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ROOT CANAL DISINFECTION USING SILVER DIAMINE FLUORIDE IN PRIMARY MOLARS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Introduction: Irrigating solutions have a key role in providing a successful root canal treatment in primary teeth. Silver diamine fluoride (SDF) is a clear liquid that has an antibacterial potential and was found to be effective against E. faecalis bacteria, which is found in resistant non healing endodontic cases.

Materials and Methods: Sixty non-vital primary molars were included in this randomized clinical trial. Each child had a molar randomly assigned to Group A and the other molar to Group B. In Group A, 30 primary molars were irrigated with 2.5% NaOCl and 17% EDTA solution as a positive control group. In Group B, 3.8% SDF was used as an irrigating solution for 30 primary molars along with the 2.5 % NaOCl and 17%EDTA. The teeth were clinically evaluated each follow up visit for the following clinical features: spontaneous pain, sensitivity to percussion, changes of the muco-buccal folds.

Results: At 3 months and 6 months periods, Group A showed statistically significant greater number of cases showing spontaneous pain. After 6 months; Group A showed a statistically significant increase in sensitivity to percussion compared to Group B (P-value = 0.035, effect size = 0.385). After 6 months; Group A showed a statistically significant changes in the mucco-buccal fold compared to Group B (P-value = 0.035, Effect size = 0.385).

Conclusions:

- SDF 3.8% can be used successfully as an irrigating solution.
- Adding SDF 3.8% in the irrigation regimen will improve the disinfection of the root canals and ultimately the treatment outcome.

KEYWORDS: Root canal disinfection, Irrigation, SDF, Clinical Trial, Molars

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INTRODUCTION

Irrigating solutions have a key role in providing a successful root canal treatment in primary teeth. Different types of irrigating solutions are used in the same tooth in order to increase the antibacterial efficacy of the procedure[1]. Copious irrigation in primary teeth with sodium hypochlorite (NaOCl) is needed for a better antibacterial effect and to dissolve any necrotic pulpal tissue left behind during root canal instrumentation [2]. After using NaOCL, 17% EDTA is advocated to be used followed by a final rinse again with NaOCL to remove the smear layer, however some endodontic cases still fail even after adopting the previous irrigation regimen[3]. Silver diamine fluoride (SDF) is a clear odourless liquid that has an anti-cariogenic potential and a high fluoride release capacity, which allows it to have some disinfectant properties[4]. SDF was found to be effective against E. faecalis bacteria, which is commonly found in resistant non healing endodontic cases[5]. The silver ions in the SDF breaks the cell wall of the micro-organisms then these ions attack the DNA to inhibit the replication of the microbes and they also disrupt cellular respiration [6]. SDF has an inhibitory effect to matrix metallo-proteinases and occludes dentinal tubules thus preventing the ingress of micro-organisms into the pulpal space [7]. Complete sterilization of the root canals is limited due to shortcomings in the currently used irrigation solutions and techniques[8]. Thus the aim of the present study was to evaluate the effectiveness of using SDF as an irrigating solution during the root canal treatment of primary molars. The hypothesis proposed is that the SDF will improve the disinfection properties of the irrigation regimen used.

MATERIALS AND METHODS

Sixty non-vital primary molars were included in this randomized clinical trial. Children who participated in the study were selected from the patients attending the outpatient clinic of Pediatric Dentistry Department, Faculty of Dentistry, Misr International University, Egypt. Approval of the Research Ethical Committee of the Faculty of Dentistry, Misr International University was obtained (MIU-IRB-2223-179) before starting the study. Thirty children with 60 primary molars who met the study inclusion criteria were selected to participate in the study. The selected children's age ranged from 4 to 8 years, and both genders had good general health, and no history of antibiotic coverage for at least two weeks.

Inclusion Criteria

- Healthy and medically free children of both genders.
- Cooperative children.
- Ages ranging from 4–8 years.
- Each child should have two primary non-vital molars with absence of a periapical abscess.
- Maxillary or mandibular primary molars with intact two thirds or more root structure.
- Remaining coronal tooth structure to hold a dental dam.

Exclusion Criteria

- Patients with allergy to silver after taking history and performing skin test.
- Internal root resorption.
- External root resorption
- Inter-radicular or periapical bone destruction (radiolucency).

Consent form and sample calculation:

Parents of the eligible children signed a consent form detailing all the procedures to be performed. Clinical and radiographic examination was done for all patients before any procedure was done and vitality testing was performed for the primary molars. 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, was 30 samples in each group.

Group classification:

Molars were divided randomly into 2 groups, using the software (random.org) into Group A and Group B. Each child had a molar randomly assigned to Group A and the other molar to Group B. In group A, 30 primary molars were irrigated with 2.5% NaOCl (Clorox,Cairo, Egypt) and 17% EDTA solution (Meta Biomed, South Korea) as a positive control group. In group B, 3.8% SDF (Kids-e-dental company, India) was used as an irrigating solution for 30 primary molars along with the 2.5 % NaOCl and 17%EDTA. The 3.8 % solution of the SDF was obtained by 1:10 dilution from the initial 38 % SDF.

Irrigation protocol:

For both Group A and B: irrigation with sodium hypochlorite was carried out through the entire visit, where 9ml of NaOcL was used. One ml of EDTA was used at the end of the preparation followed by a rinse with NaOCL. For Group B: SDF was used as a final rinse with the irrigation time being 120 seconds.

Root canal preparation and obturation:

After rubber dam application (Meta Biomed, south Korea), caries removal then access preparation were done by a diamond bur (Mani, Tokyo, Japan). The root canals of the primary molars in both groups were prepared by a hybrid technique with the ProTaper system (Dentsply Sirona, North Carolina, USA) and manual K-files (M-access, Dentsply Sirona, USA). Root canals were prepared by manual instrumentation using a size 15 K-file followed by S1 and S2 rotary files; then manual instrumentation was done with size 20 K-files followed by F1 rotary file. Finally manual instrumentation was done with size 25 and 30 K-files (10).

In both groups obturation was carried out by injection using the Metapaste (Meta Biomed, South Korea) which is a combination of calcium hydroxide and iodoform in a paste form.

Root canal preparation and obturation was performed in all molars in a single visit.

Follow up and clinical evaluation:

The clinical follow up evaluation was carried out after 3 months, 6 months, 9 months and 12 months. The teeth were clinically evaluated each follow up visit for the following clinical features: spontaneous pain (presence or absence), sensitivity to percussion (presence or absence), examination of any changes of the mucobuccal folds (swellings or sinus tracts).

Statistical analysis

Qualitative data were presented as frequencies and percentages. Since the study was a randomized design; Wilcoxon signed-rank test was used to compare between the two groups. Friedman's test was used to study the changes by time within each group. Numerical data were explored for normality by checking the distribution of data and using tests of normality (Kolmogorov-Smirnov and Shapiro-Wilk tests). Data showed normal (parametric) distribution and were presented as mean and standard deviation (SD) values. Two-way repeated measures ANOVA test was used to compare between the groups as well as to study the changes by time within each group. Bonferroni's post-hoc test was used for pair-wise comparisons. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

RESULTS

Spontaneous pain:

At base line (preoperative assessment), none of the patients in both groups complained from spontaneous pain. At 3 months and 6 months periods,

Group A showed statistically significant greater number of cases showing pain. However, after 9 as well as 12 months; there was no statistically significant difference between the two groups (*P*-value = 0.109, effect size = 0.293) and (*P*-value = 0.109, Effect size = 0.293), respectively (Table 1). Regarding the changes within each group during the follow up period, there was a statistically significant increase in the number of cases showing spontaneous pain within Group A (*P*-value <0.001, effect size = 0.367) and Group B (*P*-value <0.001, effect size = 0.187). However, from 9 to 12 months follow ups, there was no cases showing spontaneous pain.

TABLE (1) Descriptive statistics and comparison between both groups regarding the spontaneous pain:

Time	Group A (n = 30)		Group B Silver Diamine Fluoride (n = 30)		*P*-value	*Effect size (r)*
	N	%	N	%		
Base line						
(No pain)	30	100	30	100	1.000	0.000
3 months						
(No pain)	20	66.7	26	86.7		
(pain)	7	23.3	1	3.3	0.034*	0.387
Drop-out	3	10	3	10		
6 months						
(No pain)	17	56.7	24	80		
(pain)	9	30	2	6.7	0.035*	0.385
Drop-out	4	13.3	4	13.3		
9 months						
(No pain)	16	53.3	22	73.3		
(pain)	10	33.3	4	13.3	0.109	0.293
Drop-out	4	13.3	4	13.3		
12 months						
(No pain)	16	53.3	22	73.3		
(pain)	10	33.3	4	13.3	0.109	0.293
Drop-out	4	13.3	4	13.3		

: Significant at P ≤ 0.05

Sensitivity to percussion

At base line, all patients in the two groups did not complain from pain on percussion. After 3 months; there was no statistically significant difference between the two groups (*P*-value = 0.180, effect size = 0.245). However after 6 months; Group A showed a statistically significant increase in the number of patients showing sensitivity to percussion (nine patients) than Group B (two patients) (*P*-value = 0.035, effect size = 0.385). After 9 and 12 months; there was no statistically significant difference between the two groups (*P*-value = 0.109, effect size = 0.293) and (*P*-value = 0.109, effect size = 0.293), respectively (Table 2).

TABLE (2) Descriptive Statistics and Comparison between both groups regarding sensitivity to percussion :

Time	Group A (n = 30)		Group B Silver Diamine Fluoride (n = 30)		*P*-value	*Effect size (r)*
	N	%	N	%		
Base line						
(No sensitivity)	30	100	30	100	1.000	0.000
3 months						
(No sensitivity)	23	76.7	26	86.7		
(Sensitivity)	4	13.3	1	3.3	0.180	0.245
Drop-out	3	10	3	10		
6 months						
(No sensitivity)	17	56.7	24	80		
(Sensitivity)	9	30	2	6.7	0.035*	0.385
Drop-out	4	13.3	4	13.3		
9 months						
(No sensitivity)	16	53.3	22	73.3		
(Sensitivity)	10	33.3	4	13.3	0.109	0.293
Drop-out	4	13.3	4	13.3		
12 months						
(No sensitivity)	16	53.3	22	73.3		
(Sensitivity)	10	33.3	4	13.3	0.109	0.293
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						

Changes in the muco-buccal fold: (swelling or sinus tract)

At base line, the muco-buccal fold of all patients in the two groups was normal. After 3 months; there was no statistically significant difference between the two groups (*P*-value = 0.180, effect size = 0.245). After 6 months; Group A showed a statistically significant greater amount of patients with changes in the muco-buccal fold compared to Group B (*P*-value = 0.035, Effect size = 0.385). After six months, Group A showed (nine patients) with changes in the muco-buccal fold, five patients with sinus tract in the muco-buccal fold and four patients with swellings related to the teeth, while the two patients in Group B showed sinus tracts in the muco buccal fold. After 9 and 12 months; there was no statistically significant difference between the two groups (*P*-value = 0.109, effect size = 0.293) and (*P*-value = 0.109, effect size = 0.293), respectively (Table 3).

TABLE (3) Descriptive statistics and comparison between both groups regarding changes in the muco-buccal fold:

Time	Group A (n = 30)		Group B Silver Diamine Fluoride (n = 30)		*P*-value	*Effect size (r)*
	n	%	N	%		
Base line						
(No change)	30	100	30	100	1.000	0.000
3 months						
(No change)	23	76.7	26	86.7		
(Change)	4	13.3	1	3.3	0.180	0.245
Drop-out	3	10	3	10		
6 months						
(No change)	17	56.7	24	80	0.035*	0.385
(Change)	9	30	2	6.7		
Drop-out	4	13.3	4	13.3		
9 months						
(No change)	16	53.3	22	73.3	0.109	0.293
(Change)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		
12 months						
(No change)	16	53.3	22	73.3	0.109	0.293
(Change)	10	33.3	4	13.3		
Drop-out	4	13.3	4	13.3		

: Significant at P ≤ 0.05

DISCUSSION

The current study was planed on the hypothesis that the antimicrobial efficacy of SDF, NaOCL and EDTA as an irrigating regimen would be better than NaOCL and EDTA alone. The results of this study showed that the group treated with 3.8% SDF, 2.5 % NaOCl, and 17 % EDTA presented better treatment outcomes compared to the other group treated by NaOCL and EDTA alone. Therefore, the hypothesis was accepted.

Children from 4-8 years of age with primary molars having non-vital pulps were included in the present study, irrespective of their gender. This age group was selected taking into consideration the lack of co-operation of younger children. Molars with periapical infections or radiolucencies were excluded from this study to avoid the virulence of different types of microorganisms in these different teeth from having an effect on the outcome of the current study [11]. Sodium hypochlorite and EDTA still can not guarantee the complete disinfection of root canals and thus more efficient disinfectants are still needed [3]. A solution comprising ammoniated silver nitrate has been utilized decades ago for treating infected root canals. This liquid solution has a strong antibiotic and protein-coagulating properties [12]. Thus silver ions are well known for their antibacterial properties.

More recently 3.8% SDF was found to function as an effective antimicrobial root canal agent or interappointment dressing by Hiraishi et al [13]. Regarding the clinical results in the present study, there was a statistically significant decrease in the success rate within Group A when compared to Group B regarding all the tested clinical criteria (spontaneous pain, sensitivity to percussion, sinus tracts or swellings) denoting the greater incidence of periapical inflammation and disease in Group A which lacked the irrigation by the SDF . These positive clinical outcomes were also found when SDF was used as an irrigant by Maru et al [14]. The sodium hypochlorite and other chelating root canal

irrigants may have multiple limitations during canal disinfection including their low substantivity [15]. On the contrary to most irrigants, SDF posses the ability to remain longer within the root canal due to the reciprocal formation of fluoroapatite within the tooth thus preventing reinfection inside the root canal[16]. SDF was also found to have a greater substantivity than NaOCL and a comparable one to chlorohexidine while at the same time being effective against E. Faecalis. SDF was found in the dentinal tubules after three weeks from its initial application[17]. Although SDF has many advantages caution should be advised during its use because of the possibility of allergic reactions to silver compounds[18]. Thus in the current study skin tests were performed for all children to rule out any allergic potential.

CONCLUSIONS

1. SDF 3.8% can be used successfully as an irrigating solution.
2. Adding SDF 3.8% in the irrigation regimen will improve the disinfection of the root canals and ultimately the treatment outcome.

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