to design a longer follow up period than 24-months.

CONCLUSION

Within the limitations of the present study, we can state that 38% SDF represents a simple, very effective, and widely acceptable nonsurgical alternate management for early childhood caries in children compared to conventional restorative treatment.

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