Effect of Discoloration of Silver Diamine Fluoride versus Sodium Fluoride Varnish in Treatment of Carious Primary Teeth: ARandomized Clinical Trial

MarwaA. Salamoon[1], Nevine G. Waly[2], Eman S. Elmasry[2], Fatma Abdelgawad[3]

[1]Post graduate Student, Faculty of Dentistry, Cairo University, [2]Professor, Paediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University, [3]Associate Professor, Paediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University

Abstract

Background: Identifying successful and affordable method to manage decayed tooth in children with high risk caries or with difficulty to obtain proper dental care is very important to avoid probable complications and to decrease caries subsequent problems. Silver diamine fluoride (SDF) has been identified as an anticaries agent that successfully arrests dental decay and has the potential to address the epidemic of untreated decay in young children.

Aim: Evaluation of discolorationand failure of silver diamine fluoride and comparing it with sodium fluoride varnish.

Methodology: Sample size 62 Children with 298 carious primary teeth were selected following eligibility criteria and randomization was performed 1:1 allocation ratio: Group I: (38%) Silver Diamine Fluoride and group II: (5%) Sodium Fluoride Varnish. All patients recalled after 3,6,9 and 12 months to evaluate discoloration and failure.

Results: Comparison between both groups was performed using Chi square test which revealed that, group I was significantly higher regarding Black discoloration after 12 months, Group II was significantly higher than group I after 6- and 12-months regarding failure. Also, correlation between discoloration and failure revealed significant strong positive correlation in both groups.

Conclusion: Black discoloration is higher in group I, while failure is higher in group II.

Keywords: *Black discoloration, Pain free, Taste acceptability, Silver Diamine Fluoride and Sodium Fluoride Varnish.*

Introduction

Althoughdental caries, responsible for a low mortality rate, but it has a considerable influence on self-confidence. Teeth not only important for appearance but also it plays a great role in speaking and pronoun cation of many sounds.[(1).]

Teeth problems among children younger than 6 years old is described as Early childhood caries (ECC), which is as great worldwide health problem and considered one of the most predominant diseases in childhood (60% to 90% of children).[(2,3).]

Progression of untreated caries into the pulp of tooth induce pain and infection as it may spread systemically, in preschool children who are too young to withstandlong

Corresponding author:
Nevine Gamil Waly
Email: Dr_Nevinewaly@hotmail.com
Address: EL-Saraya St. Manial, Cairo, Egypt. Postal code: 11553, Telephone number: +20-101555055

dental treatment visits, its preferred to receive dental treatment under general anesthesia which poses a life-threatening risk to young children.[4].

Conserving a great part of the original, healthy tooth structure is the main goal of "minimally invasive procedures" as natural enamel and dentin are still considered as the best dental materials. Topical application of fluoride varnish considered as the most successful preventive method especially if applied every 3 to 6 months according to caries risk assessment. [9] Fluoride varnish not onlythe most successful topical fluoride agent. but also, it is considered as the only safe and practical topical fluoride agent [5].

Prevention of dental caries or delaying the progress that delay the needed treatment of the child till reach to more cooperative age can be obtained by using SDF as a preventive or therapeutic modality which depends on its combined advantageous effect of both silver and fluoride(3). However, the clinical application of silver fluoride compounds has been restrictedespecially in due to the black staining as silver compounds [6,7]

In spite of the hopeful results of SDF, the American Dental Association's Center for Evidence-Based Dentistry reported restricted evidence of using SDF among children [14]. Further clinical researches are essentialto evaluate patient acceptance, failure, and its relationship with discoloration. Also, they recommended the implementation of long term (more than 3 months) randomized clinical trials.[3]

Methodology

Study design:

This randomized Clinical Trial (RCT NCT03554980) was completed after approval by Research Ethics Committee, Faculty of Dentistry– Cairo University was gained (approval number 18.7.54).

Sample size calculation:

Power calculator for binary outcome superiority trial. was used (https://www.sealedenvelope.com/power/binary-superiority). Which revealed that a total sample size of 52 patients are required to compensate loss to follow up 20% was increased to 62 and thus 31 per group.

Recruitment strategy:

Patients were recruited from outpatient clinic of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University.

Eligibility criteria

All the included children should have onlydeciduous teeth without permanent teeth, high caries risk patients with carious lesions and unhelpful children without access to or with difficulty to obtain dental care.

Randomization and Allocation:

Patients assigned to one of the two experimental groups (1:1 ratio)

Patients grouping:

Group I (Intervention group 31 patients / 175 teeth):application of 38% Silver Diamine Fluoride SDF every 6 months.

Group II (control group 31 patients / 123 teeth): application of 5% Sodium Fluoride Varnish NaF every 3months.

- **Sequence generation:**through using Rondom. org.online software.
- **Allocation concealment:**by assistant supervisor using envelop technique.
- **Clinical procedures:**

1- Diagnosis: personal, medical and dental history were obtained, the intra and extraoral examinations were made. Also, baseline recordswere collected.

2- Clinical intervention:

- Patient preparation:

No operative intervention was initiated to achieve caries arrest, patient was protected with plastic-lined bib and glasses, cotton rolls were used for proper isolation. In group I, plastic dappen dish was used as SDF corrodes

glass and metal, while in group IIthe NaF was placed on the paper pod provided.

· **Application of tested material:**

The child waspositioned in supine position on dental chair, the affected tooth surfaces were dried with a gentle flow of compressed air, the micro sponge brush was bent on the dappen dish side to allow excessliquid removal before application.

In group I, the SDF was directlyapplied to the affected tooth surface only. the excess of SDF was eliminated using cotton roll to prevent systemic absorption. Also, isolation of the site was continued for up to three minutes as possible.

In group II, the NaF Varnish was evenly applied in a thin layer on all teeth surfaces directly, after application, the patient was instructed to close his or her mouth till complete varnish setting varnish.

· **Post-operative instructions:**

Patients of group I instructed to avoid eating or drinking for 30 -60 min., brush with fluoridated toothpaste at night not immediately after SDF application. In group II, parents instructed to don't brush or floss teeth for at least four hours and perfectly up to 24 hours after the treatment, eat soft food for the rest of the day, avoid rinsing or spitting after treatment, the teeth brushing with fluoride toothpaste should resume the following morning and children's parents or guardians were informed that the teeth may appear discolored temporarily.

3- Follow up:

The patients were recalled after 3, 6, 9 and 12 months to evaluate:

· Discoloration using visual examination of a carious lesion color that was performed by 2 assessors. Lesions determined to be successfully arrested when they black in color.

· Failure of treated teeth were assessed by the presence of pain and/or infection and visual observation of yellow color (indicate non arrested lesion).

Results

Regarding discoloration in group I, bothyellow and brown discoloration decreased gradually to 0, 2.9 % after 12 months respectively. On the contrary, black gradually increased to 95.4% after 12 months as presented in table. In group II, both yellow and brown discoloration decreased gradually to 12.2, 47.2 % after 12 months respectively. On the contrary, black gradually increased to30.9 % after 12 months. Comparison between both groups using Chi square test revealed statistical significant difference between both groups during (3, 6, 9, 12 months) except immediately as presented in table (1) and figure (1).

In failure, in group I, the highest failure percentage was at 9 months (4%), then decreased to (0%) at 12 months. While in group II, the highest percentage was at 6 months (5.3 %) then decreased to (4%) at 12 months. Comparison between failure of both groups revealed statistically significant difference after 6 and 12 months as presented in table (2).

Inter observer reliability coefficient (Kappa test) was used to evaluate the agreement between two assessors regarding discoloration and revealed strong agreement (IOC= 0.82) in group I at baseline while revealed almost perfect agreement in both groups regarding different follow up periods as presented in table (3).

In group I regarding failure, brown presented the highest percentage (100%) at 3 months, while at 6 months yellow and brown percentages were equal (50%), and at 9 months yellow revealed the highest percentages (57.1%). In group II, black presented the highest percentage (100 %) at 3 and (80%) at 9 months, while at 6 months, brown revealed highest percentage (87.5%) but yellow and brown were equal after 12 months (50%) as presented in table (4). Spearman`s correlation revealed a statistically significant difference with *P* value ($P = 0.00$)strong ($r>0.6$) positive correlation between discoloration and failure in both group Iand group II, as presented in table (4).

Table (1): Discoloration in both groups immediately, after 3, 6,9 and 12 months:

Discoloration		Group I		Group II		P value
		N	%	N	%	
Immediately	Yellow	30	17.10	27	22.00	0.24
	Brown	103	58.90	76	61.80	
	Black	42	24.00	20	16.30	
3 M	Yellow	2	1.10	22	17.90	0.001*
	Brown	2	1.10	66	53.70	
	Black	155	88.60	25	20.30	
6 M	Yellow	0	0.00	18	14.60	0.001*
	Brown	4	2.30	62	50.40	
	Black	155	88.60	29	23.60	
9 M	Yellow	0	0.00	16	13.00	0.001*
	Brown	5	2.90	62	50.40	
	Black	164	93.70	30	24.40	
12 M	Yellow	0	0.00	15	12.20	0.001*
	Brown	5	2.90	58	47.20	
	Black	167	95.4	38	30.90	

Group I: 38% Silver Diamine Fluoride SDF. Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference

Table (2): Failure of both groups immediately, after 3, 6,9 and 12 months:

Failure	Group I		Group II		P value
	N	%	N	%	
Baseline	0	0.0	0	0.0	1.00
After 3 months	1	0.6	2	1.3	0.56
After 6 months	2	1.1	8	5.3	0.031*
After 9 months	7	4.0	5	3.3	0.71
After 12 months	0	0.0	6	4.0	0.02*

Group I: 38% Silver Diamine Fluoride SDF. Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference.

Table (3): Inter observer reliability in both groups regarding discoloration report:

	Group I		Group II	
	IOC	Reliability	IOC	Reliability
Baseline	0.826	Strong	0.971	Almost perfect
3 months	1.00	Almost perfect	1.00	Almost perfect
6 months	1.00	Almost perfect	1.00	Almost perfect
9 months	1.00	Almost perfect	0.957	Almost perfect
12 months	1.00	Almost perfect	0.957	Almost perfect

Group I: 38% Silver Diamine Fluoride SDF. Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference.

Table (4): Distribution of failure among discolored teeth and correlation between them:

	Discoloration	Failure										r	P
		Baseline		3 M		6 M		9 M		12 M			
		N	%	N	%	N	%	N	%	N	%		
Group I	Yellow	0	0.0	0	0.0	1	50	4	57.1	0	0.0	0.81	0.00*
	Brown	0	0.0	1	100	1	50	3	42.9	0	0.0		
	Black	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0		
	Total	0		1		2		7		0			
Group II	Yellow	0	0.0	0	0.0	1	12.5	0	0.0	0	0.0	0.67	0.00*
	Brown	0	0.0	0	0.0	7	87.5	1	20	3	50		
	Black	0	0.0	2	100	0	0.0	4	80	3	50		
	Total	0		2		8		5		6			

Group I: 38% Silver Diamine Fluoride SDF. Group II: 5% Sodium Fluoride Varnish NaF.

*Significant difference

a. Group I discoloration at baseline, after 6month., and after 12 months

b. Group II discoloration at baseline, after 6month., and after 12 months

Figure (1): Discoloration of both groups.

Discussion

In the present study, the selected patients were less than 6 years old to ensure that they only have primary teeth. Additional, children in this age range may profit from postponed dental treatment and overall caries arrest. [(3).] Also, the written informed consent included detailed information in a simpleand understandable language about the research topic, such as possible benefits and harms, treatment procedures because SDF will darken tooth structure, so it is very important that parents understand this fact[(8).]

Therapy using fluoride application is relatively cheaper and easier treatment. In addition, it can arrest active dental caries because of fluoride ability to inhibit demineralization of enamel. Moreover, it can enhance remineralization of enamel, increasing the remineralization process speed. The incorporation of fluoride also makes the deposited mineral less soluble in acids[(9).] Also, Fluoride affect the ability of bacteria to produce a greatquantity of acid from carbohydrates [(10).]

The control group was NaF varnish according to the U.S. Preventive Services Task Force recommends application of fluoride varnish in children starting from age of primary teeth eruption till age of 5 years by primary care health professionals. A 5 % sodium fluoride varnish was considered as control group because the arrestment proportion of caries for sodium fluoride varnish according to [(11-13).]

Silver diamine fluoride was considered as intervention group. Because the American Academy of Pediatric Dentistry, 2017 stated that Silver diamine fluoride (SDF) is a brush-on liquid that arrest 87.7%

of dental caries lesions. The success rate is similar for restorations placed under general anesthesia[14-15].

A 5 % sodium fluoride varnish was applied every three months as recommended by American Dental Association ADA 2006 , American Academy of Pediatric Dentistry AAPD2018 and American Academy of Pediatric Dentistry 2017,another studies recommend application of 5 % NaF varnish every 3 months for children at high risk. Also, the best results were achieved in the treatment with 5 % NaF fluoride within a 3-month periodicity.[8, 16,17]

Regarding the Clinical procedure of SDF application there are important considerations and recommendations such as applying a protective coating (Vaseline butter) to the lips and skin to prevent temporary black stain, careful application with a micro-brush was adequate and no more than one drop of SDF was used for the entire appointment [8]

Comparison between both groups regarding discoloration revealed statistical significant difference between both groups in all follow up periods.However, discoloration of teeth after application of SDF was mentioned because of caries arrest in many studies [3] Similar to this study, another study reported that all children in SDF group came in their next visit at 3 weeks with all their treated teeth discolored. [4,18]

Regarding Correlation between discoloration and successfully treated teeth:In this study, the highest percentages were black in different follow up periods in both groups. Similar to another study which reported that the clinical success of SDF application in arresting active caries lesion may be absolutelyassociated with the presence of as a black stain appearing over the lesion (a protective layer)· [18]

In addition, other study reported that the arrested caries has a black, smooth, and hard surface when gently explored. However, according to the standards of care, a hard dentin surface and the dark color of an arrested lesion are valid clinical indications for positive outcomes benefitting the patient.[3]

In this study, the highest percentage of failure was observed in group II than group I with statistically significant difference at 6 months and 12 months, while revealed no statistically significant difference at baseline, 3 and 9 months. Despite the NaF caries-preventive effect, NaF varnish is ineffective at arresting coronal dentine caries. [19]

Ethical Clearance:· Approval by Research Ethics Committee, Faculty of Dentistry– Cairo University was gained (approval number 18.7.54) before this clinical trial started.

Funding: The study was self-funded.

Competing Interests: No conflict of interest.

References

1. Moynihan P and Petersen PE ‘Diet, nutrition and the prevention of dental diseases’, Public Health Nutrition, 2004;7;1;201–226.
2. Chen KJ, GaoSS, Duangthip D, LoEM and Chu CH. March. Managing early childhood caries for young children in China. In Healthcare.2018;6;1;11-20. Multidisciplinary Digital Publishing Institute.
3. Clemens J, Gold J and Chaffin J. ‘Effect and acceptance of silver diamine fluoride treatment on dental caries in primary teeth.’, Journal of public health dentistry. United States, 2018;78;1;63–68.
4. Duangthip D, Chen KJ, Gao SS, Lo ECM & Chu CH. Managing early childhood caries with atraumatic restorative treatment and topical silver and fluoride agents. International Journal of Environmental Research and Public Health, 2017;14;10;1204-1211.
5. Mishra P, Fareed N, Battur H, Khanagar S, Bhat MA &Palaniswamy J. Role of fluoride varnish in preventing early childhood caries: A systematic review. Dental research journal,2017;14;3;169-175.
6. Peng JJY, Botelho MG and MatinlinnaJP.‘Silver compounds used in dentistry for caries management: A review’, Journal of Dentistry. Elsevier Ltd, 2012;40;7;531–541.
7. Knight GM, McIntyre JM, Craig GG, ZilmP S& Gully NJ. An in vitro model to measure the effect of a silver fluoride and potassium iodide

treatment on the permeability of demineralized dentine to Streptococcus mutans. Australian dental journal,2005;50;4; 242-245.

8. American Academy of Pediatric Dentistry. Policy on the use of silver diamine fluoride for pediatric dental patients. Pediatric Dent, 2017;39;6;51-59.
9. Chu CH, MeiML & Lo EC. Use of fluorides in dental caries management. General dentistry, 2010;58;1;37-45.
10. Mei ML, Ito L, Cao Y, Li QL, Lo EC & Chu CH. Inhibitory effect of silver diamine fluoride on dentine demineralization and collagen degradation. Journal of dentistry, 2013;41;9;809-817.
11. Barzel R and Holt K 'Fluoride Varnish and Silver Diamine Fluoride', National Maternal and Child Oral Health Resource Center, 2020;202;784;3-18.
12. Duarte AR, Peres MA, Vieira RS, Ramos-Jorge ML & Modesto A. Effectiveness of two mouth rinses solutions in arresting caries lesions: a short-term clinical trial. Oral health & preventive dentistry,2008;6;3;11;19.
13. Milgrom P, Taves DM, Kim A S, Watson GE, & Horst JA 'Pharmacokinetics of fluoride in toddlers after application of 5% sodium fluoride dental varnish', Pediatrics, 2014;134;3;870–874.
14. Bücher K, Tautz A, Hickel R&Kühnisch J. Longevity of composite restorations in patients with early childhood caries (ECC). Clinical oral investigations, 2014;18;3; 775-782.
15. Castillo JL, Rivera S, Aparicio T, Lazo R, Aw TC, Mancl LL & Milgrom P. The short-term effects of diammine silver fluoride on tooth sensitivity: a randomized controlled trial. Journal of dental research, 2011;90;2;203-208.
16. American Dental Association Council on Scientific Affairs. Professionally applied topical fluoride: Evidence–based clinical recommendations. The Journal of the American Dental Association, 2006;137;8;1151-1159.
17. American Academy of Pediatric Dentistry 'Guideline on Fluoride Therapy. Latest Revision 2018', Pediatr Dent, pp.2018;251–282.
18. Duangthip D, Chu CH & Lo EC. A randomized clinical trial on arresting dentine caries in preschool children by topical fluorides: 18-monthresults. J Dent. 2016;44; 1:57–63.
19. Chu CH, Lo ECM and Lin HC. 'Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children.', Journal of dental research, 2002;81;11;767–70.