

INFLUENCE OF SEMI-ANNUAL AND ANNUAL SILVER DIAMINE FLUORIDE
APPLICATION ON CARIES ARREST IN PRESCHOOL CHILDREN: A RANDOMIZED
CLINICAL TRIAL

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ABSTRACT

Background: Silver diamine fluoride (SDF) is an effective non-invasive treatment for arresting dental caries in preschool children. Limited evidence exists regarding the clinical performance of newer SDF formulations such as CariCure SDF compared with established SDF systems and glass ionomer cements. **Aim:** To compare the effectiveness of CariCure SDF, Riva Star and RX Ease 2 Glass Ionomer Cement (GIC) in arresting active dentinal caries in preschool children. **Materials and Methods:** A randomized clinical trial was conducted among 240 children aged 3–5 years with active dentinal caries. Participants were allocated to five groups: CariCure SDF every 6 months, CariCure SDF every 12 months, Riva Star every 6 months, Riva Star every 12 months and RX Ease 2 GIC applied annually. Clinical evaluations were performed at baseline and every 6 months for 24 months. Caries arrest was assessed based on lesion hardness and absence of progression. **Results:** At 24 months, caries arrest rates were 94.2%, 88.6%, 90.4%, 83.7%, and 79.8% for Groups I–V, respectively ($p < 0.001$). Semi-annual CariCure SDF application demonstrated significantly greater caries arrest than all other interventions. **Conclusion:** CariCure SDF showed superior efficacy in arresting dentinal caries compared with Riva Star SDF and RX Ease 2 GIC. Semi-annual SDF application was more effective than annual application in preschool children.

KEYWORDS: Silver diamine fluoride, Glass ionomer cement, Caries arrest, Preschool children, Early childhood caries.

INTRODUCTION

Early childhood caries (ECC) continues to be a major public health concern affecting children worldwide and is associated with pain, nutritional deficiencies, impaired quality of life and increased healthcare burden.^[1,2] Despite advances in preventive dentistry, untreated carious lesions remain highly prevalent among preschool-aged children, particularly in developing countries.^[3] Contemporary caries management emphasizes minimally invasive approaches aimed at controlling disease progression while preserving tooth structure.^[4] Among these approaches, silver diamine fluoride (SDF) has gained substantial attention because of its simplicity, affordability, antimicrobial activity and ability to arrest active dentinal caries.^[5] The mechanism of SDF involves a synergistic action of silver ions and

fluoride ions. Silver provides broad-spectrum antibacterial effects and inhibits collagen degradation, while fluoride promotes remineralization of demineralized tooth structure.^[6] Numerous systematic reviews and meta-analyses have confirmed the effectiveness of 38% SDF in arresting dentinal caries in primary teeth.^[7,8] Current evidence suggests that repeated applications of SDF result in higher caries arrest rates than single annual applications.^[9] Biannual application schedules have been associated with greater lesion hardness and reduced caries progression.^[10] Riva Star (SDI, Australia) is a widely used two-step SDF system consisting of 38% SDF and potassium iodide, designed to reduce discoloration while maintaining therapeutic effectiveness.^[11] Recently, CariCure SDF (Prevest DenPro Limited, India) has been introduced as a

chairside SDF system with enhanced handling properties and promising antibacterial potential.^[12] Glass ionomer cements (GICs) have also been used as non-invasive caries management materials due to their fluoride release, chemical adhesion to tooth structure and remineralization potential.^[13] High-fluoride releasing GICs have demonstrated the ability to arrest carious lesions and prevent further demineralization.^[14] Although several studies have evaluated conventional SDF and GICs, there remains limited evidence comparing newer SDF formulations and application frequencies in preschool children.^[15] Determining the most effective protocol could significantly improve community-based caries management programs.^[16] Therefore, the present randomized clinical trial was undertaken to compare the effectiveness of CariCure SDF, Riva Star and RX Ease 2 GIC in arresting active dentinal caries in preschool children.

MATERIALS AND METHODOLOGY

The present study was designed as a prospective, parallel-arm, randomized controlled clinical trial to evaluate and compare the effectiveness of two silver diamine fluoride systems, CariCure SDF (Prevest DenPro Ltd., India) and Riva Star (SDI Limited, Australia) with RX Ease 2 Glass Ionomer Cement (Shofu) in arresting active dentinal caries in preschool children. The study was conducted in the Department of Pediatric and Preventive Dentistry Shree Bankey Bihari Dental College & Research Centre, Ghaziabad, Uttar Pradesh, India between 2023-2025 after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained from the parents or legal guardians of all participating children before enrollment. The sample size was calculated using G*Power software based on previously reported caries arrest rates of SDF-treated lesions. Assuming an effect size of 0.30, power of 80%, and alpha error of 5%, a minimum sample size of 40 children per group was required. To compensate for possible dropouts during the follow-up period, 48 children were recruited in each group, resulting in a total sample size of 240 children. Preschool children aged between 3 and 5 years attending the outpatient clinic of the Department of Pediatric and Preventive Dentistry were screened for eligibility. Children having at least one active cavitated dentinal carious lesion in a primary tooth diagnosed according to the International Caries Detection and Assessment System (ICDAS) criteria were considered for inclusion. Preschool children presenting with at least one active cavitated dentinal carious lesion in a primary tooth were considered eligible for participation in the study. Only children who were in good general health, cooperative during clinical examination and whose parents or legal guardians provided written informed consent were included. The selected lesions were required to be accessible for topical application of silver diamine fluoride or restoration with glass ionomer cement and free from signs of pulpal involvement. Children were excluded if the affected teeth exhibited symptoms or

signs of irreversible pulpitis, pulpal exposure, dental abscess, sinus tract, pathological mobility or extensive crown destruction rendering the tooth non-restorable. Children with systemic diseases requiring special medical management, known allergies to silver, fluoride, potassium iodide or glass ionomer materials, those receiving ongoing treatment for the same lesion and children who were unable to comply with the follow-up schedule were also excluded from the study. A computer-generated randomization sequence was used to allocate participants into five groups. Allocation concealment was achieved using sequentially numbered opaque sealed envelopes prepared by an investigator not involved in treatment or outcome assessment. Eligible children were randomly assigned to one of the following groups:

Group I (n=48): CariCure SDF application every 6 months.

Group II (n=48): CariCure SDF application every 12 months.

Group III (n=48): Riva Star application every 6 months.

Group IV (n=48): Riva Star application every 12 months.

Group V (n=48): RX Ease 2 Glass Ionomer Cement restoration.

At baseline, demographic information including age, gender, oral hygiene practices, dietary habits and caries experience (dmft index) was recorded. Clinical examination was performed under adequate illumination using a mouth mirror and WHO periodontal probe. The location, surface involved, lesion size and activity status of each carious lesion were documented. Standardized clinical photographs were obtained for record keeping.

Clinical Procedures

Group I – CariCure SDF (6-Month Application)

The tooth surface was cleaned using a wet cotton pellet to remove debris and plaque. The lesion was isolated with cotton rolls and gently dried using compressed air. CariCure 38% Silver Diamine Fluoride solution was dispensed into a disposable dappen dish and applied to the carious lesion using a microbrush. The solution was allowed to remain in contact with the lesion for one minute. Excess material was removed using cotton gauze. Potassium iodide solution was then applied to clear the creamy white precipitate. Reapplication was performed at 6, 12 and 18 months.

Group II – CariCure SDF (12-Month Application)

The same application protocol as Group I was followed. Reapplication was performed only once at 12 months.

Group III – Riva Star SDF (6-Month Application)

After isolation and drying, Step 1 (38% Silver Diamine Fluoride) was applied to the lesion using a microbrush and allowed to remain for one minute. Subsequently, Step 2 (potassium iodide solution) was applied until the creamy white precipitate became clear. Excess material

was removed using cotton pellets. Reapplications were performed at 6, 12 and 18 months.

Group IV – Riva Star SDF (12-Month Application)

The same protocol as Group III was followed, with reapplication performed only at 12 months.

Group V – RX Ease 2 Glass Ionomer Cement

The carious lesion was cleaned without complete caries excavation. The tooth surface was conditioned using 10% polyacrylic acid (GC Dentin Conditioner) for 10 seconds, rinsed thoroughly, and gently dried. RX Ease 2 Glass Ionomer Cement (Shofu) was mixed according to the manufacturer's instructions and placed into the lesion using an atraumatic restorative treatment (ART) approach. The restoration was protected with a varnish coating and allowed to set completely. Any defective restorations detected during follow-up were repaired or replaced.

Follow-Up Evaluation

All participants were recalled at 6, 12, 18 and 24 months. Clinical examinations were performed by two calibrated examiners who were blinded to group allocation. Examiner calibration was conducted before the study and an inter-examiner kappa value greater than 0.85 was achieved. The primary outcome was caries arrest. A

lesion was considered arrested when it exhibited: Hard surface texture on gentle probing, Absence of cavitation progression, No signs of pulpal involvement, No pain, swelling, or infection, Characteristic dark and hardened appearance in SDF-treated lesions. Lesions remaining soft or showing progression were categorized as active lesions. Secondary outcomes included comparison of caries arrest among the five study groups, evaluation of the effect of semi-annual and annual SDF application, assessment of treatment outcomes according to tooth type and surface involved, retention of RX Ease 2 Glass Ionomer Cement restorations, occurrence of adverse effects and parental acceptance of the treatment.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were calculated for all variables. Differences in caries arrest rates among the groups were analyzed using the Chi-square test and one-way ANOVA where appropriate. Repeated measures analysis and Generalized Estimating Equations (GEE) were used to assess changes over time. Logistic regression analysis was performed to identify factors associated with successful caries arrest. Statistical significance was set at $p < 0.05$.

RESULTS



A total of 240 preschool children were enrolled in the study of whom 221 (92.1%) completed the 24-month follow-up. The distribution of age, gender, baseline dmft scores, lesion characteristics, and tooth types was comparable among the five study groups, with no statistically significant differences at baseline ($p > 0.05$). At the end of the 24-month evaluation period, the highest caries arrest rate was observed in Group I (CariCure SDF applied every 6 months), followed by Group III (Riva Star SDF applied every 6 months), Group II (CariCure SDF applied every 12 months), Group IV (Riva Star SDF applied every 12 months) and Group V (RX Ease 2 Glass Ionomer Cement). The respective caries arrest rates were 94.2%, 90.4%, 88.6%, 83.7%, and 79.8% and the differences among the groups were statistically

significant ($p < 0.001$). Semi-annual application of both SDF systems resulted in significantly greater caries arrest than annual application. Logistic regression analysis demonstrated that semi-annual SDF application and treatment with CariCure SDF were significant predictors of successful caries arrest ($p < 0.001$). Anterior teeth showed a higher arrest rate than posterior teeth, although both responded favorably to SDF therapy. The RX Ease 2 Glass Ionomer Cement group exhibited satisfactory clinical performance but demonstrated significantly lower caries arrest rates compared with both SDF groups. No serious adverse events or allergic reactions were observed throughout the study, and parental acceptance of all treatment modalities remained high.

Table 1: Distribution of Participants Among Study Groups.

Group	Intervention	Application Frequency	Enrolled (n)	Completed (n)	Follow-up (%)
Group I	CariCure SDF	Every 6 months	48	45	93.8
Group II	CariCure SDF	12 months	48	44	91.7
Group III	Riva Star	Every 6 months	48	46	95.8
Group IV	Riva Star	12 months	48	43	89.6
Group V	RX Ease 2 GIC	12 months	48	43	89.6
Total			240	221	92.1

Table 2: Baseline Characteristics.

Variable	Group I	Group II	Group III	Group IV	Group V	p
Mean Age	4.2±0.8	4.1±0.7	4.3±0.9	4.2±0.8	4.1±0.8	0.81
Male n(%)	24	23	25	22	24	0.96
Female n(%)	24	25	23	26	24	
Mean dmft	5.1±1.6	5.3±1.5	5.0±1.4	5.2±1.7	5.1±1.5	0.88

Table 3: Caries Arrest Rates (%).

Group	6 M	12 M	18 M	24 M
CariCure 6M	84.4	90.2	92.8	94.2
CariCure 12M	78.6	84.5	86.8	88.6
RivaStar 6M	80.4	86.3	88.7	90.4
RivaStar 12M	73.5	79.8	81.6	83.7
RX Ease2	72.1	75.8	77.9	79.8

Table 4: Adverse Events.

Outcome	CariCure (6M)	CariCure (12M)	RivaStar (6M)	RivaStar (12M)	RX Ease 2
Soft tissue irritation	2.2	2.3	2.1	2.4	0
Allergic reactions	0	0	0	0	0
Parental acceptance	91.1	89.7	90.2	88.4	94.2

DISCUSSION

The present randomized clinical trial compared the clinical effectiveness of two silver diamine fluoride (SDF) systems, CariCure SDF and Riva Star with RX Ease 2 Glass Ionomer Cement (GIC) in arresting active dentinal caries in preschool children over a 24-month follow-up period. The results demonstrated that both SDF systems were significantly more effective than RX Ease 2 GIC in arresting dental caries, with CariCure SDF applied at 6-month intervals achieving the highest caries arrest rate (94.2%). These findings are consistent with recent clinical evidence demonstrating that 38% SDF is among the most effective minimally invasive agents for arresting dentinal caries in primary teeth and reducing disease progression in preschool children.^[17-19] The superior clinical performance of CariCure SDF observed in the present study may be attributed to the synergistic action of silver ions and fluoride ions. Silver provides potent antibacterial activity by disrupting bacterial cell walls, inhibiting enzymatic activity and preventing biofilm formation, while fluoride promotes remineralization through the formation of fluorapatite and increases dentin hardness. These mechanisms enhance lesion stabilization and prevent further demineralization. Although direct comparative clinical studies between CariCure SDF and Riva Star are currently limited, the present findings suggest that CariCure SDF is an effective material for arresting dentinal caries in preschool children. Similar

improvements in lesion hardness and caries arrest following SDF application have been reported by Hafiz et al. and Giacaman et al.^[18-19] Another important finding of the present study was that semi-annual application of both CariCure SDF and Riva Star resulted in significantly higher caries arrest rates than annual application. Children treated every six months exhibited greater lesion arrest than those receiving yearly application, indicating that repeated SDF application enhances long-term therapeutic effectiveness. This observation is in agreement with recent systematic reviews and randomized clinical trials, which have concluded that periodic reapplication of SDF maintains continuous antibacterial activity, improves fluoride uptake by demineralized dentin, and significantly increases caries arrest compared with a single annual application.^[20-22] The RX Ease 2 Glass Ionomer Cement group also demonstrated satisfactory clinical outcomes, although its caries arrest rate was significantly lower than both SDF groups. Glass ionomer cement provides chemical adhesion to tooth structure, sustained fluoride release and an adequate marginal seal, thereby contributing to remineralization of the adjacent tooth structure. However, unlike SDF, GIC lacks the potent antibacterial action of silver ions and therefore depends primarily on fluoride release and physical sealing of the lesion. Consequently, active dentinal lesions treated with SDF showed greater clinical arrest than those restored with GIC. Similar findings have been reported by recent

evidence-based reviews comparing non-restorative SDF therapy with conventional restorative approaches for management of early childhood caries.^[21-23] The present study also demonstrated higher caries arrest rates in anterior teeth compared with posterior teeth irrespective of the material used. This finding may be explained by improved accessibility during material application, reduced plaque retention, easier maintenance of oral hygiene, and greater salivary exposure around anterior teeth, all of which facilitate remineralization. Comparable observations have been reported in recent clinical investigations evaluating the effectiveness of SDF in preschool children.^[23] No serious adverse events or allergic reactions were observed during the entire follow-up period, confirming the safety of repeated application of both SDF systems in young children. The findings of the present study have important clinical implications for minimally invasive pediatric dentistry and community oral health programs. Semi-annual application of CariCure SDF can provide an effective, economical and easily applicable treatment option for arresting dentinal caries, particularly in preschool children with limited cooperation, children with special healthcare needs and populations with restricted access to conventional restorative dental care. School-based preventive programs have also demonstrated that SDF can substantially reduce untreated caries while requiring minimal clinical equipment and operator time.^[17,20] The present study has certain limitations. It was conducted at a single institution with a relatively limited sample size and a follow-up period of 24 months. In addition, microbiological analysis and assessment of lesion remineralization using advanced imaging techniques were not performed. Further multicenter randomized controlled trials with larger populations, longer follow-up periods, microbiological evaluation and direct comparison of different commercially available SDF systems are recommended to validate the findings of the present study and establish evidence-based clinical guidelines for the management of early childhood caries.^[22,23]

CONCLUSION

Within the limitations of this randomized clinical trial, both silver diamine fluoride (SDF) systems and RX Ease 2 Glass Ionomer Cement were effective in arresting active dentinal caries in preschool children. However, CariCure SDF demonstrated the highest caries arrest rate, particularly when applied at 6-month intervals and showed significantly superior clinical performance compared with Riva Star and RX Ease 2 Glass Ionomer Cement. Semi-annual application of both SDF systems resulted in better caries arrest than annual application, highlighting the importance of repeated fluoride exposure for sustained therapeutic effectiveness. Although RX Ease 2 Glass Ionomer Cement provided satisfactory clinical outcomes, its caries-arresting ability was comparatively lower than that of both SDF systems. No serious adverse events were observed during the study, confirming the safety and acceptability of these

minimally invasive treatment modalities in preschool children. Based on the present findings, semi-annual application of CariCure SDF can be recommended as an effective, safe and economical non-restorative approach for managing early childhood caries, particularly in young or uncooperative children and in community-based preventive oral health programs. Further multicenter studies with longer follow-up periods are recommended to validate these findings and assess the long-term sustainability of caries arrest.

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