

CLINICAL EFFICIENCY AND CHILD'S BEHAVIOR AFTER TREATMENT WITH HALL TECHNIQUE VERSUS SILVER DIAMINE FLUORIDE (SDF) IN THE MANAGEMENT OF CARIOUS PRIMARY MOLARS: RANDOMIZED CLINICAL TRIAL

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Abstract

Aim: This study aims to assess the clinical efficiency and child's behavior after treatment with HALL technique versus silver diamine fluoride (SDF) in the management of carious primary molars.

Methodology: RCT was conducted over 12 months and included (72 primary molars) in healthy children aged 4–6 years, the patients were recruited from Cairo University Pediatric Dentistry outpatient clinics, included vital molars were asymptomatic with decayed enamel/dentin, Children were divided into two equal groups and randomly assigned to SDF application or HALL technique. Visual and tactile examinations were used.

Results: the results concerning the clinical efficiency revealed no statistically significant differences in arresting carious lesions in both groups, positive child behavior in both groups was recorded

Conclusion: HALL technique and SDF application are effective in arresting caries in primary molars teeth, However, the chair-time management required for SDF is significantly shorter compared to HT, the best decision regarding disease management and application of SDF or HT is to be made by the dentist and the patient/parent, recognizing individuals' differences and preferences.

Keywords: silver diamine fluoride, primary molars, HALL technique, arresting caries, child behavior

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INTRODUCTION

Dental caries is a global public health problem and the most widespread non-communicable disease, children and adolescents at the most risk. It is a biofilm-mediated, multifactorial, non-communicable, dynamic disease resulting in net mineral loss of dental hard tissues and determined by biological, behavioral. psychosocial, and environmental factors. Regarding the pediatric population, many epidemiological studies showed that the prevalence of dental caries in children ranges from 60% to 90% in different communities (Cappelli and Mobley, 2017)

Early surgical intervention, minimal intervention, risk assessment, and variable recall periods based on risk and lesion monitoring constitute the secondary level of prevention. (*Wahba* et al. (2015), delayed intervention is the tertiary level of prevention where the child is in pain due to inflamed pulp, which needs anesthesia and a more complicated technique.

HALL technique was named after Norna HALL, who developed a simplified technique of treating carious lesions of primary molars with no tooth preparation, just using dental orthodontics separators to open a proximal contact and sealing the lesion using preformed metal crowns. (Altoukhi, D. H. and El-Housseiny, A. A. (2020)

Silver diamine fluoride is an FDA-approved antibiotic liquid clinically applied to control active dental caries and prevent further progression of the disease. While the ideal way to treat teeth with decay is by removing the decay and placing a restoration, this alternative treatment stops further decay with non-invasive methods, particularly with young uncooperative children (Chibinski, A. C. R. (2020).

This study aimed to assess the clinical efficiency and child's behaviour after treatment with the HALL technique versus silver diamine fluoride (SDF) in the management of carious primary molars

AIM OF THE STUDY

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Subjects & Methods:

Study design

The study was a randomized clinical trial (parallel groups design) to assess the clinical efficiency and child's behavior after treatment with the HALL technique (comparator group) versus silver diamine fluoride (intervention group) in managing carious primary molars.

Participants:

Patients were recruited from the outpatient clinic, at the Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University, according to the following criteria

Eligibility criteria:

A) Inclusion criteria:

- Age: From 4 to 6 years
- Caries in primary molars within enamel/dentin with vital pulp
- Healthy and Cooperative children

B) Exclusion criteria:

- Presence of signs and symptoms of necrosis
- Root caries
- History of Spontaneous pain

Methods:

A. Sample size:

A power analysis was designed to have adequate power to apply a two-sided statistical test of the null hypothesis that there is no difference between the child's behaviour and clinical efficacy in the management of carious primary molars with the HALL technique versus the silver diamine fluoride., randomized controlled trial's sample calculation was based on Masoumeh Ebrahimi et al. 2020. In a previous study, the response within each subject group was normally distributed with a standard deviation of 1.2. If the true difference in the experimental and control means is 0.9, 36 subjects in each group can reject the null hypothesis that the population means of the experimental and control groups are equal with probability

(power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05.

B. Grouping of molars:

The Sample size = 36 per each group

C. Follow-up periods: 3 months,6 months & 12 months

Ethical approval

Ethical approval was obtained from the Scientific Research Ethical Committee, Faculty of Dentistry, Cairo University

Informed consent:

All the trial details and the possibility of recruitment were introduced to the patient Signed informed consent was obtained for each patient before the trial conduction.

Setting and allocation:

An opaque sealed envelope was used for each patient carrying information about which side is the intervention side, or the control side, each of the two techniques was randomly assigned to the right or left sides, the randomization was performed with a 1:1 ratio, and the sequence of the subjects assigned to one of the parallel designs was computer generated. The method of randomization was carried out through RANDOM.ORG software.

Withdrawal and harms:

Harms with the HALL technique:

HT increased the occlusal vertical dimension temporally, which would resolve within 2–4 weeks

Harms with Silver Diamine Fluoride:

SDF-stained carious lesions black, it was necessary to inform patients of this outcome of SDF treatment. To avoid that, potassium iodide was immediately applied after SDF; the bad taste was another drawback. Reassurance of the patient took place that it was temporary and would quickly disappear

Intervention group: (SDF)

Preoperative assessment: All patients went through phase I therapy (oral hygiene instructions), standardized digital photographs (frontal, profile, oblique) were taken with a digital camera Nikon D7100 with macro lens sigma 105 mm for all patients, digital periapical radiographs: standardized periapical radiographs were taken for all patients.

Operative phase: Gross debris were removed from cavities to allow better SDF contact with denatured dentin. Cocoa butter was applied on gingiva and mucous membranes to avoid potential pigmentation or irritation, cotton rolls

were used to protect surrounding gingival tissues, dryness with a gentle flow of compressed air was achieved &cotton rolls/gauze, micro sponge brush was bent, dipped and dabbed on the side of the plastic dish to remove excess liquid before application of SDF directly to only the affected tooth surface.

Dryness with a gentle compressed air flow for at least one minute was done, excess SDF was removed with gauze, cotton roll, or cotton pellet to mimize systemic absorption Riva Star KI was applied until the white reactant became clear, Isolation of the site was maintained for up to three minutes.

Postoperative assessment: Several SDF clinical trials recommended no eating or drinking for 30 minutes to one hour

Photographs: Standardized digital photographs (frontal, profile, oblique) were taken with a Digital Camera Nikon D7100 with macro lens sigma 105 mm for all patients

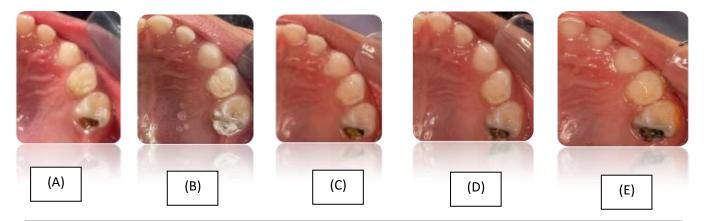


Figure 1: SDF procedure (A) pre-operative clinical photo of an upper left second primary molar, (B) showing a post-operative after SDF application, (C) after 3 months, (D) after 6 months, (E) after one year

Comparator group : (HALL technique)

Preoperative assessment: All patients went through phase I therapy (oral hygiene instructions), standardized digital photographs (frontal, profile, oblique) were taken with a digital camera Nikon D7100 with macro lens sigma 105 mm for all patients, digital periapical radiographs: standardized periapical radiographs were taken for all patients.

Operative phase:

Orthodontic separators were stretched between two pieces of floss, placed between the contact points of primary molars and were left for 5 days, The correct size of the crown would not impinge on the teeth on either side, and a slight 'spring back' was felt when the PMC was gently pushed up, the PMC was filled with a Riva self-cure capsule cement, extruded cement was quickly wiped away, and the child was asked to keep biting on the crown for two minutes until cement setting was achieved to prevent the 'spring back' of the PMC from the fully seated position, the excess cement was removed, and the contact points were flossed through. The slight increase in occlusal vertical dimension was accommodated within alveolar growth, occlusion was checked after placement.

Postoperative measures:

Photographs: Standardized digital photographs (frontal, profile, oblique).Digital Periapical Radiographs: Standardized periapical radiographs were taken for all patients

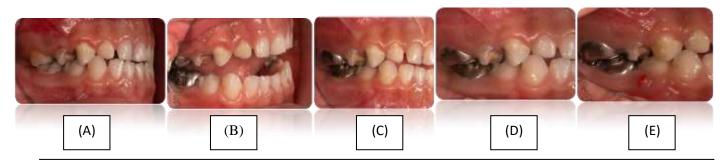


Figure 2: HALL Technique (A) Pre-operative clinical photo of a lower left second primary molar, (B) showing a post-operative lateral profile clinical photo after hall technique, (C) after 3 months, (D) after 6 months, (E) after one year

Child's behavior:

At the end of the treatment session, the dentist classified the child's behaviour during the treatment according to the Frankl scale, Frankl scale is a reliable system for rating behaviour and assessing anxiety and describes four types of behavior during dental treatment:

Score	Scoring	Observed Behavior
1	Definitely Negative	Refusal of treatment, crying forcefully, fear,
	()	or any other overt evidence of extreme
		negativism
2	Negative	Reluctant to accept treatment; uncooperative,
	(-)	some evidence of negative attitude but not
		pronounced, i.e., sullen, withdrawn
3	Positive	Acceptance of treatment; at times cautious,
	(+)	willing to comply with the dentist, at times
		with reservation but patient follows the
		dentist's directions cooperatively.
4	Definitely positive	Good rapport with the dentist, interested in
	(++)	the dental procedures, laughing and enjoying
		the situation

Materials and equipment:

X-ray holder (standardized), film sensor, Digital Camera Nikon D7100 with macro lens sigma 105 mm

For SDF application:

SDI Riva Star SDF (step 1) &SDI Riva Star KI (step 2) and brush bond

For HALL technique:

Poly gauge instrument (for canine overbite measurements), Orthodontic separators, Holder for separators, Stain steel crowns, Riva self-cure capsule cement.

• Statistical Analysis:

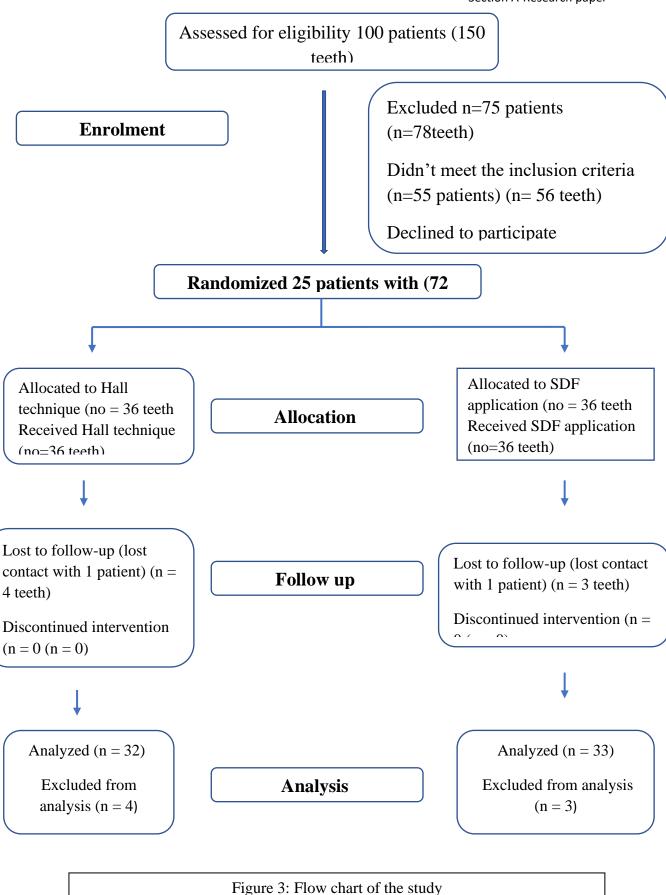
Statistical analysis was performed using SPSS 20®1, Graph Pad Prism®2 and Microsoft Excel 20163. Data were represented as mean and standard deviation, and the *p*-value was set at <0.05. Data were explored for normality by using Shapiro-Wilk and Kolmogorov-Smirnov normality test. The comparison between the two groups at different follow-up periods was

performed by the Independent T-test, and the comparison between the follow-up periods was performed by the One Way ANOVA test followed by Tukey's Post Hoc test for multiple comparisons.

• Reference software:

This study used Mendeley desktop version 1.11 software for managing references.

Section A-Research paper



Results:

Statistical analysis

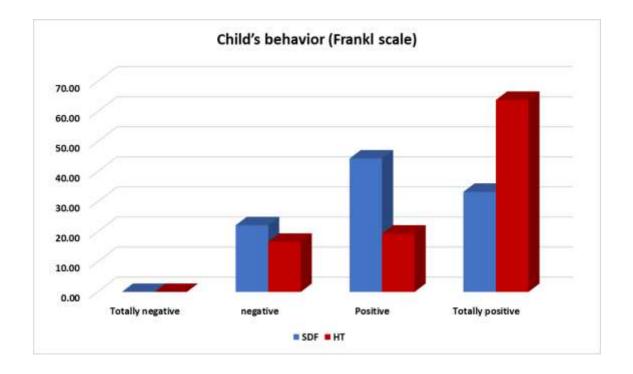
Statistical analysis was performed with SPSS2 $0^{\$}$, Graph Pad Prism $^{\$}$ and Microsoft Excel2016. All qualitative data were presented as frequency and percentages.

<u>Tests used:</u> In Qualitative data: <u>The chi-square</u> <u>test</u> was used to compare different groups_and between different intervals.

Data were presented as follows:

Child behavior (Frankel scale): The frequency and percentages of all scores of child behavior of both groups were presented Comparison between both groups was performed by using the Chi-square test, which revealed that:

- In score 1 (totally negative): both groups revealed (0) with (CI = 0.02 / 49.7)
- In score 2 (negative): There was an insignificant difference between both groups as P=0.57, and also, SDF has 33% more likely to be in the negative group than HT with (CI =3.5 / 3.4)
- In score 3 (positive): HT (19.4%) was significantly lower than SDF (44.4%) as P=0.02* and also, The SDF group has 2.2 times more likely to be in the positive group than HT
- In score 4 (totally positive): HT (63.9%) was significantly lower than SDF (33.3%) as P=0.01*.



DISCUSSION

The high caries index in primary teeth, and its improper treatment, is considered a major public health problem during childhood and may affect children's lives. (Tickle. et al.2002)

Two minimally invasive techniques were compared (HALL technique and SDF application) in clinical efficiency and child behaviour in Egyptian patients who have a high caries index .it was aimed to investigate the available evidence with regards to the management of carious lesions into dentine in primary molars using a minimal intervention approach (HALL technique and SDF application) omitting the need for local anesthetics, to our knowledge no studies in literature were conducted comparing the two minimal invasive technique, however different studies reported clinical success for each technique independently (Hu et al .2022), (Banihai et al .2022)

HALL technique: the choice of this comparator was based on biological principles. It can arrest caries and protect the primary tooth until shedding. The superficial plaque layer, an essential layer in the biofilm for caries progression, is left and sealed along with the carious lesion. The plaque biofilm composition will be changed to a less cariogenic flora. Thus, this technique may arrest or at least slow caries progression in

primary teeth (**Kidd. et al .2004**), (**Innes. et al .2006**). HALL technique aimed to increase a child's cooperation because local anesthesia is eliminated, and the child is expected to have a less traumatic dental experience (**Armfield, J. M., & Milgrom, P.** (2011).

SDF application: the choice intervention was based on its anti-cariogenic effect because it contains both fluoride and silver ions which can inhibit the formation of cariogenic biofilms. (Knight et al.2005), it was reported that the non-removal of caries is more effective than caries removal. Because of its impressive ability to arrest decayed lesions in one application, furthermore it has an unique power due to phenomenon called (the zombie's effect), It is based on the concept that the bactericidal activity of silver ions for the prolonged effect was capable of killing living bacteria (Wakshlak et al .2015) (Horst et al .2016),

Fluoride ions inhibit biofilm formation by binding to bacterial cell components and inhibit enzymes related to carbohydrate metabolism and sugar uptake. In addition, the antibacterial action of silver ions penetrates and destroys bacteria cell wall structures, inhibiting enzymatic activity so inhibiting metabolic processes, and the replication of bacterial DNA (Peng et al .2012) (Mei et al .2013), (Chen et al .2017)

Regarding child behavior for both groups, The SDF group had 48% less likely to be in a positive group than HT with (CI =0.30 / 0.883), The SDF group had 2.2 times more likely to be in the positive group than HT with CI = (1.07/4.88)

.Regarding the child's behavior in HT was the found the same results this study (page, L. A et al. 2014) reported that (90%) of children treated with the HALL Technique responded positively to the question about having "enjoyed their visit to the clinic", Nearly all children (87 out of 97) may the contrast of results based on that in this study asked the children immediately after treatment at the same session if they had enjoyed their visit to the clinic that day to facilitate the accuracy of meanwhile, this article was in answers disagreement (Santamaria et al .2015) comparing HT, conventional restoration and non-restorative caries treatment regarding child behavior using Frankel scale the result regaling HT showed 13% negative response; furthermore, this article reported (Ebrahimi et al .2020) that according to Frankl scores, patients' behavior and cooperation significantly better in the SSC group than in the HT and modified atraumatic restorative treatment (mART) groups. This similarity is due to this study using the same measurement tool as the current study (frankle scale to assess the child's behavior

CONCLUSION:

From this study, the following could be concluded:

- 1) HALL technique and SDF application are superior and effective for arresting caries in primary molars. Whereas comparable success rates were noted in both techniques
- 2) In both groups enhance the cooperation of the child due to the ease of application and exclude feeling exaggerated pain, whereas the child behaviour in both groups showed positive and totally positive scales. However, the chair-time management required for SDF was significantly shorter compared to HT.

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