

Review Article

Silver Diamine Fluoride Versus Atraumatic Restorative Treatment in Pediatric Dental Caries Management: A Systematic Review and Meta-analysis

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ABSTRACT

Introduction: The objective was to compare the clinical efficacy of silver diamine fluoride (SDF) and atraumatic restorative treatment (ART) in arresting active caries in primary teeth and first permanent molars in children. **Materials and Methods:** The study protocol was registered in PROSPERO (CRD42020205675). A systematic search was performed in PubMed, Scopus, Embase, Cochrane Library, and gray literature for randomized controlled trials (RCTs) published in English language with a minimum follow-up of 6 months, comparing the caries arrest potential of SDF with ART in primary teeth and first permanent molars in children. The risk of bias and quality assessment of the studies was done using the Cochrane Collaboration Tool and Joanna Briggs Institute Critical Appraisal Tool. Data analysis was performed using RevMan software; the outcomes were summarized in meta-analysis (MA) using the random-effects model, and the odds ratio (OR) at 95% confidence interval (CI) was computed. **Results:** A total of 1059 studies were identified, out of which 562 remained after removal of duplicates. Eight studies were considered for full-text eligibility, and four studies were included in the qualitative review. Three out of four studies were conducted on primary dentition, whereas one study was done on erupting first permanent molars in children. MA of the two studies compared 30% SDF with ART in primary molars at 12 months and revealed the OR to be 2.02 (95% CI: 0.86–4.71; $I^2 = 62\%$; $P = 0.10$). **Conclusion:** The current review points to the lack of solid evidence comparing SDF with ART for arresting active caries in primary teeth, especially in the first permanent molars. No statistically significant difference between 30% SDF and ART in primary molars at 12 months was found in the present review. Well-designed RCTs are required to determine a minimum concentration of SDF which is effective and safe for caries arrest in children.

KEYWORDS: *Atraumatic restorative treatment, dental caries arrest, minimal intervention dentistry, non-aerosol-generating procedures, pediatric dentistry, silver diamine fluoride*

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INTRODUCTION

Early childhood caries is the most prevalent preventable disease affecting 60–90% of schoolchildren globally.^[1] This significant public health

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problem is prevalent in both developed and developing countries but particularly affects the socioeconomically deprived groups in which most often it remains untreated.^[2,3] In India, as per the National Oral Health survey conducted by Dental Council of India in 2004, the prevalence of dental caries was reported to be 51.9% in 5-year-old children.^[4] The persistence of caries in primary teeth increases the caries risk of the first permanent molars as they erupt around 6–7 years of age.^[3] Untreated caries adversely impacts the oral health-related quality of life of young children,^[2] leading to pain, abscess, systemic manifestations like fever and lymphadenopathy. Severe sequelae such as spread of odontogenic infections to anatomical spaces of the head and neck may also occur.^[4] The conventional management of dental caries involves a surgical approach requiring trained clinicians and sophisticated instruments.^[5,6] However, dental anxiety and fear pose a serious challenge in delivering the treatment in young children.^[7,8] Advanced forms of behavior management like sedation and general anesthesia are used to intercept this but are accompanied by increase in the treatment cost and risk for both the patient and the dentist.^[9] Introduction of Minimal Intervention Dentistry (MID) caused a paradigm shift in the dental caries management, especially in young children. Silver diamine fluoride (SDF) and atraumatic restorative treatment (ART) come under its umbrella and are aimed at maximum conservation of the tooth with least psychological impact on the patient.^[10] These techniques play a pivotal role in improving the oral health of children, particularly in areas where access to routine dental care is limited.^[2,6] SDF is referred to as “silver-fluoride bullet” due to its ability to arrest the caries progression and simultaneously prevent the formation of new lesions.^[11] This affordable topical solution is effective due to a combined action of sclerotic dentine formation by silver salt, potent germicidal effect by silver nitrate, and remineralization aided by fluoride.^[3,11] It requires minimal training, personnel, and is especially useful in very young children who are not receptive to dental procedures.^[12] In contrast, ART involves removal of decayed tissue using hand instruments followed by restoration of the cavity with an adhesive material, mostly, glass ionomer cement (GIC).^[6] This painless and cost-effective technique produces lesser dental anxiety, has high acceptance in children, produces a good seal, and replaces the damaged tooth tissue.^[6] Additionally, it includes placement of ART sealants which involve sealing the carious pits and fissures under finger pressure using hand instruments.^[13]

The aforementioned techniques have further become clinically relevant in the ongoing COVID-19 pandemic,

in which evidence-based, minimally invasive, non-aerosol-generating procedures have been emphasized for decreasing the burden of dental caries in children. Postponement of routine dental services during the COVID-19 pandemic has inevitably created a considerable backlog of children with untreated dental caries. Therefore, recent guidelines have highlighted the use of SDF and ART in both primary and permanent teeth for caries management and arrest.^[14] The aim of the present article is to systematically review and integrate the findings of the randomized controlled trials (RCTs) comparing SDF and ART in arresting active caries in primary teeth and first permanent molars in children. This article gives an insight into the available scientific evidence to help in clinical decision-making for effective management of dental caries in children, especially during the ongoing COVID-19 pandemic.

MATERIALS AND METHODS

The present systematic review (SR) followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines [Figure 1], and the study protocol was registered at PROSPERO (CRD42020205675) before performing preliminary searches. The research question was formulated according to the PICO (Participants, Intervention, Comparison, Outcomes) framework.

SEARCH STRATEGY

Electronic searches of four databases, PubMed, Embase, Scopus, and Cochrane Library, were performed before October 2020. No restriction was placed on the publication period; however, only the literature published in English language was considered. The keywords used to search all databases were “Silver diamine fluoride” AND “Atraumatic restorative treatment”; “Silver diamine fluoride” AND “Atraumatic restorative treatment” AND “Dental Caries”; “Silver diamine fluoride” AND “Atraumatic restorative treatment” AND “Children”; “Silver diamine fluoride” AND “Atraumatic restorative treatment” AND “Randomized Controlled Trials”; “Silver diamine fluoride” AND “Atraumatic restorative treatment” AND “Early childhood caries”; “Silver diamine fluoride” AND “Children” AND “Dental Caries” and “Atraumatic restorative treatment” AND “Children” AND “Dental Caries.” The ongoing clinical trials were located from the ClinicalTrials.gov and International Clinical Trial Registry Platform. Gray literature was explored from Google and online database like Shodganga for registered dissertations. Additionally, the bibliographies of the existing studies

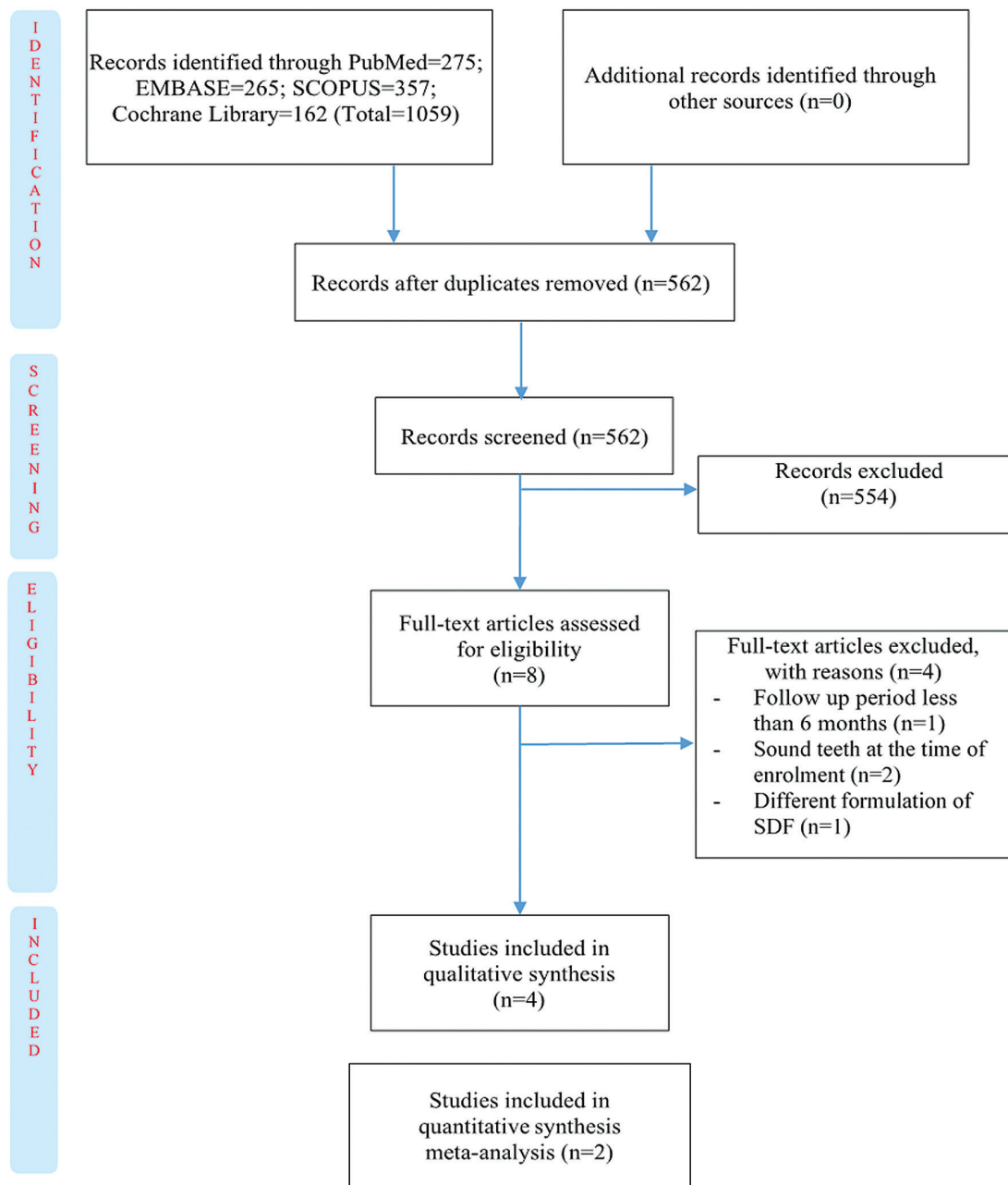


Figure 1: PRISMA flow diagram

and systematic reviews were scrutinized to identify missed studies. The literature thus obtained formed a potentially eligible list and was included for the initial screening.

STUDY SELECTION

The present SR included RCTs with parallel, split-mouth, and cluster study design comparing the efficacy of SDF with ART in arresting caries in primary teeth and first permanent molars in children. We included studies with children in the age group of 2–10 years regardless of their gender and geographical location

with active caries in primary dentition and/or first permanent molars not involving the pulp, diagnosed using any criteria. Studies with single and/or multiple surface lesions were considered. RCTs that compared SDF (with different concentrations and application frequencies) with ART (restoration or sealant) with or without excavation of caries prior to the application of these agents were included. However, studies conducted on children with significant medical history or those with non-carious teeth at the time of enrollment were excluded. Studies were excluded if SDF was compared with a placebo or a control group other than ART and

if the follow-up was less than 6 months. In addition, expert opinions, case reports, case series, narrative reviews, descriptive and analytical studies, *in vitro* studies, clinical trials investigating other aspects, guidelines, protocols, and ongoing clinical trials were excluded. The primary outcome was to compare the caries arrest caused by SDF and ART in the primary teeth and/or first permanent molars. The secondary outcome was to compare the adverse effects of the two techniques.

DATA COLLECTION

A reference management system (Mendeley Desktop) was used to list the potential literature and remove duplicates. Two trained independent reviewers performed the initial screening on the basis of title and abstract. This was followed by assessment of full-text eligibility of the relevant records which met the inclusion and exclusion criteria. In case of any ambiguity, unavailability of abstracts or full texts of studies, the authors were contacted via electronic mail or social media network like Research Gate. Disagreements between reviewers were resolved by discussion. However, third and fourth reviewers were consulted in case a consensus was not achieved. The excluded studies along with the reasons for exclusion were simultaneously documented.

QUALITY ASSESSMENT

Following the data extraction, two independent reviewers rigorously appraised the included studies for the potential risk of bias using the Cochrane Risk of bias assessment tool and Joanna Briggs Institute (JBI) Critical Appraisal Tool for RCTs. Disagreements between the reviewers were resolved via consensus before giving a final risk of bias classification and summary.

DATA EXTRACTION AND ANALYSIS

Data extraction was done by two independent reviewers: one reviewer collected the required information from the full texts of the included studies, whereas the second reviewer checked the collected data in the structured data extraction forms. The following data were extracted: publication details (author, year, country, setting, RCT design, trial registration, funding, sample size calculation), sample characteristics, intervention, comparator, statistical analysis, primary outcome, secondary outcome, follow-up, and risk of bias. The study author was contacted via e-mail to provide missing data or in case any further clarification was required. The data analysis was done using RevMan (version 5.4, Cochrane Collaboration, UK), and the outcomes were summarized in meta-analysis (MA) using the random-effects model and the odds ratio

(OR) at 95% confidence interval (CI) was computed. I² statistics was used for the assessment of heterogeneity.

RESULTS

STUDY SELECTION AND CHARACTERISTICS

The initial search identified 1059 studies in the following databases: 275 from PubMed, 265 from Embase, 357 from Scopus, and 162 from Cochrane Library [Figure 1]. After eliminating the duplicate records, a total of 562 articles remained. This was followed by scrutiny of the titles and abstracts which identified eight potentially relevant articles for full-text assessment. Of these, four studies did not meet our inclusion criteria and were excluded. Therefore, a total of four studies formed the premise of the present systematic review.

BASELINE CHARACTERISTICS

Out of the four included studies, three originated from Brazil^[2,5,16] and one from China.^[15] The included studies were mainly conducted outside the clinical setting, kindergarten and primary schools,^[5,15,16] and only one study^[2] was conducted in a dental school. The number and ages of children included in the studies ranged from 22 to 212 and 2 to 7 years, respectively. The publication period of the included studies ranged from 2009 to 2019. Three out of the four included RCTs were conducted on primary dentition and had a parallel study design,^[2,5,15] whereas one split-mouth RCT^[16] was done on erupting first permanent molar in children. The characteristics of the included studies are presented in Table 1.

All studies compared SDF with ART and primarily evaluated the caries arrest at different follow-up periods. The diagnostic criteria used for caries assessment varied in the included studies and consisted of decayed, missing, or filled teeth (dmft) or dmfs indices^[2]; International Caries Detection and Assessment System^[2,15]; Carvalho criteria^[16]; and visual inspection with tactile detection.^[5] The concentration of SDF used was 10%,^[16] 30%,^[2,15] and 38%.^[5] All studies used an annual application of SDF except one study^[5] which additionally included a group in which SDF application was repeated after 6 months. The application time of SDF was 3 min,^[2,15,16] whereas it was not specified in one study.^[5] The follow-up periods of studies ranged from 12 to 30 months. Two studies^[2,15] reported a follow-up period of 12 months, whereas the other two^[5,16] reported a follow-up period of 24 and 30 months, respectively.

Adverse effects of the two techniques were compared in one study^[2] as a secondary objective and found that 29.4% of the children from 30% SDF group and 33.3% from the ART group presented with adverse effects.^[2]

Table 1: Characteristics of the included studies

Study	Participant characteristics			Sample size		Intervention (SDF)	Comparator (ART)	Outcome		Quality (JBI Tool)
	Age (years)	Type of carious lesion	Follow-up	Children	Teeth			Dental caries arrest at 12 month follow-up (primary outcome)	Adverse effects (secondary outcome)	
1. Vollu <i>et al.</i> ^[2] ; Brazil Design: parallel RCT Setting: pediatric dental clinic Trial registration: reported Funded	2–5	Occlusal surface (primary molars)	12 months	Gp1: 34 Gp2: 33 Total: 67	Gp1: 65 Gp2: 52 Total: 117	Gp1: 30% SDF (Cariostop, Biodinamica, Parana, Brazil)	Gp2: ART using glass ionomer (Ketac Molar Easy Mix 3M)	Gp1: 55/65 Gp2: 43/52	Unit of analysis: children Gp1: 29.4% (10/34) Gp2: 33.3% (11/33)	High
2. Zhi <i>et al.</i> ^[5] ; China Design: parallel RCT Setting: kindergarten school Trial registration: reported Funded Sample size calculation: reported	3–4	Single or multiple surface (anterior and posterior primary teeth)	24 months	Gp1: 71 Gp2: 69 Gp3: 72 Total: 212	NR	Gp1: annual application (12 months) of 38% SDF (Saforide, Seiyaku Kasei Co. Ltd, Osaka, Japan)	Gp3: annual (12 months) application of glass ionomer (Fuji VII, GC Corporation, Tokyo, Japan)	NR	NR	Moderate
3. Dos Santos <i>et al.</i> ^[15] ; Brazil Design: parallel RCT Setting: municipal primary schools Trial registration: NR Funded Sample size calculation: reported	5–6	Single or multiple surfaces; (posterior primary teeth)	12 months	Gp1: 48 Gp2: 43 Total: 91	Gp1: 183 Gp2: 162 Total: 345	Gp1-annual application (12 months) of 30% SDF (Cariestop Biodynamic)	Gp2: IRT using glass ionomer (GC FUJII IX GP, GC America, Inc.)	Gp1: 113/183 Gp2: 59/162	NE	Low
4. Braga <i>et al.</i> ^[16] ; Brazil Design: split-mouth RCT Setting: dental school Trial registration: reported Funded Sample size calculation: reported	5–7	Active initial caries on occlusal surface of first permanent molars	30 months	Total: 22	Gp1: 20 Gp2: 18 Gp3: 20 Total: 58	Gp1: 10% SDF (Cariostatic, Inodon, Porto Alegre, Brazil)	Gp2: Cross tooth brushing technique (CTT) Gp3: glass ionomer (Vidrión F, SSWWhite, Rio de Janeiro, Brazil)	Gp1: 2.0 Gp2: 1.1 Gp3: 1.6 (baseline mean (3)–12 months mean)	NE	Moderate

NR = not reported, NE = not evaluated, Gp = group, SDF = silver diamine fluoride, ART = atraumatic restorative treatment

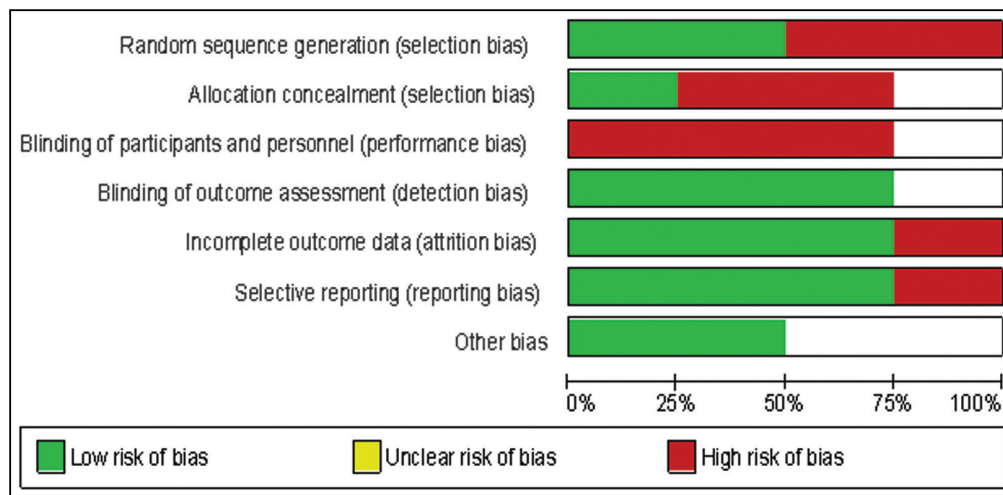


Figure 2: Risk of bias graph

Black staining and whitish discoloration of gingiva were the most commonly reported events in the SDF group.^[2] On the contrary, another study noted no adverse effects of SDF on treated teeth and soft tissues.^[5]

RISK OF BIAS IN THE INCLUDED STUDY

Cochrane Risk of bias assessment tool found two studies at high risk for randomization and allocation concealment.^[15,16] It was noted that none of the included studies reported blinding of participants and personnel because of the marked difference in the appearance of the two materials. Three studies^[2,5,16] were at low risk and one study^[15] was at unclear risk of bias for outcome assessor blinding [Figures 2 and 3]. Additionally, JBI tool was also used to score the methodological quality of the included RCTs. One study was rated as high quality^[2]; two studies^[5,16] were of moderate quality whereas one study^[15] was rated as low quality.

META-ANALYSIS

The two studies included in MA^[2,15] compared 30% SDF with ART for caries arrest in primary molars at 12 months. The data from these studies were dichotomous, i.e., number of teeth with active caries at baseline and at 12 months in both the groups was available. The third study done on primary teeth was not included in the MA as the outcome was not reported at the tooth level but as the number of arrested carious surfaces or lesions.^[5] The primary outcome was computed using a random-effects model in which two treatments, experimental (30% SDF) versus control (ART), were evaluated for caries arrest in primary molars at 12 months. The MA was conducted using the Revman 5.4 software, and the heterogeneity was evaluated using the I² test. A Forest plot [Figure 4] shows the pooled proportion of results and OR was reported to be 2.02 (95% CI: 0.86–4.71;

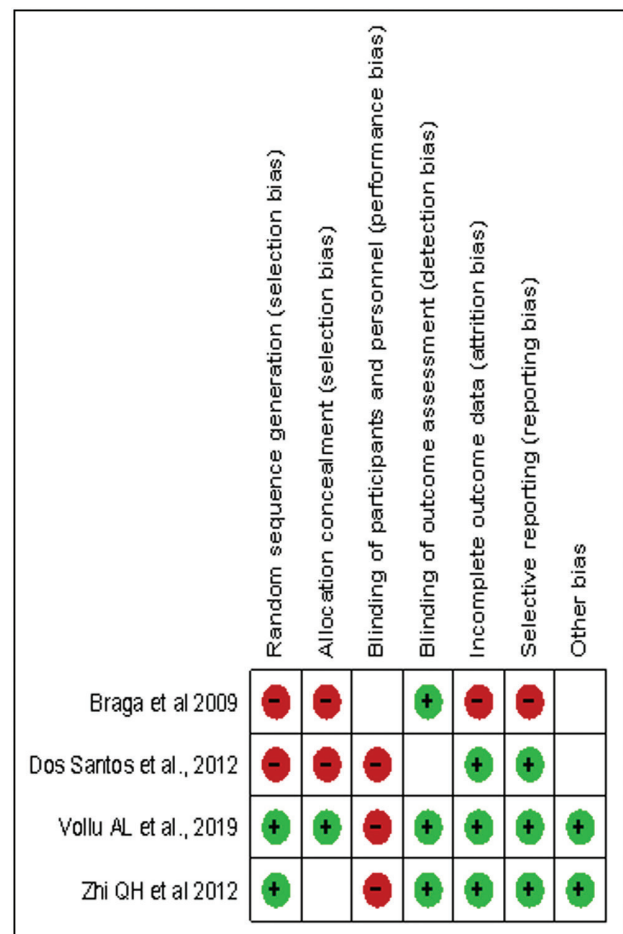


Figure 3: Risk of bias summary

$I^2 = 62\%$; $P = 0.10$). Although there was no statistically significant difference in the caries arrest between the two interventions, the numbers of arrest events were high in the children treated with SDF (168/248) than with ART (102/214).

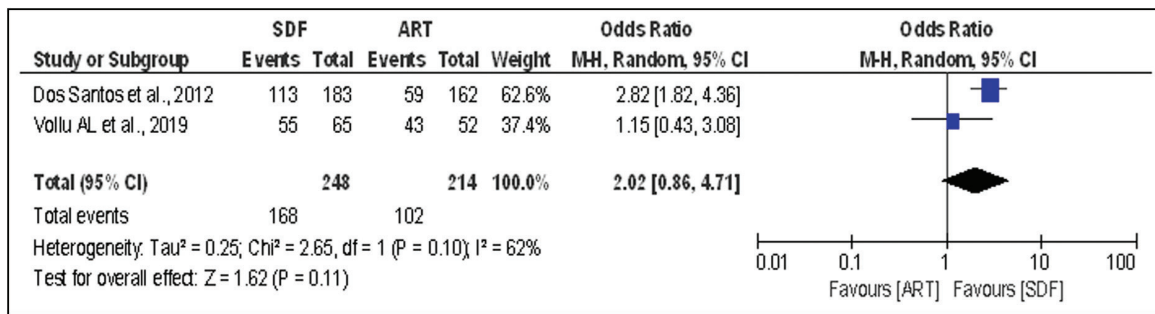


Figure 4: Forest plot at 12 months follow-up

DISCUSSION

SDF and ART have been extensively used in the pediatric and community dentistry programs for improving oral health worldwide.^[17] Hence, the focus of the current article was to investigate the superiority or non-inferiority between these two minimally invasive, non-aerosol-generating techniques in arresting active dental caries in children. Unlike the previous reviews, SDF was not compared with placebo or active treatments other than ART. Therefore, the number of studies comparing the two was very few and some studies got further excluded due to our distinct inclusion criteria. Furthermore, since the methodology and measurement of outcome variable differed between the studies, not all studies were included for MA.

Three studies^[2,5,15] compared the caries arrest potential of SDF and ART in deciduous dentition. One study reported 30% SDF to have similar results to ART at 12 months.^[2] Another study found 38% SDF and high fluoride releasing GIC to have similar results at 12 months.^[5] On the contrary, one study reported 30% SDF to be more effective than ART in primary molars at 12 months.^[15] For caries arrest in first permanent molars, one study found 10% SDF and ART to be equally effective at 12 months.^[16] Out of the three studies in deciduous dentition, two studies^[2,15] included in the MA reported the outcome at the tooth level and revealed no statistically significant difference in caries arrest between 30% SDF and ART in primary molars at 12 months. ART can therefore be an effective alternative especially in cases where the patient does not accept SDF. One study^[5] was excluded from the MA as it reported the outcome as the number of arrested carious surfaces or lesions. This highlights the need for standardization of data presentation in RCTs evaluating caries arrest. On literature review, studies comparing SDF and ART on non-carious first permanent molars were excluded^[18,19]; and since only one study^[16] was included in the qualitative review, the data on first permanent molars could not be meta-analyzed.

It is important to emphasize that the included split-mouth RCT in permanent molars^[16] does not ensure intervention fidelity as chances of a possible carryover effect between different treatment groups cannot be ruled out. Slow fluoride release from GIC could have affected the SDF-treated teeth and hence influenced the study results.^[16] Additionally, our literature search identified that aesthetic perception and acceptance of SDF induced black staining in permanent teeth in patients, and parents requires further exploration.

The American Academy of Pediatric Dentistry recommends 38% SDF application once a year; however; the included studies in the present review used different percentages (30%, 38%, 10%) of SDF for caries arrest.^[2,5,15,16] The present SR highlights the need for well-designed RCTs to determine a minimum concentration of SDF, which is effective and safe for caries arrest in children. Two studies^[5,16] found that increasing the frequency of SDF application to every 3 or 6 months increased the rate of caries arrest. It has been reported that anterior teeth, buccal, and lingual surfaces exhibit higher caries arrest rate due to easy cleanability and active silver precipitation in anterior teeth by exposure to light.^[9] Therefore, one-time SDF application for caries arrest in posterior teeth and in large cavities may not be sufficient.^[9] Customized reapplication is recommended for each patient after evaluation for caries risk and activity of the lesions on post-operative visits.^[9]

ART was developed mainly for treating caries in children living in underserved areas of the world where facilities like electricity and trained manpower are limited.^[6] The World Health Organization recommends high viscosity GIC FUJI IX as the gold standard for ART restorations. It is a biocompatible material which chemically adheres to enamel and dentine, inhibits enamel demineralization, and has lesser potential to induce recurrent caries. This esthetic restoration prevents diffusion of acids from biofilm into the carious lesion and the loss of minerals out of

the lesion, thereby causing caries arrest.^[6] In addition, it avoids food trapping and provides an occlusal area for mastication.^[2] In contrast, SDF application is a simpler technique than ART in which caries removal prior to application is not necessary and hence can also be performed by a general dentist.^[2,20] It is not a sealing material but good isolation and drying of the lesion before application are consistent with higher caries arrest rates.^[2,3,21] Interaction of silver from SDF with sulfhydryl groups of proteins and bacterial DNA leads to killing of microorganisms and inhibition of biofilm formation.^[11] Moreover, the silver phosphate formed not only contributes in the formation of a resistant outer dentine layer but also blocks the dentinal tubules reducing sensitivity, especially during tooth brushing.^[3,22]

Although the present SR and MA does not show any statistically significant difference between the two interventions at 12 months, SDF has several advantages to offer. In patients with limited cooperation, in erupting teeth where isolation is difficult to achieve and in situations in which there is a doubt regarding the stage of pulp degeneration; SDF is a better option than ART.^[15,17] It reduces the need for complex treatments especially when patients are awaiting specialist care,^[2] for example, in the ongoing COVID-19 pandemic and for those living in areas where it may be the only available treatment. Additionally, low cost and shorter chair time when compared with ART makes SDF an efficient alternative for preschoolers and in community health programs.^[2,15] The fluoride release by GIC is very low when compared with 38% SDF (44,800 ppm of fluoride),^[3] which prevents progression only in incipient caries.^[23] Another disadvantage is the relatively low retention rate of ART restorations and caries progression in areas where restoration is lost.^[5,15,22,24,25] This is overcome by use of high fluoride-releasing flowable glass ionomer for caries arrest in cases in which complete restoration of original tooth morphology is not needed.^[5] However, the commercial unavailability of this material in developing countries and the fact that FUJI IX costs almost 20 times more than SDF is a major drawback.^[3,15,17]

Although a small quantity of SDF is used for application and no associated acute illness or systemic toxicity has been reported on literature review; the present article revealed that very few studies evaluated the secondary outcome. A study found SDF to have lesser adverse effects than ART.^[2] Another study reported no adverse effects of SDF on treated teeth and surrounding soft tissues.^[15] Black staining of lesions, metallic taste, and mildly painful white lesion in gingival tissues and

oral mucosa due to inadvertent SDF contact with surrounding tissues have been commonly reported. The unaesthetic staining of SDF-treated teeth due to silver phosphate precipitation may act as a barrier for acceptance in many children and parents.^[1,22] However, the adverse effects of SDF are outweighed by its advantages.^[2,27] Incorporation of potassium iodide to SDF during application has reported to reduce the tooth discoloration.^[25] Additionally, a clinical trial found nano silver fluoride to effectively arrest dental caries without causing the black staining.^[26]

Our search revealed two studies comparing the adverse effects and failure of treatment between SDF and ART in deciduous teeth as their primary objectives, respectively.^[17,28] One study reported that when an appropriate dental setting is not available, SDF resulted in fewer adverse effects when compared with IRT.^[17] But this study was excluded due to less than 6 months follow-up. Another study used a different formulation and application technique of SDF, i.e., 40% silver fluoride, 10% stannous fluoride followed by covering the tooth by gelatin and compared it with ART for failure of treatment^[28] and found that more teeth required re-treatment in the silver fluoride group. Since this formulation has not been formally evaluated and was a marked deviation from the standard application protocol, this study was excluded.^[28] The present SR included studies published only in English language; therefore, publications of countries using languages other than English in which SDF has been extensively used could have been missed.

CONCLUSION

The current SR points to the lack of solid evidence comparing SDF with ART for arresting active caries in primary teeth, especially in the first permanent molars. No statistically significant difference in the caries arrest between 30% SDF and ART in primary molars at 12 months was found in the present review. Well-designed RCTs are required to determine a minimum concentration of SDF which is effective and safe for caries arrest in children.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

AUTHORS CONTRIBUTIONS

Not applicable.

ETHICAL POLICY AND INSTITUTIONAL REVIEW BOARD STATEMENT

Not applicable.

PATIENT DECLARATION OF CONSENT

Not applicable.

DATA AVAILABILITY STATEMENT

Not applicable.

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