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Effectiveness of Silver diamine fluoride vs sodium fluoride and acidulated phosphate fluoride as a topical fluoride in caries prevention of primary teeth: A systematic review.

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Abstract

Objective: This systematic review examines the effectiveness of silver diamine fluoride (SDF) compared to sodium fluoride and acidulated phosphate fluoride in caries prevention and arrest in primary dentition.

Background: Silver diamine fluoride has been extensively researched and proven effective for caries prevention and arrest. Limited studies support its effectiveness as topical fluoride in children.

Materials and methods: Multiple databases were searched according to specified inclusion-exclusion criteria. Quality assessment used modified Centre for Evidence-Based Medicine worksheets.

Results: Four randomised controlled trials were identified that addressed the effectiveness of SDF in comparison with sodium fluoride and acidulated phosphate fluoride in caries prevention and arrest. Caries prevention and arrest rate for SDF were significantly higher than sodium fluoride and acidulated phosphate fluoride.

Conclusion: This systematic review evaluates the effective use of SDF for both caries prevention and arrest. Existing reports of SDF trials support effectiveness in caries prevention and arrest, remineralization of deep occlusal lesions in children.

Keywords: silver diamine fluoride, preventive treatment, primary dentition, carries arrest, SDF, systematic review.

Introduction

Dental caries has been on the increase in many countries and has become a significant health problem especially in socially disadvantaged populations [1]. It is one of the most common chronic infectious disease found in children worldwide and if left untreated, is rapidly progressed. Oral rehabilitation in children requires time, resources and effort of dental specialists, the child and parents. Caries is a destructive condition of organic and inorganic components of the tooth structures but reversible and most importantly, preventable.

Conventional dental treatment to manage carious lesions can be time consuming and expensive, and in some cases, (eg. children with disabilities and those with dental fear) these approaches may not be feasible. Moreover, current research suggests that carious lesions do not always need to be managed using a traditional 'drill and fill' approach and can be managed and arrested using alternative methods [2].

Background

Currently, management of dental caries involves preventive and non-preventive treatment methods, preventive caries protocols are implemented to prevent the onset of caries and protect the teeth from the conditions that favour dental caries. These protocols include: nutritional counselling, fluoride use, oral hygiene instructions, topical antimicrobial agents [3].

Fluoride therapy has been the cornerstone of caries-preventive strategies since the introduction of water fluoridation schemes over 5 decades ago [4]. Fluoride controls the initiation and progression of carious lesions [5]. Various modes of fluoride use have evolved, each with its own recommended concentration, frequency of use, and dosage schedule. The use of topically applied fluorides in particular, which are much more concentrated than the fluoride in drinking water, has increased over recent decades

Topical fluorides, such as NaF varnish, APF gel are used as preventive reagents because of their remineralization and antimicrobial abilities [6]. In 2014, the FDA approved SDF use for tooth sensitivity, with an off-label use in caries treatment and prevention and additionally approved the marketing of SDF with potassium iodide (Riva Star, SDI Limited) in 2018. SDF (38% Ag (NH3)2F) is a colourless liquid composed of 24–29% silver and 5–6% fluoride. It is also an alkaline reagent with pH 109, which provides an unfavourable environment for dentine collagen enzyme activation [7]. Also, silver has been used as a medical antimicrobial since the 17th century [8] and in dentistry during 1917 [9].

Untreated dental caries is a global pandemic in young children. However, the generalizability of using these alternative treatments in young children has been questioned since the success of a treatment for decayed primary teeth also depends on children's behaviours. To date, there is a lack of scientific evidence for clinically-effective preventive caries management with topical fluoride, focusing on primary teeth. This systematic review is aimed to assess the effectiveness of SDF as topical fluoride in primary teeth.

Methods

Search strategy (Table-1):

This systematic review was performed using the Preferred Reporting Items for Systematic reviews and Meta-Analysis statement (PRISMA).

Table 1- Search strategy

Databases used	PubMed, PubMed Clinical Queries, EMBASE, Clinical trials registry - India, Cochrane Central Register of Controlled Trails, Web of Science, SCOPUS, and Google Scholar.
Search terms (MeSH, Brand names, Other terms) for SDF:	'Silver Diamine Fluoride" OR "Diammine Silver Fluoride" OR "Ammonical Silver Fluoride" OR Silver Ammonia Fluoride" OR "Silver Fluoride" OR "Quaternary Ammonium Compounds" (MeSH)
MeSH terms for caries in children:	"primary + Caries + Silver" OR "Dental Caries + Therapy + Silver" OR" children + Care Management + Dental" OR "Cariostatic Agents + Therapeutic + children" OR "Dental Atraumatic Restorative Treatment/Methods" OR "Dental Caries + Prevention + Control+ Silver"

Systematic search was conducted on the common electronic databases such as PubMed, PubMed Clinical Queries, EMBASE, Clinical trials registry - India, Cochrane Central Register of Controlled Trails, Web of Science, SCOPUS, and Google Scholar were searched for articles published from 1946 to October 2019.

A literature search was conducted under two broad categories:

• Silver diamine fluoride: Under search terms (MeSH, Brand names,

Other terms) "Silver Diamine Fluoride" OR "Diammine Silver

Fluoride" OR "Ammonical Silver Fluoride" OR Silver Ammonia

Fluoride" OR "Silver Fluoride" OR "Quaternary Ammonium

Compounds" (MeSH)

• Caries in older adults: Under search terms "Elderly+Caries+Silver"OR "Dental Caries+Therapy+Silver" OR "Older Adult+Care Management+Dental" OR "Cariostatic Agents+Therapeutic+Elderly"

OR "Dental Atraumatic Restorative Treatment/Methods" OR "Dental Caries+Prevention+Control+Silver"

We continued to update our search through monthly reruns of our search terms in PubMed. The bibliographies of the selected manuscripts were subsequently hand-searched.

Inclusion criteria

- **Type of Studies -** Clinical studies of randomized controlled trials, controlled trial were included.
- **Type of participants -** Children aged 6 – 9 years were considered for inclusion in this review.
- **Type of interventions and outcomes -** Various intervention methods that included topical fluorides such as SDF, NaF and APF were included.
- **Outcome -** The primary outcomes of the included studies were caries arrest, progression or regression. There could be comparisons of outcomes of SDF with other topical fluorides (NaF, APF).

Exclusion criteria

- **Type of reports –** systematic review, meta-analysis, case reports, in vitro studies, comments on articles and narrative reviews
- **Type of dentition –** studies on permanent dentition
- **Type of population –** older adults and animal
- **Language –** any other than English

Data extraction: Summary tables were used to organise the study characteristics and results for each study (Table 2).

Table 2: Data extraction sheet and characteristics of included studies.

Article, year, country.	Sample size, Study population, loss to follow up	Type of study, duration	Intervention, Comparison	Outcome	Statistical analysis used	Results
Lo *et al*, 2001, Hong Kong.	Baseline N= 375 Children Boys 209 (56%), Girls 166 (44%) Mean age 4.0±0.8 y Loss to follow up N = 365 at 6m (3%) N = 353 at 12m (6%) N = 341 at 18m (9%)	RCT, 18m	• Caries excavation with 38% SDF every 12 m (Gp 1) • No caries excavation with 38% SDF every 12 m (Gp 2), • Caries excavation, and then 5% NaF applied at Day 0 and every 3 m (Gp 3) • No caries excavation, and then 5% NaF applied at Day 0 and every 3 m (Gp 4) • Water application (Gp 5)	DMFS, Caries arrest	• Kappa • ANOVA • Scheffe's multiple comparison (0.05) • Chi2 ($p < 0.001$)	• Intra-examiner reproducibility: Baseline (Kappa, 0.98), 6 m (Kappa, 0.98), 12 m (Kappa, 0.95), 18 m (Kappa, 0.96) • No significant difference in all groups at baseline: DMFS, number of tooth surfaces with active caries, mean number of non-vital upper anterior teeth, mean number of retained roots (ANOVA, not significant) • No significant difference between Gp1-Gp5 (Chi2, $p > 0.05$) – tooth brushing behaviour, use of fluoridated toothpaste

						• At all follow up exams (6 m, 12 m, 18 m)- significant difference in mean number of arrested caries among 5 Gps • Caries arrest is statistically significantly higher in SDF Groups (Gp1 and Gp2) (ANOVA, Scheffe's multiple comparisons, p < 0.001) • Annual SDF application (Gp 1 and Gp2) higher incidence of arrested caries appearing black (P <0.001) than Gp 4, followed by Gp 3 (ANOVA, p <0.001) • No statistical difference in increment of nonvital teeth among 5 Gps • No adverse side effects observed • No difference in mean number arrested caries tooth surfaces @18 m with or without caries

						excavation (No significance) • Caries excavation before NaF application reduced proportion of arrested caries lesions that had become black • Caries excavation before SDF application, no significant benefit
Chu *et al*, 2002, Hong Kong.	Baseline N= 375 Children Boys 209 (56%), Girls 166 (44%) Mean age 4.0±0.8 y Loss to follow up N = 308 (18%) •Gp1(20%), Gp2(19%), Gp3(18%), Gp4(16%), Gp5(15%),	RCT, 30m	• Caries excavation with 38% SDF every 12 m (Gp 1) • No caries excavation with 38% SDF every 12 m (Gp 2), • Caries excavation, and then 5% NaF applied at Day 0 and every 3 m (Gp 3) • No caries excavation, and then 5% NaF applied	DMFS, Caries arrest	• Kappa • ANOVA • Scheffe's multiple comparison (0.05) • Chi2 ($p < 0.001$) • ANCOVA • McNemar Test	• DMFS score of upper anterior teeth between baseline vs 30 m exam, not significant ($p > 0.05$) • intra-examiner reproducibility (Kappa >0.95) at baseline and follow up exams • No significant difference (ANOVA, $p > 0.05$) - Mean age, dmfs scores, number of decayed tooth surfaces, number of non-vital teeth, # new caries, # of arrested caries, increment of

			at Day 0 and every 3 m (Gp 4) • Water application (Gp 5)			nonvital teeth at each follow up exam • at 24 m follow up, no significant difference between Gp1-Gp5 (Chi2, $p > 0.05$) – tooth brushing behaviour, use of fluoridated toothpaste • at 24 m follow up, significant difference from baseline (McNemar Test, $p < 0.001$) – tooth brushing behaviour, use of fluoridated toothpaste • at 30 m ($p< 0.001$) – significant different in mean # arrested carious tooth surfaces in Gp1-Gp5 • Gp1 and Gp2 had more arrested caries than all other groups (ANOVA, $p < 0.001$) • Gp1 and Gp2 had more arrested caries appear black than all other

						Gps (Chi2, p < 0.001) • Children in Gp5 developed more new caries lesions than all other Gps (ANOVA, p <0.001) • No significant difference in increment of nonvital teeth in all Gps • No adverse side-effects (discoloration/damage to gingival tissues) • No significant difference in parental satisfaction with their child's dental appearance and dental health (McNemar, p <0.05) − 2/5 s of children received other dental care during study (majority performed on primary molars, unrelated to study) • Significantly more arrested caries at 30 m Higher baseline caries (ANCOVA, p < 0.001),

						SDF applications (ANCOVA, p < 0.001), brushed teeth more often (ANCOVA, p = 0.003) • No difference in mean number arrested caries with excavation between • Gp1 and Gp2 (95% CI = 0.75 to −1.42) • Gp3 and Gp4 (95% CI = 0.04 to −2.12)
Shah et al, 2014, India	Baseline N= 123 children Boys 82 Girls 41 Mean age 8.38 ± 0.75 Loss to follow up N = 115	RCT, 18m	38% SDF applied at 0,6 and 12 months (Gp 1) Fluoride varnish applied at 0,6 and 12 months (6% NaF, 6% Caf_2) (Gp 2) APF gel applied at 0,6 and 12 months (1.23%) (Gp 3)	DMFS, Baseline fluoride content.	• Paired t-test, • multiple comparison tucky HSD. • ANOVA • Mann-Whitney Test.	Inter group comparison for fluoride content baseline vs 6 months Overall (p <0.001) extremely significant. • 0-6 months: Compared to baseline, one new carious surface was found in Group 1 (SDF), six were found in Group 2 (Fluoride Varnish) and four were found in Group 3 (APF Gel). • 6-12 months: Between 6 and 12 months, one was

						found in Group 1 (SDF), two were found in Group 2 (Fluoride Varnish) and three were found in Group 3 (APF Gel). • 12-18 months: Between 12 and 18 months, No new carious surface was present in Group 1 (SDF), two were found in Group 2 (Fluoride Varnish) and two were found in Group 3 (APF Gel). • 0-12 months: Compared to baseline, two carious surfaces were found in Group 1 (SDF), eight were found in Group 2 (Fluoride Varnish), and seven were found in Group 3 (APF Gel). • 0-18 months: Compared to baseline, 2 carious surfaces were found in Group 1 (SDF), 10 were found in Group 2 (Fluoride

						Varnish), and 9 were found in Group 3 (APF Gel). No statistically significant difference in number of new carious surfaces was found between any of the Group at different time period (*P* > 0.05).
Duangthip *et al*. 2016, Hong Kong	Baseline N= 304 Children Boys 183 (60%), Girls 121 (40%) Mean age 41 ± 4 m Anterior and Posterior Teeth Loss to follow up N = 275 (9.5%) Gp1(11%), Gp2(8%, Gp3(9%)	RCT, 18m	30% SDF applied at 0 and 12 months (Gp 1) 30% SDF applied at 0, 7, 14 days (Gp 2) 5% NaF 3x applied at 0, 7, 14 days (Gp 3)	DMFS, Caries arrest	Kappa • ANOVA • Bayesian models • Multi-level survival analysis (Win BUGS)	Examination performed at: 0, 6, 12, 18 m • No difference among Gp1, Gp2 or Gp3 in demographic background, oral health behaviours, oral hygiene status, caries experience at baseline • 18 m - Caries arrest rate, (Chi2, p < 0.001) Gp1(40%), Gp 2(35%), and Gp3 (27%) • 6 m and 12 m - Caries arrest rate Gp2 > Gp1 • Factors significantly affecting time to caries arrest (95% C.I.) Gp, presence of

						plaque on lesions, tooth type, tooth surface • Factors NOT significantly affecting time to caries arrest (95% C.I.) Demographic background, oral health related behaviours, baseline caries experience • SDF caries arrest (Gp1 or Gp2) was better than NaF at 6 m (Chi2, $p < 0.001$), 12 m (Chi2, $p < 0.001$), and 18 m (Chi2, $p < 0.001$).
Gp – Group, M – Months N – number SDF – silver diamine fluoride, NaF – sodium fluoride, APF – acidulated phosphate fluoride RCT – randomized controlled trials						

Data Assessment

The Critical Appraisal Worksheet For Randomised Controlled Trials From The Oxford Centre For Evidence-Based Medicine (CEBM 2018) Provided The Framework To Assess The Quality And Risk Of Bias Of The Selected Articles [10]. All Four Authors Recorded Their Findings In An Assessment Table (Table 3) And Discussed Disagreements Until Achieving Consensus.

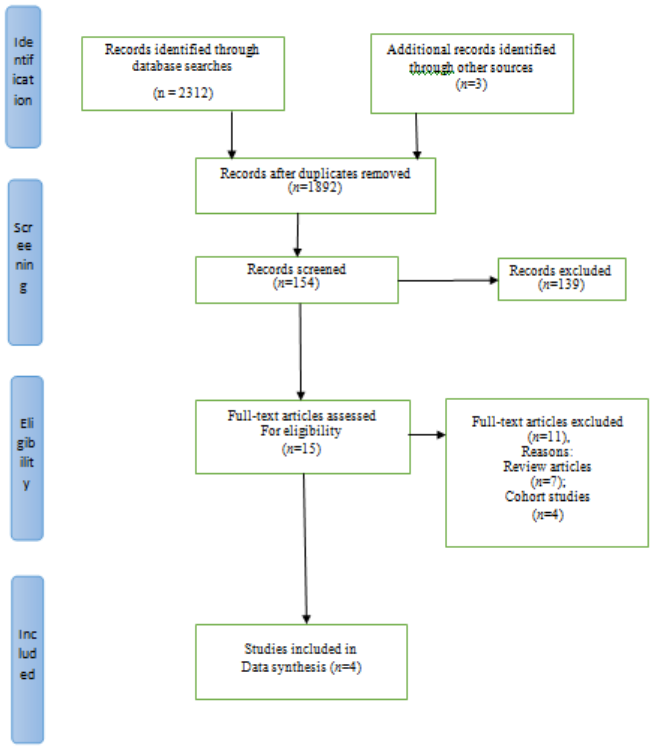
Table 3: The critical appraisal worksheet for randomised controlled trials from the Oxford Centre for Evidence-based Medicine

Author, Year, country, Study type.	R- Was the assignment of patients to treatments randomised?	R- Were the groups similar at the start of the trial?	A – Aside from the allocated treatment, were groups treated equally?	A – Were all patients who entered the trial accounted for? And were they analysed in the groups to which they were randomised?	M - Were measures objective or were the patients and clinicians kept "blind" to which treatment was being received?	Results Large effect Size	Precision of estimate	External validity/ applicability	Extent to which CEMB criteria were met
Lo et al, 2001, Hong Kong, RCT	YES	YES	YES	YES	YES	YES	YES	YES	This study met all the CEBM criteria.
Chu et al, 2002, Hong Kong, RCT	YES	YES	YES	YES	YES	YES	YES	YES	This study met all the CEBM criteria.
Shah et al, 2014, India, RCT	YES	YES	YES	YES	YES	YES	YES	YES	This study met all the CEBM criteria.
Duangthip et al, 2016, Hong Kong, RCT	YES	YES	YES	YES	YES	YES	YES	YES	This study met all the CEBM criteria.

Results

The initial search identified 2312 articles. Category #1 "SDF" yielded 509 articles. Search for articles in category #2, "SDF in primary dentition," yielded 1026 articles. An additional 3 articles were subsequently identified. After removing duplicates and applying inclusion and exclusion criteria, 176 abstracts were selected for initial review by all authors. Eighteen articles were selected for full review. Four articles were selected for final inclusion in this systematic review (Figure 1). Selected RCT's investigated the effect of SDF when compared with other topical fluoride (NaF, APF). Measures used to quantify findings of the studies reviewed are shown in Table 3.

Figure 1 - Flow chart of the literature search



Assessment of Clinical Trials Reviewed

Using the quality assessment framework, CEBM criteria. All three studies exhibited a low degree of bias. (Tables 2 and 3) All four RCT's investigated the effect of SDF when compared to other topical fluorides such as NaF, APF and reported a significant effect of SDF on the prevention and/or arrest of caries in primary dentition. Effectiveness of SDF was measured using the following parameters:

• lo et al [11] investigated the difference between baseline DMFS score, number of teeth surface with active caries lesion, mean number of non – vital upper anterior teeth, mean number of retained roots and at the end of 18 months comparing SDF and NaF.

• chu et al [12] measured the difference between the DMFS score of upper anterior teeth between baseline vs 30 months later. Caries arrest at 30 months after the application of SDF with excavation and without excavation of caries with the application of SDF and NaF.

• shah et al [13] evaluated the base line fluoride content in enamel and DMFS index at base line and at 18 months after the application of SDF and APF gel.

• Duangt hip at al [14] calculated the new caries experience, oral hygiene status, caries arrest rate in comparison with the application of SDF and NaF.

Discussion

Dental caries is one of the most common chronic childhood diseases [15]. It is therefore essential to identify approaches for the management of dental caries that are minimally invasive and less traumatic, such as water fluoridation, fluoridated toothpastes, topical fluoride applications [16]. Fluoride interferes with microbial processes of the oral biofilm and inhibits demineralization of tooth [17]. Thus fluoride is not only a preventive mean to reduce caries prevalence, but can also partake in caries arrest. The results of this systematic review found that SDF, when compared to NaF and APF, was a more effective fluoride containing reagent for caries arrest in children. After reviewing the published literature, four articles met inclusion criteria for this systematic review Although four articles were identified, three included studies are based on two clinical trials. It would be ideal to conduct further clinical trials to formulate stronger clinical

recommendations. In summary, SDF is more effective as a caries arresting reagent than NaF, APF and has many implications for paediatric dentistry. The ease of application can result in greater delivery of the reagent to a larger population of children with untreated caries. The main reported disadvantage being the non-aesthetic black colouring of carious lesions after SDF application [11,12,14,18], however the additional use of potassium iodide has been reported to reduce the discolouration [19]. Surveys report a higher parental acceptance of SDF associated black staining on posterior teeth than anterior teeth, additional factors such as behavioural barriers, socioeconomic status, and indications for sedation and/or hospital dentistry also increased parental acceptance [20]. Though the quality of evidence is strong, the findings were only based on three studies. Further studies are needed to evaluate the minimal necessary concentration and frequency of application to arrest caries of primary and permanent teeth.

Recommendations

Our recommendations for the use of SDF in primary are based on the current state of evidence found in this systematic review. SDF is an appropriate option to caries prevention and management to optimise oral health across the life course.

AAPD Recommendations

Case selections for application of silver diamine fluoride Patients who may benefit from SDF include those:

• With high caries risk who have active cavitated caries lesions in anterior or posterior teeth

• Presenting with behavioural or medical management challenges and cavitated caries lesions

• With multiple cavitated caries lesions that may not all be treated in one visit

• With dental caries lesions that are difficult to treat

• Without access to or with difficulty accessing dental care. Criteria for tooth selection include

• No clinical signs of pulpal inflammation or reports of unsolicited/spontaneous pain.

• Cavitated caries lesions that are not encroaching on the pulp. If possible, radiographs should be taken to assess depth of caries lesions.

• Cavitated caries lesions on any surface as long as they are accessible with a brush for applying SDF. (Orthodontic separators may be used to help gain access to proximal lesions.) SDF can be used prior to restoration placement and as part of caries control therapy [21]. Informed consent, particularly highlighting expected staining of treated lesions, potential staining of skin and clothes, and need for reapplication for disease control, is recommended. ***Clinical application of silver diamine fluoride***

• Remove gross debris from cavitation to allow better SDF contact with denatured dentin.

• Carious dentin excavation prior to SDF application is not necessary. As excavation may reduce proportion of arrested caries lesions that become black, it may be considered for aesthetic purposes.

• A protective coating may be applied to the lips and skin to prevent a temporary henna-appearing tattoo that can occur if soft tissues come into contact with SDF.

• Isolate areas to be treated with cotton rolls or other isolation methods. If applying cocoa butter or any other product to protect surrounding gingival tissues, use care to not inadvertently coat the surfaces of the caries lesions.

• Caution should be taken when applying SDF on primary teeth adjacent to permanent anterior teeth that may have non-cavitated (white spot) lesions to avoid inadvertent staining.

• Careful application with a micro brush should be adequate to prevent intraoral and extra oral soft tissue

exposure. No more than one drop of SDF should be used for the entire appointment.

• Dry lesion with gentle flow of compressed air.

• Bend micro sponge brush. Dip brush into SDF and dab on the side of the plastic dampen dish to remove excess liquid before application. Apply SDF directly to only the affected tooth surface. Remove excess SDF with gauze, cotton roll, or cotton pellet to minimize systemic absorption.

• Application time should be at least one minute if possible. (Application time likely will be shorter in very young and difficult to manage patients. When using shorter application periods, monitor carefully at post-op and re-care to evaluate arrest and consider re-application.)

• Apply gentle flow of compressed air until medicament is dry. Try to keep isolated for as long as three minutes.

• The entire dentition may be treated after SDF treatment with five percent sodium fluoride varnish to help prevent caries on the teeth and sites not treated with SDF.

Conclusion

This systematic review evaluates the effectiveness of SDF in comparison with NaF and APF for prevention and caries arrest in children. In view of the findings in this systematic review, SDF is a more effective caries preventing and arresting agent than NaF and APF. Existing reports of SDF trials support effectiveness in caries prevention and arrest, remineralization of deep occlusal lesions.

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