PARENTAL SATISFACTION AFTER USING SILVER DIAMINE FLUORIDE ON THEIR CHILDREN'S PRIMARY TEETH: A RANDOMIZED CLINICALTRIAL

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ABSTRACT

BACKGROUND: Despite the effectiveness of silver diamine fluoride (SDF) in arresting caries, black staining of carious lesions is a major drawback.

OBJECTIVE: To assess parental satisfaction after using SDF versus atraumatic restorative treatment (ART) to manage ECC in their children. **MATERIALS AND METHODS:** A randomized controlled clinical trial with patient reported outcomes; 100 children with ECC (2-5 years) were equally and randomly divided into two groups; Experimental group (N=50, n=268) received 38% SDF; Control group received ART (N=50, n=286). Parental satisfaction was assessed after 2 weeks using 4-item, 5-level, Likert-scale questionnaire. Quantitative data were represented using mean, and standard deviation (SD). Qualitative variables were displayed using frequency and percentages. Monte Carlo simulation method for Pearson's chi square statistics was applied to compare both groups regarding parental satisfaction. Significance level was set at P value ≤ 0.05 .

RESULTS: Eighty percent of parents/guardians strongly agreed, agreed or were neutral regarding their children's esthetics after SDF versus 98% after ART (P=0.06). All SDF parents/guardians strongly agreed or agreed it was an easy procedure versus 30% among ART group (P<0.0001). Among SDF parents/guardians, 96% reported the procedure to be pain free versus 74% in ART group (P=0.008). Among SDF parents/guardians, 88% "strongly agreed" that the taste of received treatment was acceptable to their children versus 82% in ART group. (P=0.614).

CONCLUSION: Parental satisfaction regarding esthetics and taste was comparable after SDF and ART. Significantly more SDF parents/guardians viewed the procedure easy and pain free.

KEYWORDS: Silver diamine fluoride, parental satisfaction, acceptance, early childhood caries, randomized clinical trial.

RUNNING TITTLE: Parental satisfaction after SDF.

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INTRODUCTION

Early childhood caries (ECC) begins early in life, rapidly progresses, and when untreated, leads to consequences that eventually extend to jeopardize the child's general health and well-being (1). The so called 'ideal' restorative treatment of ECC requires sophisticated procedures, special equipment and a highly trained dental team able to deal appropriately with children either on the dental chair or under general anesthesia (GA). Moreover, high treatment costs, lengthy stressful appointments, relying on parental compliance along with the extensive waiting times result in further disease progression (2). Furthermore, the traditional restorative approach is a symptomatic treatment which focuses on treating the cavities but does not address the caries disease itself. A high recurrence rate of lesions after traditional treatment, as well as developing new carious lesions were therefore expected finding (3).

In primary dentition, the goal is to maintain the tooth asymptomatic and infection free till the time of its exfoliation. This concept had shifted the focus from evaluating the survival of restorations to another valuable clinical outcome; the survival of the tooth (4). The International Caries Consensus Collaboration (ICCC) recommended the use of minimal invasive approaches for managing ECC in preschool children in order to delay the restorative cycle as much as possible in order to minimize anxiety, discomfort and pain together with their consequent negative impacts on oral health (5).

Literature has been consistently supporting silver diamine fluoride (SDF) as a non-invasive management of ECC (6). The major disadvantage of SDF is black staining of demineralized or cavitated surfaces as a result of silver phosphate precipitation (7). Some researchers have suggested applying potassium iodide after SDF application to reduce the staining effect by generating silver iodide (8). However, silver iodide is photosensitive and can as well turn dark when exposed to light (9). Nano-silver fluoride is currently under research and its effectiveness in arresting caries without resulting in black stains is promising (10). Further research is still necessary to find an approach to solve the staining problem of SDF without reducing its effectiveness in arresting caries. However, in the meantime, despite the poor esthetic results of SDF, benefits of caries arrest and absence of pain and dental infection especially at times when access to dental care is challenging, may overshadow this side effect.

In December 2016, the FDA Black Box Warning on the use of general anesthesia before the age of three had definitely shifted parental attitudes towards avoiding general anesthesia and accepting the non-esthetic results of SDF. It was found that even though staining was a concern, SDF treatment was still more accepted by parents to advanced pharmacological approaches. Since the primary goal of parents while having their children's teeth treated is to eliminate pain, therefore they tend to accept the poor esthetics after SDF as long as their children received an effective treatment that reduced their suffering (11).

Parental perception of SDF was variable in literature. A systematic review conducted by Sabbagh et al. (12) in 2020, concluded that tolerance to SDF was significantly higher in posterior teeth than anterior ones and in uncooperative children than cooperative ones. They also recommended giving pre-operative instructions to the parents which had a significant positive impact on parental acceptance to SDF treatment.

The aim of this study was to assess parental satisfaction after the use of SDF versus ART in managing ECC in their children. The null hypothesis stated that there will be no difference in parental satisfaction levels among SDF and ART groups.

MATERIALS AND METHODS

Study design and ethical considerations: This study was a part of a randomized clinical trial (RCT) analyzing patient reported outcomes (13). The primary aim of the RCT was to assess caries arrest rates of SDF compared to ART. The trial was registered as: (NCT04514094 - ClinicalTrials.gov). It was conducted after receiving ethics approval from the Research Ethics Committee (19.8.2018), Faculty of Dentistry - Alexandria University, Alexandria, Egypt. Parents/guardians received a thorough explanation of the study's nature, the importance of managing early childhood caries, the possibility that their child could join either groups of the trial and the possible side effects illustrated with pictures of the black stain accompanying SDF. Parents/guardians signed 'informed consent' stating that they approve to let their child join the trial and that their child will be randomly allocated to either arms of the study while being given the right to refrain from the trial at any time. Parents/guardians also consented to fill the parental satisfaction questionnaire.

Sample size estimation

The sample size for the current study was based on the primary outcome of the RCT; caries arrest. It was calculated using <u>http://powerand sample size.</u> <u>com/Calculators/Compare -2-Proportions/2-Sample-Equality</u> and was estimated based on: 30% difference in success rates of both groups reported by Dos Santos et al. (14), 5% statistical significance level and power of 80, the least required sample size was 45 per group. The sample size was increased to 50 children per group (total sample: 100) to make up for possible losses.

Participants: Participants were parents/guardians of children who received SDF or ART for non-restorative caries management. Those children were 100 healthy children, aging 2-5 years, diagnosed with ECC and were referred to dental treatment under general anesthesia because they were all unable to cooperate for the traditional restorative treatments.

In order to join the study, parents/guardians had to be living with their children to be able to provide their personal data and dental history.

Randomization and allocation concealment: Children who were eligible for the trial were randomly and equally assigned using a computer-generated list of random numbers (Random Allocation Software, version 1.0.0), to either the SDF or the ART group.

An assistant -independent of the trial- was responsible for giving each participant a serial number indicating his/her allocation. A duplicate of this number was put in an opaque envelope that was kept by the assistant who was assigned the role of opening it only at the time of intervention; so that the group to which the child was allocated was concealed from the investigator.

Clinical examination: Baseline screening and examination were done for all patients by one calibrated examiner between September and November 2018, in the clinics of Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Alexandria University, under the same dental setting that included a standard light source, 2-way syringe and suction device.

Intervention: Children in the clinical component of the study received intervention to all eligible teeth as follows:

Experimental group (N=50, n=268): Thirty eight percent SDF (Advantage Arrest-Elevate Oral Care USA) was applied according to the American Academy of Pediatric Dentistry (AAPD) guidelines (15); Gross debris was removed without caries excavation, affected surfaces were dried and then, SDF was applied using a micro sponge brush.

Control group (N=50, n=286): According to the ART approach described by Frencken et al., (16) caries removal by hand instruments was done mainly from the periphery of lesions with care not to expose the pulp, cavities were then cotton roll isolated and restored by glass ionomer cement (GC Fuji IX, GC America).

Outcome assessment: Parental satisfaction was assessed at the 2 weeks recall appointment by using a 4-item, 5-level, Likert-scale questionnaire that provided a general evaluation of the parental satisfaction level regarding their children experience of the treatment received; either ASDF or ART. It included esthetic acceptability (Q1: You are comfortable with your child's esthetics after SDF/ART placement), ease of application (Q2: SDF/ART application is an easy process), pain perception (Q3: SDF/ART application is pain free for your child) and taste (Q4: SDF/ART taste is acceptable to your child). Each response was scored using 5level Likert scale as follows: strongly agree, agree, neutral, disagree and strongly disagree.

The English version of the questionnaire was originally designed by Clemens et al. (17) in 2018 and was validated and tested for reliability. It was translated into Arabic by the aid of three professionals, whose native language was Arabic, independently. The three Arabic versions were then compared, and the best translation version was chosen which was then back-translated into English and a comparison between the original and the back-translated forms was undertaken. In the pre-testing stage, a convenient sample of 20 parents/guardians were recruited following the same criteria in the main study-except that they were not included in the study's results-replied to the questionnaire. Deviations and errors in the translation were checked and necessary adjustments were done.

Each response was scored as follows: (5) strongly agree, (4) agree, (3) neutral, (2) disagree and (1) strongly disagree. These scores were summed and analyzed for each

parental questionnaire and provided a general evaluation of the parental satisfaction level regarding their children experience of the treatment received; either SDF or ART.

Blinding: Blinding of examiners or patients was impossible to be done during intervention and follow up due to different natures of the materials. However, the assistant who was responsible for giving and collecting the questionnaires from parents/guardians as well as the statistician who analyzed the data, did not know the group to which the child belonged.

Statistical analysis: Data were analyzed using IBM SPSS software package version 25.0. (Armonk, NY: IBM Corp). Quantitative data were represented using mean, standard deviation (SD). Qualitative variables were displayed using frequency and percentages. Monte Carlo simulation method for Pearson's chi square statistic was applied to compare the two groups regarding the parental satisfaction. Significance level was set at P value ≤ 0.05 .

RESULTS

One hundred children, 47 boys and 53 girls, aging 2-5 years were enrolled in the study, (SDF N=50, ART N=50). Mean age \pm (SD) for children in the SDF group was 2.98 \pm 0.85, while that for the ART group was 3.08 \pm 0.99. The total number of teeth included in the clinical component of this trial was 554, (SDF n=268, ART n=286). At baseline, no significant differences were found between both groups regarding gender, mean age & maternal educational level, oral health related habits, mean dmft, average number of teeth per patient nor the type of teeth included either anterior or posterior. (Table 1) All 100 parents/guardians responded to the questionnaires, where no dropouts were recorded at the two weeks recall appointment.

Parental satisfaction levels regarding the type of treatment their children had received among SDF and ART groups: (Table 2 & Figure 1)

Concerning parental esthetic perception after SDF/ART placement, among the SDF group, 8% strongly agreed that they were comfortable with their children's esthetics, 26% agreed, and 46% were neutral, however, 20% were not comfortable with the esthetics and replied either disagree (18%) or strongly disagree (2%). Among the ART group, 12% of parents/guardians strongly agreed that they were comfortable with their child's esthetics, 44% agreed, 40% were neutral and 4% disagreed. Among both groups, no significant differences were evident regarding parental acceptance of their children's esthetics after intervention (P=0.06).

Regarding the ease of the application procedures, among the SDF group, 100% of the parents/guardians either strongly agreed (94%) or agreed (6%) that SDF application was an easy procedure. Among the ART group, only 10% strongly agreed that ART application was easy, 20 % replied "agree", 26% were neutral and 44% either disagreed (32%) or strongly disagreed (12%). These responses represented a strong statistically significant difference amongst both groups (P<0.0001).

Reporting pain perceived during SDF/ART application procedures, all parents/guardians whose children received SDF confirmed that its application seemed to be pain free; where 96% replied "strongly agree" and 4% replied "agree". In the ART group, 74% of the parents/guardians strongly agreed that the procedure was pain free, 18% replied "agree", "agree", 4% were neutral and 4% disagreed. The difference among both groups regarding this question was significant statistically (P=0.008).

Regarding parental judgments of children acceptability of taste of SDF/ART, the majority of parents/guardians in both groups "strongly agreed" that the received treatment was acceptable to their children in terms of its taste; 88% in the SDF group and 82% in the ART group. Also, in the SDF group, the remaining 12% replied "agree". In the ART group, 14% replied "agree", 2% replied "neutral", and 2% replied "disagree". The responses among both groups regarding this question did not make a difference that is statistically significant. (P=0.614).



Figure 1: Parental satisfaction levels among SDF and ART groups.

Variables			SDF (N=50 children, n=268 teeth)	RT N=50 children, n=286 teeth)	value	
	Age: Mean (SD)		2.98(0.85)	3.08 (0.99)	.61	
Demographic Background	Gender: n (%)	Boys	21 (42%)	6 (52%)	.32	
		Girls	29 (58%)	24 (48%)		
	Mother education	elementary or less	26 (52%)	22 (44%)	.626	
		Secondary	18 (36%)	21 (42%)		
		University	6 (12%)	7 (14%)		
Oral health related habits	Daily tooth	Yes	9 (18%)	3 (26%)	.344	
	brushing	No	41 (82%)	37 (74%)		
	Frequency of snacks/day	<1	0 (0%)	0 (0%)		
		-2 times	23 (46%)	19 (38%)	.418	
		3 or more	27 (54%)	31 (62%)		
Teeth type	Type of teeth examined: n (%)	Anterior	141(52.6%)	163 (57%)	20	
		Posterior	127(47.4%)	123 (43%)	.30	
Caries experience	dmft:		6.60 (3.57)	6.38 (3.86)	.71	

Table 1: Baseline demographic and clinical characteristics for SDF

 and ART groups

SDF: Silver diamine fluoride, **ART:** Atraumatic restorative treatment, **SD:** Standard deviation **dmft:** decayed, missing, filled teeth

Table 2: Parental satisfaction levels among SDF and ART groups.

		SDF	ART	
		(n=50	(n=50	P value
		ciliaren)	()	
01.	Strongly	11 (70)		
You are	agree	4 (8%)	6 (12%)	
comfortable	Agree	13 (26%)	22 (44%)	
with your	Neutral	23 (46%)	20 (40%)	
child's	Disagree	9 (18%)	2 (4%)	0.06
esthetics	Strongly		_ (1,1)	
after	disagree	1 (20)	0 (00())	
SDF/ART		1 (2%)	0(0%)	
placement				
Q2:	Strongly	47 (04%)	5 (10%)	
SDF/ART	agree	47 (94%)	5 (10%)	
application is	Agree	3 (6%)	10 (20%)	
an easy	Neutral	0 (0%)	13 (26%)	< 0.0001*
process	Disagree	0 (0%)	16 (32%)	
	Strongly disagree	0 (0%)	6 (12%)	
Q3: SDF/ART	Strongly agree	48 (96%)	37 (74%)	
application is	Agree	2 (4%)	9 (18%)	
pain free for	Neutral	0 (0%)	2 (4%)	0.008*
your child	Disagree	0 (0%)	2 (4%)	
	Strongly disagree	0 (0%)	0 (0%)	
04:	Strongly	44 (000)	11 (0.001)	
SDF/ART	agree	44 (88%)	41 (82%)	
taste is	Agree	6 (12%)	7 (14%)	
acceptable to	Neutral	0 (0%)	1 (2%)	0.614
your child	Disagree	0 (0%)	1 (2%)	
	Strongly disagree	0 (0%)	0 (0%)	

*Statistically significant difference at *P* value ≤ 0.0

DISCUSSION

The null hypothesis that stated that there will not be any difference in parental satisfaction levels among SDF and ART groups was partially rejected. Parental satisfaction was comparable regarding esthetics and taste of SDF and ART, while significantly more parents in the SDF group viewed the treatment procedure easy and pain free, when compared to the ART group.

A clinically successful intervention is not always satisfactory in the patient's point of view. The patient is in the best position to evaluate his own improvement, also, in addition to health improvement, patients have other goals, expectations and priorities. True evidence ought to be tailored to patients' needs, which not only adds value to clinically successful results, but also is equally important. This highlights the worth of patient reported outcomes along with the clinical outcomes regarding any intervention so as to weigh the real value of this intervention and pertain evidence-based medicine to patientcentered medicine together (18).

The current study is a randomized controlled clinical trial with patient reported outcome measures (13). The experimental group received SDF whilst the control group was treated with ART. The outcome was parents' satisfaction concerning the type of treatment their children had received to arrest ECC.

Compromised esthetics following SDF is a major concern among dentists which usually holds them back from using it. In 2016, Nelson et al. (19) sent a survey to 500 active members of the AAPD, where 43% of them had admitted that they eventually follow parent preferences even if this was against their clinical judgment, furthermore, 28% mentioned that they never use amalgam since it is unacceptable by parents. However, this conclusion was based on the dentists' opinions, and thus, subjective perception of parents of the SDF application procedure and its esthetic outcome was thus necessary to justify its use.

Parental acceptance of the esthetic outcomes in the present trial was insignificantly higher for the ART group than SDF group, where 96% and 80% of parents/guardians, respectively, were either satisfied or neutral with their children's esthetics. This high acceptance of esthetics, among both groups, could be due to many reasons; parents/guardians wanted to avoid exposing their children to general anesthesia either due to financial concerns, long waiting times or fear from the associated health risks. Adding to this, parents/guardians have observed the simplicity of the procedure followed with subside of sensitivity. Besides, they must have noticed the indifference of their young children regarding the black stain which was also noted in previous studies (20, 21).

Our findings were consistent with multiple studies, where high parental acceptance of their children's esthetics after SDF had been reported as well (17, 22, 23). Nevertheless, applying SDF on primary teeth of children up to 72 months old with high dmft scores and/or history of uncooperative behavior was more tolerated by parents than applying it on permanent teeth of older cooperative children with less dmft scores (24-26).

On the other hand, high parental dissatisfaction was also reported in some studies (27, 28) Alshammari et al. (27) reported that 100% and 97% of the parents refused or totally refused the black stain on anterior teeth and posterior teeth, respectively. This was probably because of the handiness of dental care which might have influenced their expectations. Also, parents had made their judgments after seeing images of the black stain of SDF unlike parents/guardians in our study, who experienced the caries problem with their children as well as the financial burden and risks of treatment. Moreover, many parents refused the black stain on anterior teeth, however, when they were told that esthetic options could only be delivered under general anesthesia, parental acceptance levels significantly increased (28).

Apart from discoloration, there was a significant difference between parental opinions regarding the simplicity of the treatment procedures among both groups, where 100% of the SDF parents/guardians versus only 30% of the ART parents/guardians either agreed or strongly agreed that the treatment procedure was an easy process. Also, 100% of parents/guardians in the SDF group against 92% of the parents/guardians in the ART group believed that the treatment procedure was pain free. SDF is easily and quickly applied using a brush and does not involve caries excavation nor anesthesia, therefore it was not surprising that almost all parents/guardians rated the procedure as simple and pain free. Parents have repeatedly agreed on the ease of the SDF application procedure in previous studies (17, 20). On the other hand, ART is relatively time consuming and involves caries excavation together with the uncooperative behavior of children, explains why parents/guardians did not rate the procedure as simple nor pain free.

About the acceptability of taste after treatment, this issue was not significant among both groups in the current study, where only one parent who was in the ART group reported that his child disliked the taste. Similar parental views were reported by Clemens et al. (17) in 2018. Metallic taste was mentioned in some studies after SDF application but was not a true problem anyhow (23).

This study has its limitations; the lack of possibility of blinding the parents/guardians might have biased their responses to the questionnaire. Additionally, since the sample was a convenient sample, the results cannot be generalizable to the Egyptian population. Parents with higher educational level, higher income or those having access to high quality dental care could have other visions. Nonetheless, our findings may help dentists understand parents' tolerance and expectations while keeping in mind that it may not be applicable to all social categories.

CONCLUSIONS

Within the limitations of the current study, it can be concluded that parental satisfaction levels regarding esthetics and taste were comparable after SDF and ART, however, significantly more parents on the SDF side viewed the procedure as an easy and pain free procedure. Therefore, SDF can be used as a means of instant caries control in children till the circumstances permit a more definitive treatment despite the black stain.

CONFLICT OF INTEREST

The authors declare that they have no interest conflicts. **ACKNOWLEDGEMENT**

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