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Clinical Effectiveness of Silver Diamine Fluoride in Primary Dentition: A Systematic Review

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Abstract

Introduction: Silver diamine fluoride (SDF) is a widely used, cost-effective method for arresting dental caries in primary teeth, though acceptance remains limited by the permanent black staining left on treated lesions. The aim to this study is to evaluate the clinical effectiveness of 38% silver diamine fluoride in arresting caries in the primary dentition of pediatric patients.

Materials and Methods: Electronic searches of PubMed/MEDLINE and Google Scholar identified 53 articles published between 2016 and 2026. Eligible studies were randomized controlled trials, randomized clinical trials, controlled clinical trials, or prospective clinical studies enrolling participants younger than 18 years. Two reviewers independently screened and assessed articles in accordance with PRISMA 2020 guidelines; 13 studies met the inclusion criteria and were analyzed.

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Results: Biannual application of 38% SDF produced high rates of caries arrest and outperformed placebo, lower-concentration SDF, and fluoride varnish, with shorter application intervals yielding stronger outcomes. Adverse effects were limited to transient gingival irritation and permanent, cosmetic black staining of arrested lesions.

Conclusion: 38% SDF is an effective, minimally invasive option for arresting caries and helping preserve primary teeth when conventional restorative treatment is not feasible. Black staining remains the main barrier to parental acceptance and should be discussed with caregivers before treatment.

Keywords
Silver diamine fluoride; Early childhood caries; Primary dentition; Caries arrest; Minimally invasive dentistry.

Introduction
Early childhood caries (ECC) remains one of the most prevalent chronic diseases affecting children worldwide, with a pooled global prevalence of approximately 48% among preschool children [17]. Left untreated, ECC can result in pain, infection, impaired growth, poor school performance, and diminished quality of life for both children and their caregivers [16]. Despite decades of preventive efforts, the burden of untreated caries in primary dentition continues to disproportionately affect children from low-income and underserved communities, where access to traditional restorative care is often limited.

Conventional management of cavitated lesions typically relies on operative restoration, which frequently requires local anesthesia, rubber dam isolation, and, in young or uncooperative children, pharmacologic behavior guidance or general anesthesia. These requirements increase cost, treatment time, and risk, and are frequently inaccessible in community- or school-based settings. Silver diamine fluoride (SDF) has emerged as a minimally invasive alternative capable of arresting active carious lesions without the need for caries removal or local anesthesia. Its therapeutic effect is attributed to the combined antibacterial action of silver ions, the remineralizing effect of fluoride, and the coagulation of exposed dentin proteins, which together stabilize the lesion and reduce further demineralization [10].

While multiple randomized and community-based trials have reported favorable caries arrest rates with 38% SDF, the black staining left on treated lesions continues to raise concerns regarding parental acceptance, particularly for lesions on anterior teeth [2]. Variability in SDF concentration, application frequency, and comparator interventions across the existing literature has made it difficult to draw consistent conclusions regarding its optimal clinical use. The aim of this systematic review was therefore to evaluate the clinical effectiveness of 38% silver diamine fluoride in arresting caries in the primary dentition of pediatric patients and to assess whether it may help preserve primary teeth for a longer period by delaying disease progression.

Materials and Methods
Literature search strategy
This systematic review was conducted to evaluate the effectiveness of silver diamine fluoride in arresting dental caries in pediatric patients. The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines to ensure a reproducible study selection process. The study aimed to determine whether 38% SDF was clinically effective for arresting caries in the deciduous dentition of pediatric patients and was developed using the PICOS framework, summarized in (**Table 1**).

Component	Description
Population	Children aged 0–17 years diagnosed with dental caries in the primary dentition
Intervention	38% silver diamine fluoride (SDF)
Comparison	Placebo, sodium fluoride varnish, atraumatic restorative treatment (ART), or lower-concentration SDF
Outcome	Caries arrest

Table 1: PICOS framework used to guide the search strategy.

A comprehensive literature search was conducted using the PubMed/MEDLINE and Google Scholar databases. Articles published between January 2016 and August 2026 were searched. Search terms were developed using MeSH terms and keywords related to silver diamine fluoride and pediatric dental caries. The search strategy included combinations of the following terms:

("silver diamine fluoride" OR SDF) AND ("dental caries" OR caries OR "early childhood caries") AND (child* OR pediatric OR preschool) AND ("randomized controlled trial" OR randomized OR "clinical trial")

Inclusion and exclusion criteria

Studies were included if they met the following criteria:

- Published between January 2016 and August 2026.
- Included participants between 1 and 17 years of age.
- Evaluated silver diamine fluoride for arresting dental caries.
- Included caries in the deciduous dentition.
- Reported caries arrest as a primary or secondary outcome.
- Were randomized controlled trials, randomized clinical trials, controlled clinical trials, or prospective clinical studies.

Studies were excluded if they:

- Were systematic reviews or narrative reviews.
- Were case reports or case series.
- Were in vitro or animal studies.
- Included non-pediatric patients.
- Did not evaluate caries arrest outcomes.

Study selection and quality assessment

The electronic database search initially identified 53 relevant articles. Duplicate records were removed before screening. Two independent reviewers screened all remaining articles according to the eligibility criteria. Studies considered potentially eligible underwent full assessment by both reviewers. Any disagreement regarding study eligibility was resolved through discussion and consensus to reduce the risk of bias. Following the screening process, 13 studies met all inclusion criteria and were included in the review (**Figure 1**).

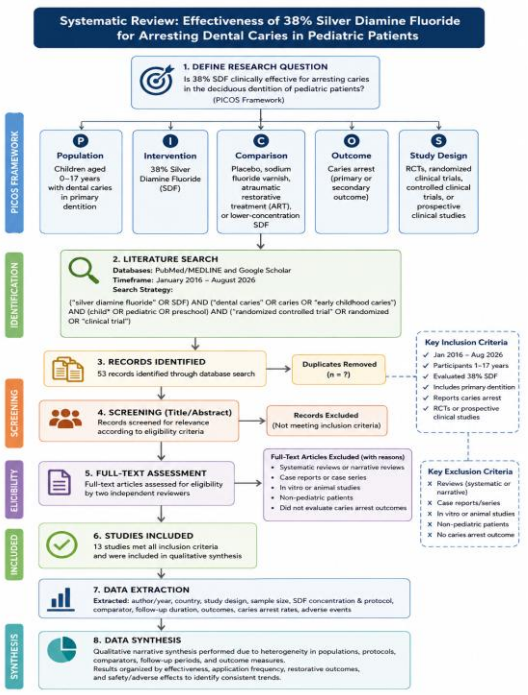


Figure1: PRISMA 2020 flow diagram of study identification, screening, eligibility, and inclusion.

Data extraction was performed independently by two reviewers using a standardized extraction template including: author(s) and year of publication; country of origin; study design; sample size; SDF concentration and application protocol; comparator intervention; follow-up duration; primary and secondary outcomes; caries arrest rates; and adverse events.

Data synthesis

A qualitative narrative synthesis was performed because of heterogeneity among the included studies with respect to study population, intervention protocols, comparator groups, follow-up periods, and reported outcome measures. Results were organized according to study characteristics, effectiveness of SDF in arresting dental caries, application frequency, restorative outcomes, and safety and adverse effects, to identify consistent trends regarding the effectiveness of SDF in pediatric caries management.

Results

Study characteristics

A total of 13 studies published between 2016 and 2026 met the inclusion criteria and were included in this systematic review (**Figure 1, Table 2**). By study design, the evidence base included nine randomized controlled/randomized clinical trials 4,5,6,8,9,11,12,14,15, one randomized trial reported primarily as a safety analysis 3, one secondary analysis of a randomized controlled trial 7, one pragmatic randomized trial reported as a preprint 13, and one clinical effectiveness study [1]. Thus, most of the included evidence was randomized, while a smaller proportion consisted of secondary, pragmatic/preprint, or clinical-effectiveness analyses. Studies were conducted in the United States, Hong Kong, Thailand, Canada, and India.

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Sample sizes varied considerably between studies, ranging from 66 preschool children in a double-blind randomized controlled trial to nearly 3,000 participants in a large community-based trial. Participants primarily consisted of preschool and elementary school children with cavitated lesions or early childhood caries affecting the primary dentition. Interventions typically involve biannual application of 38% SDF, with or without sodium fluoride varnish, compared with placebo, 5% sodium fluoride varnish, 12% SDF, a traumatic restorative treatment, or different SDF application intervals. Follow-up periods ranged from 14 days to 30 months.

Study	Country	Design	Population / sample	Intervention vs. comparator	Follow-up	Key result
Fontana et al., 2024	USA	Phase III multicenter placebo-controlled RCT	599 children (12–71 mo) with severe ECC; 1,413 lesions	38% SDF vs. placebo	6 mo (interim)	Caries arrest 54% vs. 21% (P<0.001); trial stopped early for efficacy
Milgrom et al., 2018	USA	Double-blind RCT	66 preschool children with active cavitated caries	38% SDF vs. placebo	14–21 days	72% of SDF lesions arrested vs. 5% placebo
Clemens et al., 2018	USA	Clinical effectiveness study	Children with primary tooth caries	SDF treatment (no SDF comparator)	Short-term	SDF effective in arresting caries; assessed caregiver acceptance and staining concerns
Fung et al., 2018	Hong Kong	RCT	Preschool children with dentin caries	38% vs. 12% SDF	18 mo	38% SDF achieved greater caries arrest than 12% SDF
Duangthip et al., 2018	Hong Kong	RCT (safety analysis)	888 preschool children (799 remaining at 30 mo)	12% and 38% SDF, annual vs. semiannual	30 mo	No serious adverse events; minor effects: tooth/gingival pain 6.6%, gingival swelling 2.8%, gingival bleaching 4.7%
Gao et al., 2020	Hong Kong	RCT	1,070 preschool children with ECC	Silver/fluoride-based interventions incl. SDF vs. alternative fluoride/silver therapy	30 mo	Sustained caries arrest; mean 3.6 ± 3.7 arrested surfaces per child
Jiang et al., 2020	Hong Kong	RCT	194 children with dentin caries (101 SDF+ART, 93 ART alone)	SDF pretreatment + ART vs. ART alone	24 mo	Prior SDF application did not reduce ART restoration success
Mabangkhru et al., 2020	Thailand	RCT	Young children with dentin caries	38% SDF vs. 5% NaF varnish	12 mo	Caries arrest 35.7% (SDF) vs. 20.9% (NaF varnish)
Jiang et al., 2022	Hong Kong	Secondary analysis of RCT	Preschool children receiving ART	ART + prior SDF vs. ART alone	24 mo	SDF-assisted ART improved parental satisfaction and OHRQoL
Ruff et al., 2023 (CariedAway)	USA	Cluster-randomized RCT	2,998 school-aged children enrolled; 1,398 completed follow-up	SDF + fluoride varnish vs. sealants + ART + fluoride varnish	Longitudinal	Arrest 56% vs. 46%; caries-free 81% vs. 82%; noninferior for arrest and prevention
Ruff & Niederman, 2024	USA	Pragmatic randomized trial (preprint)	Low-income rural schoolchildren	School-based SDF vs. alternative prevention strategy	Ongoing	Supports SDF effectiveness in underserved rural populations; peer review pending

Study	Country	Design	Population / sample	Intervention vs. comparator	Follow-up	Key result
Schroth et al., 2024	Canada	Open-label RCT	84 children; 505 lesions	38% SDF at monthly vs. 4-month vs. 6-month intervals	Per protocol	Arrest rates: 98% (monthly), 95.8% (4-month), 72% (6-month)
Thakur et al., 2022	India	RCT	Children with primary tooth caries	SDF applied for 30 vs. 60 vs. 90 seconds	Short-term	No statistically significant difference in arrest beyond 30 seconds of contact time

Table 2: Summary of the 13 studies included in the qualitative synthesis.

Effectiveness of SDF for caries arrest

Across the included studies, 38% SDF consistently demonstrated effectiveness in arresting cavitated lesions in pediatric patients. In a multicenter, phase III, placebo-controlled trial conducted in the United States, Fontana et al. [4] analyzed 1,413 lesions among 599 of 680 enrolled children (ages 12–71 months) with severe ECC who completed a six-month interim exam; caries arrest was significantly higher in the SDF group than in the placebo group (54% vs. 21%, P<0.001), leading to early termination of the trial due to demonstrated efficacy. Milgrom et al. [11] similarly found that 72% of SDF-treated lesions were arrested after 14–21 days in 66 preschool children, compared with 5% in the placebo group.

Comparative studies also showed superiority of 38% SDF over alternative fluoride therapies. Fung et al. [5], found that 38% SDF achieved greater caries arrest than 12% SDF over an 18-month follow-up period in Hong Kong. Mabangkhru et al. [9], reported higher arrest rates with 38% SDF (35.7% of lesions) than with 5% sodium fluoride varnish (20.9% of lesions) after 12 months in Thailand.

Large community-based trials further supported the effectiveness of SDF. Gao et al. 6 reported sustained caries arrest over 30 months among 1,070 Hong Kong children with ECC receiving silver- and fluoride-based interventions, including SDF, with a mean of 3.6 ± 3.7 arrested surfaces per child. In the Caried Away school-based cluster-randomized trial, Ruff et al. [12] enrolled 2,998 U.S. schoolchildren with untreated dental caries, of whom 1,398 completed follow-up; SDF combined with fluoride varnish achieved a 56% caries arrest rate compared with 46% for sealants and ART with fluoride varnish, and 81% of children in the SDF group remained free of new caries compared with 82% in the control group indicating that SDF with fluoride varnish was noninferior to sealants and ART with fluoride varnish for both caries arrest and prevention. Ruff and Niederman 13 extended these findings to low-income rural schoolchildren in a pragmatic randomized trial, further supporting SDF effectiveness in underserved populations.

Influence of application frequency

Several studies evaluated whether treatment frequency influenced clinical outcomes. Schroth et al. [14] compared monthly, 4-month, and 6-month application intervals of 38% SDF among 84 Canadian children with 505 lesions and reported lesion arrest rates of 98%, 95.8%, and 72%, respectively, suggesting that shorter treatment intervals are associated with greater effectiveness. In contrast, Thakur et al. [15] reported that extending SDF contact time beyond 30 seconds did not significantly improve arrest

outcomes, indicating that application duration and application frequency influence outcomes independently.

Restorative outcomes following SDF treatment

Jiang et al. [8] evaluated the use of SDF before ART in 194 Hong Kong children (101 receiving SDF prior to ART and 93 receiving ART alone) and found that prior application of SDF did not negatively affect restorative survival over a 24-month follow-up period. A subsequent secondary analysis by Jiang et al. [7] reported improved parental satisfaction and oral health-related quality of life among children receiving ART with prior SDF application compared with ART alone.

Safety and adverse effects

Duangthip et al. [3] followed 888 preschool children assigned to 12% or 38% SDF applied annually or semiannually and reported no serious adverse events over 30 months, with 799 children remaining in the study at follow-up. Minor adverse effects included transient tooth or gingival pain (6.6%), gingival swelling (2.8%), and gingival bleaching (4.7%), all of which resolved without lasting harm. The most common treatment-related effect across the included studies was permanent black discoloration of arrested carious lesions. Clemens et al. [1] similarly evaluated caregiver acceptance alongside clinical effectiveness, reinforcing staining as a key consideration in treatment planning.

Discussion

This systematic review found that 38% silver diamine fluoride (SDF) is an effective, minimally invasive option for arresting active caries in primary teeth in pediatric patients. Across the included studies, SDF consistently performed better than placebo, lower-concentration SDF, and sodium fluoride varnish, with more frequent applications generally producing stronger arrest outcomes. In relation to the original research question, the evidence supports the use of SDF as a practical approach to slow or halt caries progression and help retain primary teeth for a longer period, especially when conventional restorative treatment is difficult because of age, behavior, access to care, or treatment cost.

The findings also suggest that the clinical value of SDF extends beyond short-term lesion arrest alone. By stabilizing cavitated lesions, SDF may reduce pain, lower the immediate need for invasive procedures, and create an opportunity to preserve the function of primary teeth until normal exfoliation or until definitive restorative care becomes feasible. This is especially relevant in early childhood caries, where maintaining primary teeth supports mastication, speech development, arch integrity, and quality of life.

The observed effectiveness of SDF is biologically plausible and consistent with its known mechanism of action. Silver ions provide antibacterial effects, fluoride enhances remineralization, and the alkaline solution promotes protein coagulation within dentin, together limiting lesion progression [10]. The superiority of 38% SDF over lower concentrations suggests that a higher concentration of active ions produces a stronger caries-arresting effect, although this benefit must be weighed against more visible staining [5]. In addition, the better outcomes reported with shorter recall intervals indicate that SDF effectiveness is influenced not only by concentration but also by application frequency, which appears to play an important role in sustaining lesion arrest over time [14].

These findings are broadly consistent with, and extend, the existing literature on SDF. The reviewed studies confirm previous reports that SDF is superior to placebo and more effective than some fluoride-based alternatives for arresting dentin caries in primary teeth [4,9,11]. They also extend prior work by showing that SDF can be integrated into a broader minimally invasive care pathway: studies evaluating SDF before atraumatic restorative treatment found that pretreatment did not compromise restoration survival and may improve parental satisfaction and oral health-related quality of life [8,7]. This suggests that SDF should not be viewed only as a temporary or stand-alone measure, but also as part of a staged management strategy for children with a high caries burden.

The practical implications of these findings are important. 38% SDF appears particularly useful for young, anxious, uncooperative, medically compromised, or special healthcare needs children, as well as for children in underserved communities where access to traditional restorative care is limited. In such settings, SDF offers a low-cost, simple, and noninvasive method to control disease without local anesthesia, rotary instrumentation, or advanced clinical infrastructure. Its effectiveness in school-based and community programs further supports its value as a public health intervention that can expand access to care and reduce untreated disease burden [12,13]. Based on the findings of this systematic review, a clinical decision-making pathway is proposed to assist clinicians in determining when 38% SDF may be appropriate for the management of caries in the primary dentition (**Figure 2**).

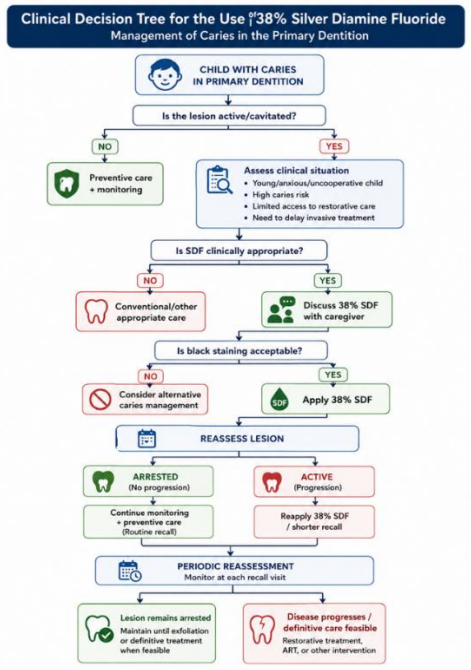


Figure 2: Clinical decision-making tree for the use of 38% Silver Diamine Fluoride – Management of Caries in the Primary Dentition.

At the same time, the review highlights that clinical success does not automatically equal treatment acceptance. The most consistent drawback of SDF was permanent black staining of arrested lesions. Although this is not harmful and is primarily cosmetic, it remains a major factor influencing caregiver

acceptance, especially for anterior teeth [2]. This means that the use of SDF in pediatric dentistry should be accompanied by clear communication with parents and caregivers regarding benefits, limitations, esthetic consequences, and alternative treatment options.

Several limitations of this review should be acknowledged. The included studies were heterogeneous in study design, sample size, follow-up period, comparator interventions, and application protocols, which limited direct comparison across studies and made a quantitative meta-analysis inappropriate. Follow-up durations varied considerably, with some studies reporting only short-term outcomes, which restricts conclusions about how long arrested lesions remain stable. In addition, the studies were conducted in different healthcare systems and populations, which may affect generalizability. Factors such as oral hygiene, dietary habits, baseline caries severity, and caregiver preferences were not uniformly controlled and may have influenced outcomes. An additional limitation is that the review focused specifically on 38% SDF in the primary dentition, which strengthens clinical relevance but narrows scope; conclusions should not be generalized beyond primary teeth or to other SDF concentrations without caution. Some included evidence, such as pragmatic or preprint data, also differs in level of maturity, which should be considered when interpreting the strength of the conclusions.

One of the more notable and somewhat unexpected findings was the apparent sensitivity of outcomes to reapplication intervals. While SDF is often discussed as an effective caries-arresting agent in general terms, the reviewed studies suggest that its success is more protocol-dependent than may be assumed. Markedly higher arrest rates with monthly or shorter-interval application compared with longer intervals indicate that the durability of its effect may decline when retreatment is delayed. However, this greater clinical effectiveness must be balanced against the additional cost and logistical burden associated with more frequent applications. Although SDF is generally considered a low-cost intervention, repeated visits increase material use, clinical time, caregiver time, transportation needs, and program-level costs, potentially reducing one of SDF's principal advantages over conventional restorative treatment. This trade-off may be particularly important in public health, school-based, and outreach settings, where repeated follow-up can be difficult to sustain. Therefore, the optimal application schedule should consider not only caries-arrest effectiveness but also cost-effectiveness, feasibility, patient adherence, and access to follow-up care.

Future research should focus on longer-term outcomes to determine how effectively SDF helps maintain primary teeth until natural exfoliation, and on direct comparisons of application schedules to identify the minimum frequency required to sustain lesion arrest while remaining practical and cost-effective in real-world settings. Direct economic evaluations should compare the incremental benefit of more frequent SDF application with the added costs of additional clinical visits and follow-up. Additional work is also needed to explore methods for improving esthetic acceptability and caregiver acceptance, including communication strategies, shared decision-making tools, and adjunctive techniques aimed at masking or reducing discoloration. Finally, future studies should examine cost-effectiveness, quality-of-life outcomes, and implementation in diverse healthcare systems to better define the role of SDF in both clinical and community pediatric dentistry.

Overall, the evidence in this review supports 38% silver diamine fluoride as an effective and clinically meaningful option for arresting caries in primary teeth. For many children particularly those at high risk or with limited access to care SDF represents an important tool for maintaining primary dentition and improving disease control in a practical, patient-centered manner until definitive care or natural exfoliation. For dental providers providing pediatric care, this study highlights that Thirty-eight percent of SDF can arrest active caries in primary teeth and may help retain affected teeth until definitive care or natural exfoliation. Application of the protocol matters: repeated application, with recall intervals selected according to lesion activity and patient risk, appears more effective than a single application. SDF is particularly useful for young, anxious, medically complex, or underserved children, but caregivers must be informed that arrested lesions become permanently black-stained. More frequent application appears to improve outcomes, and current evidence supports its use as part of a minimally invasive, evidence-based approach to pediatric caries management. While it does not restore tooth structure, it can help preserve primary teeth for longer by stopping or slowing disease progression, delaying invasive treatment, and supporting minimally invasive pediatric care. Its greatest strengths lie in accessibility, simplicity, and effectiveness, while its greatest limitation remains in esthetic staining. For many children particularly those at high risk or with limited access to care SDF represents an important tool for maintaining primary dentition and improving disease control in a practical, patient-centered manner until definitive care or natural exfoliation.

Conclusion

This systematic review supports the use of 38% silver diamine fluoride (SDF) as an effective, minimally invasive approach for arresting active dental caries in primary teeth, particularly when conventional restorative treatment is challenging or not feasible. Repeated applications appear to enhance caries-arrest outcomes, highlighting the importance of individualized recall intervals, regular reassessment of lesion activity, and consideration of each child's caries risk. SDF represents a valuable treatment option for young, anxious, medically complex, and underserved pediatric populations, potentially improving access to care while reducing the need for more invasive interventions. However, the permanent black staining of arrested carious lesions remains an important consideration and should be discussed with caregivers to support informed, shared decision-making. Overall, SDF is a valuable component of evidence-based, patient-centered caries management in pediatric dentistry.

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Conflict of Interest statement

The authors declare no conflicts of interest related to this work.

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