

## Query answer sheet [MUHS – 032324]

**Query 1.** English language and spelling correction are needed.

**Answer** – English language and spelling correction has been done.

**Query 2.** Need for the study has to be emphasized. Merely less number of studies should not be the only criteria, there should be some added advantage of Silver nitrate over already proven material like silver diamine fluoride. All the advantages mentioned of silver nitrate are also true for SDF.

**Answer** - silver nitrate solution contains lower concentrations of silver and fluoride than in 38 % SDF solution; hence could be considered more favourable in young children. [ chun et.al.]<sup>[34]</sup>  
[ page no. 5]

**Query 3.** Carious lesion was gently explored with the CPI probe is mentioned in the method. However in the color plate a straight probe has been shown and no CPI probe can be seen.

**Answer** - In the methodology straight probe has been used, however there was a typing error in methodology as no CPI probe was used. [ page no. 43]

**Query 4.** What was the reason for rinsing / washing the instrument with distilled water, before drying or packing and sterilization?

**Answer** - To remove mechanical debris. [ page no. 42]

**Query 5.** The major disadvantage of SDF is staining carious dental tissue black. However, in the present study nothing has been mentioned regarding any staining due to silver nitrate.

**Answer** - A temporary henna-appearing stain was appear when silver nitrate solution comes into contact with skin. The skin pigmentation is temporary and will disappear within one to

two weeks because the silver does not penetrate into the dermis. Silver nitrate stain were comparatively lighter than stains of silver diamine fluoride on the tooth surface.[Gao SS]<sup>17</sup>

[ page no. 73]

**Query 6.** There is mentioning of chi square test. Needs explanation.

**Answer** - Inter and Intra group comparison has been done by using chi square test. [ page no. 63]

**Query 7.** The value in the text [result] have discrepancy with the value mentioned in the table 4 and 5.

**Answer** – The discrepancy in between table 4 and 5 has been corrected as follows. [ page no. 63,64,65]

### **Intragroup comparison of lesion activity according to ICDAS code in group 1**

64 Lesion activity according to ICDAS code was inactive from baseline to 3 months in 67.5% patients and active in 32.5% patients of Group 1. By using chi square test statistically significant difference was found in lesion activity from baseline to 3 months in patients of Group 1 ( $\chi^2=11.52, p=0.0007$ ).

Lesion activity according to ICDAS code was inactive from baseline to 6 months in 82.5% patients and active in 17.5% patients of Group 1. By using chi square test statistically significant difference was found in lesion activity from baseline to 6 months in patients of Group 1 ( $\chi^2=87.12, p=0.0001$ ).

Lesion activity according to ICDAS code was inactive from baseline to 9 months in 90% patients and active in 10% patients of Group 1. By using chi square test statistically

significant difference was found in lesion activity from baseline to 9 months in patients of Group 1 ( $\chi^2=128, p=0.0001$ ). [Table 4, Graph 4]

### **Intragroup comparison of lesion activity according to ICDAS code in group 2**

Lesion activity according to ICDAS code was inactive from baseline to 3 months in 73.75% patients and active in 26.25% patients of Group 2. By using chi square test statistically significant difference was found in lesion activity from baseline to 3 months in patients of Group 2 ( $\chi^2=46.08, p=0.0001$ ).

Lesion activity according to ICDAS code was inactive from baseline to 6 months in 87.5% patients and active in 12.5% patients of Group 2. By using chi square test statistically significant difference was found in lesion activity from baseline to 6 months in patients of Group 2 ( $\chi^2=115.5, p=0.0001$ ).

Lesion activity according to ICDAS code was inactive from baseline to 9 months in 95% patients and active in 5% patients of Group 2. By using chi square test statistically significant difference was found in lesion activity from baseline to 9 months in patients of Group 2 ( $\chi^2=162, p=0.0001$ ). [Table 5, Graph 5]

**“COMPARISON OF THE EFFECTIVENESS OF  
25% SILVER NITRATE FOLLOWED BY 5% SODIUM  
FLUORIDE VARNISH WITH 38% SILVER DIAMINE  
FLUORIDE IN ARRESTING CARIES IN CHILDREN  
- A RANDOMIZED CONTROL STUDY.”**

**Dissertation submitted to Maharashtra  
University of Health Sciences, Nashik in the  
Partial Fulfillment of Regulations for the  
award of the Degree of**

**MDS**

**IN**

**PEDODONTICS AND PREVENTIVE DENTISTRY**

**BRANCH VIII**

**2021**

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## LIST OF ABBREVIATIONS

<b>Short Form</b>	<b>Full Form</b>
SDF	Silver Diamine Fluoride
FDA	Food and Drug Administration
Ag <sub>2</sub> O	Silver oxide
KI	Potassium Iodide
NSF	Nano Silver Fluoride
NaF	sodium fluoride
ppm	Parts per million
SN	Silver nitrate
AgF	Silver Fluoride
AgI	Silver Iodide
Ag <sub>3</sub> PO <sub>4</sub>	Silver Phosphate
K <sub>3</sub> PO <sub>4</sub>	Potassium Phosphate
AgNPs	Silver nanoparticles
AAPD	American Academy of Pediatric Dentistry
ICDAS II	International Caries Detection And Assessment system
P value	Probability value
DFT-1M	index decayed + filled first permanent molars
S. mutans	Streptococcus mutans
SEM	scanning electron microscopy
CI	Confidence Interval
SD	Standard Deviation
WHO	World Health Organization
GIC	Glass Ionomer
IPC	Indirect Pulp capping

MIC	minimum inhibitory concentration
MBC	minimum bactericidal concentration
CHX	chlorhexidine
ANOVA	Analysis of variance
BHI	brain heart infusion
IOPA	Intra oral periapical
SMH	Surface Microhardness
CPP-ACP	casein phosphopeptide-amorphous calcium
VPI	visible plaque index
CFU	Colony forming Unit
OLD	outer lesion depth
WLD	wall lesion depth
CR	Composite Restoration
S	Significant
N.S.	Not significant
D	Distal
M	Mesial

## **INTRODUCTION**

Oral health is an integral part of general health and no individual can be considered healthy while there is active disease in the mouth. <sup>[1]</sup> The dental problems are initially painless but as time progresses, they become chronic and destroy the tooth.<sup>[2]</sup>

Dental caries is a bacterial motivated, chronic, multifactorial, site-specific disease resulting from imbalance in physiologic equilibrium between the tooth mineral and plaque. Due to the imbalance, pH of oral cavity drops resulting in net mineral loss of tooth structure over the time.<sup>[3]</sup> Despite the advances in dental care, dental caries remains one of the most communal oral diseases among children. International data on caries epidemiology confirm that dental caries remains a significant disease of childhood that is found in children at risk to dental caries in both developing and developed countries. Also, in developing countries, due to limited economic resources,

deprived access to basic oral care and the high cost of restorative treatment, children have their general health, social well-being, and education opportunities affected by untreated dental caries.<sup>[4]</sup>

The conservative treatment for a cavitated tooth involves excavation of infected, demineralized tooth structure and restored with a restorative material.<sup>[5]</sup> But, treatment of dental caries can be challenging requiring advanced skill of the clinician and good cooperation from patient. Especially when dental caries is present in very young children because of their limited cooperation it is difficult for the clinician to remove all the caries and give a proper restoration.<sup>[6]</sup>

When it comes to prevention, epidemiological studies indicate that, in patient with high bacterial challenge or those with lack of salivary components, natural remineralization is insufficient to prevent or arrest the caries process. Thus, there is a need to enhance the remineralization process to decrease caries experience and attain improved outcomes of oral health.<sup>[7]</sup> This situation calls for a paradigm change in caries prevention and management. Specifically, we need more effective, affordable, accessible, and safe treatments that are easy to implement in all the difficult settings, and are available to the all kind of populations.

Silver diamine fluoride is a colorless liquid which contain approximately 24.4% to 28.8% (weight/volume) silver ion and 5.0 to 5.9 % fluoride ion having the pH of 10. SDF is indicated for desensitization; for inhibiting bacterial growth and for arresting caries.<sup>[11]</sup> Carious lesions treated with SDF have shown to increase in mineral density and hardness, and decrease in size.<sup>[12]</sup> SDF can be used in the highest rates of tooth decay: children, bed-bound patients, people with mental disabilities, post-radiation and

chemotherapy patients and people with very low socioeconomic situations. The low cost of SDF treatment and ease of its application make it as a treatment option in dental offices and community dental health projects. In children, SDF applied annually is more effective at remineralising teeth and preventing caries than fluoride varnish when applied twice a year. SDF can also be used in modern dentistry as a preventive treatment once or twice a year.<sup>[13]</sup>

In 1970 one of the study examined the efficacy of SDF, a varnish made of ammonium and silver fluoride. The ammonia ions bind to silver ions to form a complex ion called silver diamine. The silver diamine is then binds to fluoride ion to forms silver diamine fluoride. The silver ion acts as an antibacterial agent, while the fluoride balances the bonding and helps with remineralization.<sup>[8]</sup> Some commercially available SDF product for dental treatment are “**Advantage arrest**” (38% SDF, Elevate Oral Care, USA) , “**Bioride**” (38% SDF, Densply Industriae Comercio Ltda, Brazil), “**Cariostatic**” (10% SDF, Inodon Laboratorio Brazil), “**Cariostop**” (12% SDF, Biodinamica Quimica e Farmaceutica Ltda Brazil), “**Fagamin**” (38% SDF, Tedequim SRL Argentina), “**Fluoroplat**” (38% SDF, NAF Laboratorios Argentina), “**Saforide**” (38% SDF, Toyo Seiyaku Kasei Co. Ltd. Japan), “**Riva star**” (30-35% SDF, SDI Dental Limited Australia).<sup>[9]</sup> 38% SDF is commonly used for treatment of hypersensitivity and caries control, and was approved as a therapeutic agent in Japan in the 1960. It has also been used in many countries like Argentina, Australia, Brazil and China for many years to treat dental caries. SDF in 2014, cleared as the first product for use in the USA by Food and Drug Administration (FDA). Since 1969, SDF has been used to arrest caries of the primary teeth in children especially toddlers and children with uncooperative behavioral issues, prevent pit and fissure caries and also prevent root caries. Apart from

caries management, SDF is also used to treat tooth hypersensitivity and to sterilize infected root canal.<sup>[10]</sup>

Meanwhile, SDF has some undesirable side effects, such as discoloration of the organic tissue of teeth, a metallic taste, and irritation following contact with soft tissues. The discoloration by SDF tends to happen because SDF is photosensitive. Positive silver ions react with oxygen to form  $\text{Ag}_2\text{O}$ , which then discolor organic tissue, especially the collagen tissue in dentine.<sup>[14]</sup> The skin pigmentation is temporary and disappears within one to two weeks because the silver does not penetrate into the dermis.<sup>[15]</sup>

Another anti cariogenic agent, Silver nitrate discovered in the 13th century as nitric acid was used to dissolve silver out of a silver/gold alloy. In the year, 1881 it was first used for newborns to protect their eyes from perinatal transmission of gonorrhoea, the effective concentrations being 1%. GV BLACK in 1920 was the first person to use it in dentistry who wrote about the technique for caries arrest with silver nitrate. From 1950-1970 its use is documented in dental literature as HOWE'S solution. Eventually it was phased out of dentistry because of shift of focus on fluoride and local anesthesia which aided surgical management of caries. Presently, silver nitrate sticks are used in medicine for hemostasis and chemo cautery.<sup>[16]</sup> Silver nitrate act as strong antibacterial agent and sodium fluoride act as a good remineralising agent, therefore a combined application of silver nitrate solution with sodium fluoride varnish was introduced for managing dental caries.<sup>[17]</sup>

25% silver nitrate followed 5% sodium fluoride is a simple, low-cost, and non-invasive protocol to control pain and infection due to caries progression. The treatment

does not required proper infrastructure like piped water and electricity and can be carried out in a simple clinical setting with basic instruments. Para-dental staff can be trained to provide the treatment under a dentist's supervision. Silver nitrate has a low cost of the material and required short time for application thus this protocol should be affordable in most communities. Last but not least, this treatment protocol is non-invasive, and the risk of cross-infection is low.<sup>[15]</sup>

As there are limited clinical trials investigating effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish in 3-6 year old children and to best of our knowledge there are only few studies till date comparing the effectiveness of Silver Nitrate and Silver diamine fluoride. Silver nitrate solution contains lower concentrations of silver and fluoride than in 38 % SDF solution; hence could be considered more favorable in young children. [chun et.al.]<sup>[34]</sup> Thus present study was planned to investigate the effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish and 38% Silver Diamine Fluoride in arresting dental caries in children.

## **AIM AND OBJECTIVES**

### **Aim:**

Comparison of the effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish with 38% silver diamine fluoride varnish in arresting caries in children  
- A Randomized Controlled Study.

### **Objectives:**

1. To evaluate the effectiveness of silver nitrate followed by sodium fluoride in arresting dental caries in children.
2. To evaluate the effectiveness of silver diamine fluoride in arresting dental caries in children.
3. To compare the effectiveness of silver nitrate followed by sodium fluoride varnish and silver diamine fluoride in arresting dental caries in children.

## **REVIEW OF LITERATURE**

**Chu, CH; Lo, ECM; Lin, HC (2002)<sup>[18]</sup>** studied Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children. Total Children of 375, with a mean age of 4.0 yrs attended the baseline examination. A total of 308 children attended the 30-month examination, giving an overall drop-out rate of 18%. After baseline examination, the children were sequentially allocated to one of five treatment groups, i.e. SDF + excavation, SDF, NaF + excavation, NaF and Control. Fluoride was repeated after 12 months. Mean number of tooth surfaces with active caries at baseline was 3.92. The differences in the above parameters between the initial group of 375 children and the 308 children who remained in the study were not statistically significant ( $p > 0.05$ ). Hence they concluded that the annual application of silver diamine fluoride solution is effective in arresting dentin caries in primary anterior teeth in Chinese preschool children.

**J.C. Llodra, A. Rodriguez, B. Ferrer, V. Menardia, T. Ramos and M. Morato (2005)<sup>[19]</sup>** studied the efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molar of school children. The study included 452 school children of both sexes, none below 6 years of age. Each child underwent 7 examinations, one at baseline and then every 6 months until the end of the study at 3 yrs. The school children were assigned on an individual random basis to the either SDF or control group by a third researcher. Sample size estimation was conducted with a 95% confidence interval and statistical power of 80%. The entire study period was completed by 373 school children (82%). Forty-five children (20%) were lost to the follow-up in the SDF group and 34 (15%) in the control group. In the 373 children followed up throughout the study, the mean baseline decayed, missing, and filled surface (dmfs) index scores were  $3.68 \pm 0.30$  and  $3.35 \pm 0.26$  in the SDF and control groups, respectively. The mean number of surfaces with active caries was  $3.29 \pm 0.28$  in the SDF group and  $2.91 \pm 0.22$  in the control group. Hence they concluded that biannual application of 38% silver diamine fluoride solution is efficacious to control caries in primary teeth as well as in first permanent molars.

**GM Knight, JM McIntyre, GG Craig, Mulyani, PS Zilm, NJ Gully [2005]<sup>[20]</sup>** conducted An in vitro model to measure the effect of a silver fluoride and potassium iodide treatment on the permeability of demineralized dentine to *Streptococcus mutans*. Forty dentine discs were bonded to the base of forty 5mL polycarbonate screw top vials, filled with nutrient medium, sterilized and placed into a continuous culture of *S. mutans*. Samples were divided into four groups as follows: 10 samples of demineralized dentine as a control, 10 samples of demineralized dentine treated with AgF/KI, 10 samples of demineralized dentine treated with KI and 10

samples of demineralized dentine treated with AgF. After two weeks the optical density of the growth medium chambers was measured to determine bacterial penetration and growth. Cultures were plated out to determine migration through the discs by *S. mutans*. They Concluded that Under the conditions of this study, treatment of demineralized dentine discs with AgF followed by KI allowed the penetration of *S. mutans*. Based on optical density measurements, the treatment resulted in significantly fewer microorganisms being present subjacent to the discs treated with AgF and KI than the control discs at the end of the experimental period.

**GM Knight, JM McIntyre, Mulyani [2006]<sup>[21]</sup>** studied The effect of silver fluoride and potassium iodide on the bond strength of auto cure glass ionomer cement to dentine. Ten recently extracted human third molars were embedded into methyl methacrylate resin and sliced to form a square block of exposed dentine surfaces. Each of the four surfaces were treated by one of the following procedures: (a) etching with 37 per cent phosphoric acid; (b) applying GC dentine conditioner; (c) etching, followed by application of AgF/KI then washing off the precipitate and air drying; and (d) etching, applying AgF/KI and air drying the reaction products on the surface. Fuji VII auto cure glass ionomer cement was bonded onto each sample and fracture tested. This study found that the application of AgF/KI to etched dentine samples followed by washing off the precipitate, created bond strengths that were not significantly different to conditioned samples. Leaving the AgF/KI precipitate on the dentine surface significantly reduced the bond strength of auto cured glass ionomer cement to dentine. Washing away the reaction products and air drying is recommended as the clinical protocol for using AgF and KI on dentine surfaces prior to application of an auto cure glass ionomer cement.

**Alberto Carlos Botazzo Delbem , Maurício Bergamaschi , Kikue Takebayashi Sasaki , Robson Frederico Cunha (2006)<sup>[22]</sup>** studied Effect of fluoridated varnish and silver diamine fluoride solution on enamel demineralization: pH-cycling study. In the present investigation, the anticariogenic effect of fluoride released by two products commonly applied in infants was evaluated. Bovine sound enamel blocks were randomly allocated to each one of the treatment groups: control (C), varnish (V) and diamine silver fluoride solution (D). The blocks were submitted to pH cycles in an oven at 37°C. Next, surface and cross-sectional microhardness were assessed to calculate the percentage loss of surface microhardness (%SML) and the mineral loss (DZ). The fluoride present in enamel was also determined.  $F/P \times 10^{-3}$  (ANOVA,  $p < 0.05$ ) in the 1<sup>st</sup> layer of enamel before pH-cycling were (C, V and D): 1.61<sup>a</sup>; 21.59<sup>b</sup> and 3.98<sup>c</sup>. The %SMH (Kruskal-Wallis,  $p < 0.05$ ) were: -64.0<sup>a</sup>, -45.2<sup>b</sup> and -53.1<sup>c</sup>. %DZ values (ANOVA,  $p < 0.05$ ) were: -18.7<sup>a</sup>, -7.7<sup>b</sup> and -17.3<sup>a</sup>. And they conclude according to the data collected that fluoride released by varnish showed greater interaction with sound enamel and provided less mineral loss when compared with silver diamine solution.

**C.H. Chu, E.C.M. Lo (2008)<sup>[23]</sup>** studied promoting caries arrest in children with silver diamine fluoride : A review. There has been a decrease in the prevalence and the severity of dental caries in children over the past few decades, the benefits have not been equally shared by many low-income or underserved children in many industrialised countries, or children in developing countries. Dental caries is still the most common and challenging dental disease in children for a clinician to treat. Silver diamine fluoride (SDF) has been in use to arrest dental caries in many countries. A 38% (44,800 ppm fluoride ions) SDF solution is commonly used to arrest caries in primary

teeth of children, especially those children who are young and difficult to manage. Application of SDF to arrest dental caries is a non-invasive procedure that is quick and simple to use. However, it stains the carious teeth and turns the arrested caries black. It also has an unpleasant metallic taste that is not liked by patients, especially children. The low cost of SDF and its simplicity in application suggest that SDF is an appropriate therapeutic agent for use in community dental health projects. Reports of available studies found no severe pulpal damage after SDF application. The current literature suggests that SDF can be an effective agent in preventing new caries and in arresting dental caries in the primary teeth of the children. It can be used to arrest caries progression in very young children who are less cooperative, and it allows definitive restoration to be performed when they grow older and become more receptive to dental procedures.

**R. Yee, C. Holmgren, J. Mulder, D. Lama, D. Walker, and W. van Palenstein Helderma (2009)**<sup>[24]</sup> compared the effectiveness of a single spot application of two concentrations of SDF, 38% or 12%, in arresting caries, with or without the use of tannic acid from tea as a reducing agent. This prospective randomized clinical trial on a cohort of 976 kindergarten and primary school children, with ages ranging from 3-9 yrs was conducted in Kathmandu, Nepal. Estimation of the sample size was based on the expected number of arrested caries surfaces. The data were entered into a computer and analyzed with SAS 9.1 software and concluded that a single spot application of 38% SDF is effective in arresting caries lesions, but the effectiveness decreases over time; tannic acid from tea confers no additional benefit; and 12% SDF is not effective.

**N. Sinha , A Gupta , A Logani and N Shah (2011)**<sup>[25]</sup> studied Remineralizing efficacy of silver diamine fluoride and glass ionomer type VII for their proposed use as indirect pulp capping materials – Part II (A clinical study). They evaluate the remineralizing efficacy of silver diamine fluoride (SDF), glass ionomer Type VII (GC VII) and calcium hydroxide (Dycal) in vivo. In this study 60 subjects in the age group of 18-35 years, matching the inclusion criteria and having deep carious lesions in the permanent first and second molars were selected. The teeth were aseptically opened under rubber dam and after gross caries removal, approximately 0.4mg of soft discolored dentin was removed with a sharp spoon excavator from the mesial or distal aspect of the cavity. The test material was randomly selected and applied in a thickness of 1.5-2mm and the cavity sealed with cavif. The patients were followed up at regular intervals with radiographic evaluation at 12 weeks. At 3 months the temporary restoration was removed and dentin samples were collected from the other half of the cavity which was left in the first appointment. Atomic absorption spectrophotometry, Colorimetric test using UV-vis spectrometer and potentiometric titration were used for determining calcium, phosphorous and fluoride respectively. Almost equivalent rise in the percentage of calcium level was seen in GC VII and Ca(OH)<sub>2</sub> groups, followed by SDF group. Highest percentage rise in phosphate ions was seen in GC VII group followed by SDF group and Ca(OH)<sub>2</sub> group. Highest percentage of fluoride rise was seen in GC VII group followed by SDF group and Ca(OH)<sub>2</sub> group. The results indicated that both GC VII and SDF can be potential indirect pulp capping materials.

**Chun Hung Chu , Lei Chaminda jayampath, Seneviratne Edward, Chin Man Lo** [2011]<sup>[26]</sup> studied the effects of SDF on dentine carious induced by *Streptococcus mutans* and *Actinomyces naeslundii*. Thirty-two artificially

demineralized human dentine blocks were inoculated: 16 with *S. mutans* and 16 with *A. naeslundii*. Either SDF or water was applied to eight blocks in each group. Biofilm morphology, microbial kinetics and viability were evaluated by scanning electron microscopy, colony forming units, and confocal microscopy. The crosssection of the dentine carious lesions were assessed by microhardness testing, scanning electron microscopy with energy-dispersive x-ray spectroscopy and Fourier transform infrared spectroscopy. Biofilm counts were reduced in SDF group than control ( $P < 0.01$ ). Study showed that SDF possess an anti-microbial activity against cariogenic biofilm of *S. Mutans* or *A. Naeslundii* formed on dentine surfaces. SDF slowed down demineralization of dentine. This dual activity could be the reason behind clinical success of SDF.

**Zhi, QH; Lo, ECM; Lin, HC (2012)**<sup>[27]</sup> conducted a randomized clinical trial on effectiveness of frequency of application of silver diamine fluoride and glass ionomer in arresting dentine caries in preschool children. A total of 212 children, aged 3-4 years, were randomly allocated to one of three groups for treatment of carious dentine of primary teeth: Gp1-annual application of SDF, Gp2-semi-annual application of SDF, and Gp3-annual application of glass ionomer. Follow-up examinations were carried out every six months to assess whether the treated caries lesions had become arrested. The caries arrest rates were 79%, 91% and 82% for Gp1, Gp2 and Gp3, respectively ( $p=0.007$ ). In the logistic regression model using GEE to adjust for clustering effect, higher caries arrest rates were found in lesions treated in Gp 2 (OR=2.98,  $p=0.007$ ), those in anterior teeth (OR=5.55,  $p<0.001$ ), and those in buccal/lingual smooth surfaces (OR=15.6,  $p=0.004$ ). And hence concluded that the effectiveness of annual application of SDF solution and that of annual application of a flowable high fluoride-releasing

glass inomer in arresting active dentine caries in primary teeth does not differ significantly, increasing the frequency of application of SDF solution to every 6 months can increase the caries arrest rate.

**Liu, BY; Lo, ECM; Chu, CH; Lin, HC ( 2012)<sup>[28]</sup>** conducted a randomized trial on silver diamine fluorides, sodium fluoride and resin fissure sealants for fissure caries prevention in permanent molar based on the 24-month results. A total number of 3078 pit/fissure sites (1539 molars) in 501 children (50% boys), mean age 9.1 years, were included. From that, 485 children with 1491 molars and 2982 sites (97%) were followed for 24 months. At the 24-month examination, 46% of the sealants were partially or fully retained. Proportions of pit/fissure sites with dentin caries were not significantly different ( $p>0.05$ ) in the resin sealant, NaF, and SDF groups, 1.6%, 2.4%, and 2.2% respectively. The percentage of sites with dentin caries in the control group 4.6% was significantly higher than those in the three treatment groups ( $p=0.002$ ). The site-level prevented fractions (PF) were 65%, 48%, and 52% for resin sealant, NaF varnish, and SDF solution, respectively. So it is concluded that the three preventive methods, placement of resin sealant, semi-annual application of NaF varnish, and annual application of SDF solution, are effective in preventing pit and fissure caries in permanent molars.

**RL Quock ,JA Barros , SW Yang , SA Patel [2012]<sup>[29]</sup>** studied the effect of Silver Diamine Fluoride on Microtensile Bond Strength to Dentin. The aim of this in vitro study was to investigate the effect of the cariostatic and preventive agent silver diamine fluoride (SDF) on the microtensile bond strength of resin composite to dentin. Forty-two caries-free, extracted molars were flattened occlusally and apically using a

diamond saw, and the exposed occlusal dentin was polished with a series of silicon carbide papers, all under water irrigation. The teeth were then randomly divided into six groups of seven teeth each that were treated as follows: 1) Peak SE self-etch bonding agent; 2) 12% SDF + Peak SE; 3) 38% SDF + Peak SE; 4) Peak LC etch-and-rinse bonding agent; 5) 12% SDF + Peak LC; and 6) 38% SDF + Peak LC. Two-way analysis of variance and post hoc Tukey tests were performed to compare the effects of the SDF on microtensile bond strength, with statistical significance set at  $\alpha = 0.05$ . they conclude that SDF seems to present exciting possibilities for the minimally invasive treatment and prevention of dental caries. Although this in vitro study indicates the bonding compatibility of SDF-treated noncarious dentin with a resin composite filling.

**May L. Mei , Chun H. Chu , Kan H. low , Ching M. Che and Edward CM .Lo (2013)**<sup>[30]</sup> studied Caries arresting effect of silver diamine fluoride on dentine carious lesion with *S. mutans* and *L. acidophilus* dual-species cariogenic biofilm This in vitro study investigated the effects of silver diamine fluoride (SDF) on dentine carious lesion with cariogenic biofilm. Thirty human dentine blocks were inoculated with *Streptococcus mutans* and *Lactobacillus acidophilus* dual-species biofilm to create carious lesion. They were equally divided into test and control group to receive topical application of SDF and water. After incubation anaerobically using micro-well plate at 37oC for 7 days, the biofilms were evaluated for kinetics, morphology and viability by colony forming units (CFU), scanning electron microscopy (SEM), and confocal microscopy (CLSM), respectively. The carious lesion underwent crystal characteristics analysis, evaluation of the changes in chemical structure and density of collagen fibrils using x-ray diffraction (XRD), Fourier transform infrared spectroscopy (FTIR) and immune-labeling. The log CFU of *S. mutans* and *L. acidophilus* in the test group was

significantly lower than control group. SEM and CLSM showed confluent biofilm in control group, but not in test group. XRD showed the loss of crystallinity of dentine due to the dissolution of hydroxyapatite crystal structure in test group was less than control group. FTIR showed that log [Amide I: HPO<sub>4</sub><sup>2-</sup>] for test vs. control group was 0.31±0.10 vs. 0.57±0.13 (p<0.05). The gold-labeling density in test vs. control group was 8.54±2.44/μm<sup>2</sup> vs. 12.91±4.24/μm<sup>2</sup> (p=0.04). And they conclude that SDF had antimicrobial activity against the cariogenic biofilms and reduced demineralization of dentine.

**May Lei Mei, Quan-li Li, Chun-Hung Chu, Edward Chin-Man Lo and Lakshman Perera Samaranayake ( 2013)<sup>[31]</sup>** studied Antibacterial effects of silver diamine fluoride on multi-species cariogenic biofilm on caries Using a computer-controlled artificial mouth, studied the effect of 38% SDF on cariogenic biofilms and dentin carious lesions. They used five common cariogenic bacteria (Streptococcus Mutans, Streptococcus Sobrinus, Lactobacillus acidophilus, Lactobacillus Rhamnosus and Actinomyces naeslundii) to form a cariogenic biofilm that generated carious lesions with a depth of approximately 70 um on human dentin blocks. They applied 38% SDF to the lesions in the test group and water to those in the control group. The blocks were incubated in the artificial mouth for 21 days before evaluation. Microbial kinetics, architecture, viability and distribution were evaluated every 7 days using colony forming unit (CFU), scanning electron microscopy and confocal laser scanning microscopy. The physical properties of the carious lesions were evaluated with microhardness testing, energy dispersive spectroscopy (EDS) and Fourier transform infra-red spectroscopy (FTIR). The CFU results revealed fewer colony forming units in the test group compared with the control group (p < 0.01). Scanning electron

microscopy and confocal microscopy showed less bacterial growth in the test group, and confluent cariogenic biofilm in the control group ( $p < 0.01$ ). The microhardness and weight percentages of calcium and phosphorus in the test group from the outermost 50µm were higher than in the control group ( $p < 0.05$ ). EDS showed that calcium and phosphorus were higher in outer 50 µm in test groups than in the control FTIR revealed less exposed collagen I in the test lesions compared with the control group ( $p < 0.01$ ). And they conclude that 38% SDF inhibits multi-species cariogenic biofilm formation on dentin carious lesions and reduces the demineralization process.

**May L. Mei , L. Ito , Y. Cao , Edward C.M. Lo , Q.L. Li b,, C.H. Chu [2013]<sup>[32]</sup>** conducted ex vivo study compared the physico-chemical structural differences between primary carious teeth biannually treated with silver diamine fluoride (SDF) and carious teeth without such treatment. Twelve carious primary upper-central incisors were collected from 6-year-old children. Six teeth had arrested caries after 24-month biannual SDF applications and 6 had active caries when there was no topical fluoride treatment. The mineral density, elemental contents, surface morphology, and crystal characteristics were assessed by micro-computed tomography (micro-CT), energy-dispersive X-ray spectrometry (EDX), scanning electron microscopy (SEM), and transmission electron microscopy (TEM). They concluded that a highly remineralised zone rich in calcium and phosphate was found on the arrested cavitated dentinal lesion of primary teeth with an SDF application. The collagens were protected from being exposed in the arrested cavitated dentinal lesion.

Juliana Mattos-Silveira, Isabela Floriano, Fernanda R Ferreira, Maria E F Viganó, M A Frizzo, Alessandra Reyes, Tatiane F Novaes, Caroline M Moriyama,

Daniela P Raggio, José C P Imparato, Fausto M Mendes and Mariana M Braga [2014]<sup>[33]</sup> studied New proposal of silver diamine fluoride use in arresting approximal caries. This was a randomized clinical trial, double-blinded, placebo-controlled study. Children/adolescents presenting at least one approximal initial caries lesion in primary molars/permanent premolars and molars were included. Surfaces with advanced dentine lesions identified by radiography and participants who refuse to participate or present negative behaviors were excluded. A minimum sample size of 504 surfaces required for each subgroup. Individuals were randomly allocated in three groups of interventions: SDF, resin infiltration, and control group. Depending on the allocation, the patients were received the active treatment and respective placebo therapies. All patients were oriented to daily flossing the included surfaces.. Individuals will be assessed at 1 and 3 months after treatment to evaluate dental biofilm and at 6, 12, and 24 months to assess caries progression by visual examination and/or radiography. Multilevel analyses will be used to verify if the type of treatment influenced on the tested outcomes. Costs will be compared and analyses of cost-efficacy will be performed. At the end of this study they expect that point out option(s) would be definitely more efficacious/cost-effective than the mechanical removal of biofilm from approximal surface by flossing.

**Chun-Hung Chu, Sherry Shiqian Gao, Samantha KY Li, May CM Wong and Edward CM Lo (2015)<sup>[34]</sup>** compared the efficiency of 25% silver nitrate followed by 5% sodium fluoride varnish with that of 38% SDF solution in arresting the ECC in half yearly interval over a 30 month period in preschool children. This was a randomised, double-blind, non-inferiority clinical trial. The children aged 3–4 years and were attending the first year of kindergarten they were be generally healthy, have

parental consent and had at least 1 tooth with untreated caries with cavitations that extends into the dentine at baseline examination. This non-inferiority trial aims to measure the anti-caries efficacy of a 25 % AgNO<sub>3</sub> solution followed by 5 % NaF varnish versus a 38 % SDF solution with a non inferiority margin of -0.5 for the difference in mean number of arrested caries surfaces, which was considered clinically negligible corresponding to an effect size = 0.25, assuming a standard deviation of 2.5 and true difference of 0. They expect that 25 % AgNO<sub>3</sub> solution followed by 5 % NaF varnish are as effective as 38 % SDF solution in arresting childhood caries.

**D. Duangthip, C.H. Chu, E.C.M. Lo (2015)<sup>[35]</sup>** conducted a randomized clinical trial on arresting dentine caries in preschool children using topical fluorides application —18 month results Children aged 3–4 years who had at least one active dentine caries lesion were randomly allocated into three intervention groups: Group 1—application of 30% silver diammine fluoride (SDF) solution every 12 months; Group 2—three applications of 30% SDF solution at weekly interval at baseline; and Group 3—three applications of 5% sodium fluoride (NaF) varnish at weekly interval at baseline. A masked examiner carried out follow up examinations every 6 months to assess whether the treated lesions had become arrested. A total of 304 children with 1670 tooth surfaces with dentine caries received treatment at baseline. After 18 months, 275 children (91%) remained in the study. The caries arrest rates at tooth surface level were 40%, 35% and 27% for Groups 1, 2 and 3, respectively (  $p < 0.001$ ). And concluded that among high caries risk preschool children living in a fluoridated area, annual or three consecutive weekly applications of SDF solution is more effective in arresting dentine caries in primary teeth than three consecutive weekly applications of NaF varnish.

**Yasmi O Crystal, Richard Niederman (2016)**<sup>[36]</sup> studied caries prevention by SDF. It offers an alternate care path for patients for whom traditional restorative treatment is not immediately available. In this study data collected from controlled clinical trials encompassing more than 3900 children, indicates that biannual application of SDF reduces progression of current and risk of subsequent caries. This commentary highlights the best evidence from systematic reviews and clinical trials for clinicians to consider the benefits, risks and limitations as they implement SDF therapy on young children. So they conclude that SDF appears to be a useful immediate treatment for children who can't receive traditional restorative treatment for dental decay. It is effective for caries arrest and prevention of new lesions on the teeth where it is applied, and is a minimal intervention treatment that is safe and affordable.

**S.S. Gao, I.S. Zhao, N. Hiraishi, D. Duangthip, M.L. Mei, E.C.M. Lo, and C.H. Chu [2016]**<sup>[37]</sup> studied the review aims to investigate the clinical effectiveness of silver diamine fluoride (SDF) in arresting dental caries among children. A systematic search of publications was conducted with the key words “silver diamine fluoride,” “silver diamine fluoride,” “silver fluoride,” “diamine silver fluoride,” or “diamine silver fluoride” as well as their translation in Chinese, Japanese, Portuguese, and Spanish in 7 databases: The full text of the remaining publications was retrieved. Prospective clinical studies of SDF that reported a caries-arresting effect among children were included. Meta-analysis was performed for quantitative analysis. A total of 1,123 publications were found, including 19 publications of clinical trials. Sixteen clinical trials studied the caries-arresting effect on primary teeth, and 3 clinical trials were on permanent teeth. Fourteen studies used 38% SDF, 3 used 30% SDF, and 2 used 10% SDF. Meta-analysis was performed on extracted data from 8 studies using 38%

SDF to arrest caries in primary teeth. The overall percentage of active caries that became arrested was 81% (95% confidence interval, 68% to 89%;  $P < 0.001$ ). Apart from staining the arrested lesion black, no significant complication of SDF use among children was reported. They concluded that SDF was commonly used at 38%. It was effective in arresting dentine caries in primary teeth among children.

**May L. Mei, Edward Chin-Man Lo, and Chun-Hung Chu [2016]<sup>[38]</sup>** studied Clinical Use of Silver Diamine Fluoride in Dental Treatment. The use of a topical fluoride solution, namely silver diamine fluoride (SDF), in dental treatment has been drawing increasing attention. SDF has been used in some countries in Asia, including Japan and China, as a caries arresting and anti-hypersensitivity agent. It was recently cleared by the Food and Drug Administration in the United States as a fluoride to manage hypersensitive teeth. Topical application of SDF is a noninvasive procedure that is quick and simple to use. Promising results of laboratory studies and clinical trials have suggested that SDF is more effective than other fluoride agents to halt the caries process. A review concluded that SDF is a safe, effective, efficient, and equitable caries control agent that has a potentially broad application in dentistry and may meet the criteria of both the WHO Millennium Development Goals and the US Institute of Medicine's criteria for 21st century medical care.

**Ryan N. Hansen, PharmD, PhD, R. Mike Shirdiff, DMD, Jeanne Dysert, Peter M. Milgrom, (2017)<sup>[39]</sup>** studied Costs and Resource Use Among Child Patients Receiving Silver Nitrate/Fluoride Varnish Caries Arrest they conducted a retrospective matched cohort study. This was a human observational study that conforms to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) .

The organization provides services in 183 primary care and 63 specialist private practices and 40 staff-model. During the study period, clinicians in the Advantage system received continuing education on the application of topical silver nitrate used sequentially with fluoride varnish at the same appointment and chose whether or not to use the treatment based on dental caries risk. They included all patients with Medicaid dental claims in the Advantage network younger than 21 years old. However, they excluded patients who received prosthodontic treatment (primarily children with cleft palate) during the study period. They compared the children treated with SN/FV and those treated conventionally in terms of demographic characteristics and the initial treating dental provider's specialty. Continuous variables were compared using the student's *t* test, while categorical variables were compared using the chi-square test. The number of dental services and costs were summed at the patient level separately over one year and total follow-up time. Based on that, they conclude that. Silver nitrate/fluoride varnish treatments and silver diamine fluoride offer potentially cost-effective treatments for dental caries with the potential to improve oral health in the U.S. and other countries. But this is a relatively new technology, guidelines for treatment are needed.

**Zhao, IS; Mei, ML; Li, Q; Lo, ECM; Chu, CH (2017)<sup>[40]</sup>** studied Arresting simulated dentine caries with adjunctive application of silver nitrate solution and sodium fluoride varnish: an in vitro study. In this study dentine slices were prepared and demineralised. Each slice was cut into three specimens for three groups (SF, SDF and W). Specimens of the SF group received topical application of 25% silver nitrate solution followed by 5% sodium fluoride varnish. The SDF group received topical application of 38% silver diamine fluoride solution (positive control). Specimens of the

W group received deionised water (negative control). All specimens were subjected to pH cycling for 8 days. Dentine surface morphology, crystal characteristics, carious lesion depth and collagen matrix degradation were evaluated by scanning electron microscopy, X-ray diffraction, X-ray microtomography and spectrophotometry with a hydroxyproline assay. Scanning electron microscopy showed that dentine collagen was exposed in group W, but not in groups SF and SDF, while clusters of granular spherical grains were formed in groups SF and SDF. The mean lesion depths (standard deviation) of groups SF, SDF and W were 128 ± 19, 135 ± 24 and 258 ± 53 µm, respectively (SF, SDF < W; P < 0.001). The X-ray diffraction analysis indicated that silver chloride was formed in groups SF and SDF. The concentration of hydroxyproline released from the dentine matrix was significantly lower in groups SF and SDF than in group W (P < 0.05). The results of this in vitro study indicate that the use of silver nitrate solution and sodium fluoride varnish is effective in inhibiting dentine demineralization and dentine collagen degradation.

**Sophia Khan, Sayamol Voraragsa, Ralph Cunningham, Noel Brown, Page W. Caufield, (2017)<sup>[41]</sup>** studied Conservative Management of Dental Caries Using Silver Nitrate and Atraumatic Restorative Treatment in Remote Rural Setting. The treatment period consisted of two sessions, two years apart. Twenty-one adults and 133 children from one of five rural community health centers received one of the dental procedures described below. The ages of the patients ranged from 21 to 72 for adults, and 3 to 20 years for children. Parental consent for treatment was obtained by school administrators prior to the visit and again as verbal consent from adults and/or children at the appointment time. Patients having readily visible caries lesions and tentatively determined not to have pulpal involvement were selected for treatment. Two basic

regimens were implemented after lesion debridement and preparation: 1. SN with and without NaF varnish or SDF alone; 2. SN/SDF via the ART approach (SN-ART). Caries proximal to pulp were left to avoid exposure. Single surface lesions surrounded by sound enamel were ideal for SN -ART, due to retention. Proximal lesions where access and retention were limited received the SN/SDF treatment. Primary teeth were mostly treated with either SN, SN-NaF varnish (Duffin procedure) or SDF alone and the treated lesion left unrestored. In some instances, primary teeth received the SN-ART, depending upon the clinician's judgment as to the retentiveness and accessibility of the prepared lesion. The two silver solutions used were Final selection between SDF or SN must await proper side-by-side comparisons. So far, only SDF has the backing of RCTs. We placed GIC restorations after SN/SDF treatment in permanent teeth, compared to primary teeth for two reasons: 1. lesions tend to be larger and more accessible in permanent teeth; 2. lesions in permanent teeth and young adults are more likely to progress to eventual extraction, something we wanted to avoid. We had both SN (50% AgNO<sub>3</sub>) and SDF (38% Ag(NH<sub>3</sub>)<sub>2</sub>F) available to use in the field. There was no difference noted in the application of either SN or SDF, as both turned black after being light-cured for 10 seconds. From a cost perspective, the cost per drop of SN is about 1/10th the cost of SDF.

**Violeta Contreras, Milagros J. Toro, Augusto R. Elías-Boneta, Angeliz Encarnación-Burgos (2017)**<sup>[42]</sup> studied to evaluate the scientific evidence regarding the effectiveness of silver diamine fluoride (SDF) in preventing and arresting caries in the primary dentition and permanent first molars. A systematic review (SR) was performed by 2 independent reviewers using 3 electronic databases (PubMed, Science Direct, and Scopus). Database searches provided 821 eligible publications, of which 33

met the inclusion criteria. After the abstracts were prescreened, 25 articles were dismissed based on exclusion criteria. The remaining 8 full-text articles were assessed for eligibility. Of these, 7 publications were included in the SR. These included 1 study assessing the effectiveness of SDF at different concentrations; 3 studies comparing SDF with other interventions; 2 investigations comparing SDF at different application frequencies and with other interventions; and 1 study comparing semiannual SDF applications versus a control group. The literature indicates that SDF is a preventive treatment for dental caries in community settings. At concentrations of 30% and 38%, SDF shows potential as an alternative treatment for caries arrest in the primary dentition and permanent first molars. To establish guidelines, more studies are needed to fully assess the effectiveness of SDF and to determine the appropriate application frequency. Dental caries can be prevented or arrested, Moreover preventive measures for ECC are more cost effective than emergency room visits or restorative treatments when the illness has been established. A variety of evidence-based approaches for caries prevention have been reported; however, these strategies demand significant financial investment and depend on the availability of oral health workforces and facilities. Effective ECC preventive measures include the use of fluoride varnish—such as 5% sodium fluoride (NaF)—and the use of fluoridated toothpaste. In the management of cavitated ECC, atraumatic restorative treatment (ART) has been recommended. ART is painless, is low cost, and can be applied outside the clinical setting or when conventional treatment is not available. A disadvantage of this treatment is its high rate of failure. Interest in the use of silver diamine fluoride (SDF) has been growing. SDF has been used as an alternative treatment for caries prevention and arrest. In 2014, SDF was approved by the US Food and Drug Administration as a treatment for dentinal

sensitivity. SDF had been used off-label for caries arrest; however, it was recently approved (code D1354) as an interim caries arresting medicament. Clinical studies have demonstrated the effectiveness of SDF in childhood caries prevention and arrest. Semiannual applications of SDF at 38% concentration have been recommended. SDF has been suggested for difficult-to-treat lesions and patients are uncooperative. A systematic review of 7 studies conclude that SDF, at concentrations of 30% and 38%, is more effective than other preventive management strategies for arresting dentinal caries in the primary dentition. Additionally, 30% and 38% concentrations of SDF show potential as a caries preventive treatment in primary teeth and permanent first molars. Standardized SDF protocols must be developed to allow meaningful study comparisons and establish treatment guidelines.

**Crystal YO, Marghalani AA, Ureles SD, et al.[2017]<sup>[43]</sup>** studied Use of silver diamine fluoride for dental caries management in children and adolescents, including those with special health care needs A guideline workgroup formed by the American Academy of Pediatric Dentistry developed guidance and an evidence-based recommendation regarding the application of 38 percent SDF to arrest cavitated caries lesions in primary teeth. The basis of the guideline's recommendation is evidence from an existing systematic review "Clinical trials of silver diamine fluoride in arresting caries among children: A systematic review." (JDR Clin Transl Res 2016;1[3]:201-10). A systematic search was conducted in PubMed®/MEDLINE, Embase®, Cochrane Central Register of Controlled Trials, and gray literature databases to identify randomized controlled trials and systematic reviews reporting on the effect of silver diamine fluoride and address peripheral issues such as adverse effects and cost. The Grading of Recommendations Assessment, Development, and Evaluation (GRADE)

approach was used to assess the quality of the evidence and the evidence- to-decision framework was employed to formulate a recommendation. The panel made a conditional recommendation regarding the use of 38 percent SDF for the arrest of cavitated caries lesions in primary teeth as part of a comprehensive caries management program. After taking into consideration the low cost of the treatment and the disease burden of caries, panel members were confident that the benefits of SDF application in the target populations outweigh its possible undesirable effects. Per GRADE, this is a conditional recommendation based on low-quality evidence. And they concluded that guideline intends to inform the clinical practices involving the application of 38 percent SDF to enhance dental caries management outcomes in children and adolescents, including those with special health care needs. These recommended practices are based upon the best available evidence to-date.

**Kitty Jieyi Chen, Sherry Shiqian Gao, Duangporn Duangthip, Edward Chin Man Lo and Chun Hung Chu [2018]<sup>[44]</sup>** conducted a randomized, double-blind controlled trial. The null hypothesis tested is that no difference exists between the effectiveness of a 25% AgNO<sub>3</sub> solution plus a 5% NaF varnish with functionalized tricalcium phosphate [fTCP] and a 25% AgNO<sub>3</sub> solution plus a 5% NaF varnish in arresting dentine caries in preschool children when applied semi-annually. According to the sample size calculation, approximately 2000 3- to 4-year-old kindergarten children will be screened, and at least 408 children with coronal dentine caries will be recruited. The children will be randomly allocated to two treatment groups via stratified randomization: group A – biannual application of a 25% AgNO<sub>3</sub> solution followed by a 5% NaF varnish, and group B – biannual application of a 25% AgNO<sub>3</sub> solution followed by a 5% NaF varnish with fTCP. Clinical examinations will be conducted

every 6 months to assess whether the carious lesions have become arrested (primary outcome). Confounding factors, such as demographic background and oral hygiene behaviors, will be collected through a parental questionnaire. The effectiveness of the topical application of a 25% AgNO<sub>3</sub> solution followed by a 5% NaF varnish with [ f TCP] in arresting coronal dentine caries among preschool children remains unknown. Because the proposed caries-arresting methods are simple, noninvasive and low cost, these can be widely recommended for caries control in young children.

**Ollie Yiru Yu, Irene Shuping Zhao, May Lei Mei, Edward Chin-Man Lo and Chun-Hung Chu [2018]<sup>[45]</sup>** investigated the effect of 25% silver nitrate (AgNO<sub>3</sub>) and 5% sodium fluoride (NaF) varnish with functionalized tri-calcium phosphate (fTCP) on a *Streptococcus mutans* (*S. mutans*) biofilm and dentine caries lesion. Demineralized dentine specimens were treated with 25% AgNO<sub>3</sub> and 5% NaF + fTCP (Group 1), 25% AgNO<sub>3</sub> and 5% NaF (Group 2), 25% AgNO<sub>3</sub> (Group 3), or water (Group 4). The specimens were subjected to a *S. mutans* biofilm challenge after treatment. The biofilm was then studied via scanning electron microscopy (SEM), confocal laser scanning microscopy (CLSM), and colony forming units (CFU). The specimens were assessed by micro-computed tomography, X-ray diffraction (XRD), and Fourier transform infrared spectroscopy (FTIR). SEM and CLSM revealed less biofilm in Groups 1 to 3. This study revealed that AgNO<sub>3</sub> and NaF + fTCP reduced the damage of dentine caries by cariogenic biofilm.

**Irene Shuping Zhao, Sherry Shiqian Gao, Noriko Hiraishi, Michael Francis Burrow, Duangporn Duangthip, May Lei Mei, Edward Chin-Man Lo and**

**Chun-Hung Chu [2018]<sup>[46]</sup>** wrote a review regarding the mechanisms of silver diamine fluoride (SDF) for arresting caries. A literature search was conducted using the keywords silver diamine fluoride, and its alternative names, in seven databases: PubMed, Embase and Scopus (English); China National Knowledge Infrastructure (Chinese); Bilioteca Virtual em Saude (Portuguese); Biblioteca Virtual en Salud Espana (Spanish); and Ichushi-Web (Japanese). The titles and abstracts were screened. Full texts were retrieved for publications that studied mechanisms of actions of SDF, including its effects on remineralisation of carious lesions and on cariogenic bacteria. A total of 1,123 publications were identified. Twenty-nine articles were included and they investigated the effect of SDF on cariogenic bacteria and dental hard tissues. Eleven studies investigated the antibacterial properties of SDF. They found that SDF was bactericidal to cariogenic bacteria, mainly *Streptococcus mutans*. It inhibited the growth of cariogenic biofilms on teeth. Twenty studies reported the remineralization of demineralised enamel or dentine by SDF. They found that mineral loss of demineralised enamel and dentine was reduced after SDF treatment. A highly mineralised surface rich in calcium and phosphate was formed on arrested carious lesions. Four studies examined the effect of SDF on dentine collagen. They found that SDF inhibited collagenases (matrix metalloproteinases and cysteine cathepsins) and protected dentine collagen from destruction. They concluded that SDF is a bactericidal agent and reduces the growth of cariogenic bacteria. It inhibits demineralisation and promotes the remineralisation of demineralised enamel and dentine. It also hampers degradation of the dentine collagen.

**Najmeh Mohammadi, Mohammad Hossein Farahmand Far [2018]<sup>[47]</sup>** studied Effect of fluoridated varnish and silver diamine fluoride on enamel

demineralization resistance in primary dentition. Forty-five caries-free deciduous canine teeth extracted due to orthodontic reasons, devoid of any defects were selected. Teeth were mounted on acrylic blocks as their buccal surface was exposed and baseline surface microhardness (SMH) determination was accomplished. Enamel samples were randomly distributed into three groups with 15 specimens each. One group was used as control (distilled and deionized water) (C); in the other groups, either a fluoridated varnish (V) or an SDF solution was applied to the enamel blocks. The blocks of each group were submitted to pH-cycling solutions and treatment regimen. After pH-cycling process, SMH determination was done again for all samples. According to the present findings, the percentage of decrease in SMH of control group is numerically greater than other groups and also SDF group shows the most resistance against mineral loss. However, based on one-way ANOVA test, this difference is not statistically significant ( $P = 0.217$ ). SDF solution and fluoride varnish display similar effectiveness in preventing the demineralization of deciduous anterior teeth, and no significant difference was observed.

**Rebecca L. Slayton, Olivia, Margherita Fontana, Sandra Guzmán-Armstrong, Marcelle M. Nascimento, Brian B. Nový, Norman Tinanoff et al [2018]<sup>[48]</sup>** Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions The authors conducted a systematic search of the literature in MEDLINE and Embase via Ovid, Cochrane CENTRAL, and Cochrane database of systematic reviews to identify randomized controlled trials reporting on nonrestorative treatments for noncavitated and cavitated carious lesions. The authors used the Grading of Recommendations Assessment, Development and Evaluation approach to assess the certainty in the evidence and move from the evidence to the decisions. The expert panel

formulated 11 clinical recommendations, each specific to lesion type, tooth surface, and dentition. Of the most effective interventions, the panel provided recommendations for the use of 38% silver diamine fluoride, sealants, 5% sodium fluoride varnish, 1.23% acidulated phosphate fluoride gel, and 5,000 parts per million fluoride (1.1% sodium fluoride) toothpaste or gel, among others. The panel also provided a recommendation against the use of 10% casein phosphopeptide–amorphous calcium phosphate. Although the recommended interventions are often used for caries prevention, or in conjunction with restorative treatment options, these approaches have shown to be effective in arresting or reversing carious lesions. Clinicians are encouraged to prioritize use of these interventions based on effectiveness, safety, and feasibility.

**Tamara Kerber Tedesco , Thais Gimenez, Isabela Floriano, Anelise Fernandes Montagner, Lucila Basto Camargo, Ana Fla´via Bissoto Calvo,Susana Morimoto, Daniela Procida Raggio [2018]<sup>[49]</sup>** studied Scientific evidence for the management of dentin caries lesions in pediatric dentistry: A systematic review and network meta- analysis A search was conducted using the MEDLINE/PubMed, Web of Science and Scopus databases through December 2017. The primary search terms used in combination were primary teeth, caries lesion and restoration. The grey literature was also screened, as were the reference lists of eligible studies. A search of prospective studies with at least 12 months of follow up that compared different techniques was performed. The exclusion criteria were the absence of a comparison group; no evaluation of different restorative techniques; the evaluation of other outcomes unrelated to this review; and the recruitment of specific patient. The risk of bias was evaluated by the tools: the Cochrane Handbook for Systematic Reviews of Interventions and ROBINS-I. A network meta-analyses and meta-analyses were

conducted considering CLA or SR as outcomes according to the surface involved and the depth of progression. Of the 1671 potentially eligible studies, 15 were included. For occlusal surfaces, only two studies presented data regarding the outer half of the dentin, with conventional restorative treatment (CRT) using composite resin showing superior results; five studies presented data regarding the depth of caries lesions, and CRT with compomer resulted in the best results. Seven studies considered occlusoproximal surfaces, and the Hall technique showed the best SR among the evaluated treatments. Finally, two annual applications of silver diamine fluoride showed the best nonrestorative approach to arrest caries lesions on occlusal and smooth surfaces.

**Alice Trieu, Ahmed Mohamed2 & Edward Lynch [2019]<sup>[50]</sup>** studied Silver diamine fluoride versus sodium fluoride for arresting dentine caries in children: a systematic review and metaanalysis. This study systematically reviewed the dentine caries arrest capabilities of silver diamine fluoride (SDF) and sodium fluoride (NaF). A comprehensive search strategy was developed to identify the relevant publications in electronic databases and hand searched journals and reviews (to March 2018). By applying strict inclusion and exclusion criteria, only six papers (two randomized controlled trials, two follow-up articles and two secondary statistical analysis studies) were considered for full text qualitative and quantitative assessment. The included studies were critically appraised and statistically evaluated. Only four articles were considered for meta-analysis, as the other two were secondary analyses of included studies. When comparing the caries arrest lesions of SDF and NaF, SDF was found to be statistically more effective in dentine caries arrest of primary teeth during the 18 and 30 month clinical examinations. The weighted total effect size of the differences between SDF and NaF regarding arrested caries surfaces was calculated and showed

nearly double the effectiveness of SDF to NaF at 30 months. Therefore, SDF is a more effective caries management reagent than NaF. Further clinical research is needed to consolidate the findings of this systematic review.

**Sunnypriyatham Tirupathi , Nirmala SVSG , Srinitya Rajasekhar , Sivakumar Nuvvula [2019]<sup>[51]</sup>** studied Comparative cariostatic efficacy of a novel Nano-silver fluoride varnish with 38% silver diamine fluoride varnish a double-blind randomized clinical trial. A total of 159 active dentinal carious lesions in primary molars (from 50 children) were selected and randomly divided into two groups; NSSF and SDF. Varnish application was performed at the baseline visit and follow-up is carried out at 1, 3, 6 and 12 months. Parameters such as caries activity, depth, size, colour, and presence or absence of pain were noted at baseline and follow-up visits. The intergroup comparison of caries activity status did not reveal significant difference between the number of active and arrested caries lesions in NSSF and SDF groups at any visit ( $p>0.05$ ) during the 12-month follow-up. There was no difference between overall failure and success rates between the two groups at any follow-up period ( $p=0.48$ ). Annual application of 5% NSSF is better than or equal to 38% SDF in preventing the progression of dentinal caries of primary molars. NSSF does not cause dark staining of dentinal tissue compared to the SDF and the use of NSSF can be recommended in children.

**Jeremy A. Horst and Masahiro Heima [2019]<sup>[52]</sup>** studied Prevention of Dental Caries by Silver Diamine Fluoride. The use of silver diamine fluoride (SDF) for management of dental caries has gained considerable attention due to recent regulatory clearance in United States. The primary focus of policies, presentations, and

publications has been the arrest of caries lesions (cavities) because of the material's unique ability to non-invasively achieve this elusive and clinically important goal. However, SDF also has proven efficacy in prevention, ie, decreasing the incidence of new caries lesions. Analysis of nine clinical trials in children shows that SDF prevented 61% of new lesions compared to controls. To prevent one new caries lesion, clinicians need to treat four primary teeth (one patient) or 12.1 permanent molars (three patients) with SDF. The preventive effect appears to be immediate and maintains at the same fraction over time. Direct comparisons of SDF applied once per year with alternative treatments show that SDF is more effective than other topical fluorides placed two to four times per year and more cost-effective than dental sealants. Enamel lesions may be even more responsive than cavitated dentin lesions. Annual application of SDF to high-risk surfaces (eg, mesial surfaces of permanent first molars where the distal surface of the second primary molar is carious) in patients with any risk of new caries lesions appears to be the most cost-effective approach available to prevent dental caries. SDF is an underutilized evidence-based preventive agent for dental caries.

**Yasmi O. Crystal and Richard Niederman[2019]<sup>[53]</sup>** studied Evidence-Based Dentistry Update on Silver Diamine Fluoride. In their update they stated as Silver diamine fluoride incorporates the antibacterial effects of silver and the remineralizing actions of a high-concentration fluoride. It effectively arrests the disease process on most lesions treated. Systematic reviews of clinical trials confirm the effectiveness of silver diamine fluoride as a caries-arresting agent for primary teeth and root caries and its ease of use, low cost, and relative safety. No caries removal is necessary to arrest the caries process, so the use of silver diamine fluoride is appropriate when other forms of caries control are not available or feasible. A sign of arrest is the dark staining of the

lesions and affected tooth structures. That could be a deterrent for patients who have esthetic concerns. A thorough informed consent is recommended to ensure high patient satisfaction. Silver diamine fluoride use for caries control is recommended as part of a comprehensive caries management program, where individual needs and risks are considered.

**Branca Heloisa Oliveira, Anjana Rajendra, Analia Veitz-Keenan and Richard Niederman [2019]<sup>[54]</sup>** studied The Effect of Silver Diamine Fluoride in Preventing Caries in the Primary Dentition: A Systematic Review and Meta-Analysis. Systematic review (CRD42016036963) of controlled clinical trials. Searches were performed in 9 electronic databases, 5 registers of ongoing trials, and reference lists of identified review articles. Two researchers carried out data extraction and quality appraisal independently. The primary outcome was the difference in caries increment (decayed, missing, and filled surfaces or teeth – dmfs or dmft) between SDF and control groups. These differences were pooled as weighted mean differences (WMD) and prevented fractions (PF). Searches yielded 2,366 unique records; 6 reports of 4 trials that randomized 1,118 and analyzed 915 participants were included. Two trials compared SDF to no treatment, 1 compared SDF to placebo and sodium fluoride varnish (FV), and 1 compared SDF to high-viscosity glass ionomer cement (GIC). All studies had at least 1 domain with unclear or high risk of bias. After 24 months of follow-up, in comparison to placebo, no treatment, and FV, SDF applications significantly reduced the development of new dentin caries lesions (placebo or no treatment: WMD = -1.15, PF = 77.5%; FV: WMD = -0.43, PF = 54.0%). GIC was more effective than SDF after 12 months of follow-up but the difference between them was not statistically significant (WMD, dmft: 0.34, PF: -6.09%). So they concluded

that When applied to caries lesions in primary teeth, SDF compared to no treatment, placebo or FV appears to effectively prevent dental caries in the entire dentition. However, trials specifically designed to assess this outcome are needed.

**Sherry Shiqian Gao, Kitty Jieyi Chen, Duangporn Duangthip, May Chun Mei Wong, Edward Chin Man Lo and Chun Hung Chu [2020]<sup>[55]</sup>** studied Preventing early childhood caries with silver diamine fluoride: study protocol for a randomised clinical trial. This is a phase II, single-centre, randomised, double-blind, active-controlled, parallel-group pragmatic trial. The hypothesis tested is that 38% SDF would be more effective than 5% NaF in preventing new caries development in primary anterior teeth. Approximately 730 3-year-old children who are generally healthy and with parental consent will be recruited from Hong Kong kindergartens. This sample size will be sufficient for appropriate statistical analysis of a superiority trial with 90% power, allowing for a 20% drop-out rate. Stratified randomisation will be adopted for allocating the intervention. The intervention will either be 38% SDF or 5% NaF (as a positive control) therapy on primary upper anterior teeth. A single trained examiner will conduct a dental examination every 6 months until 30months in kindergarten. Another operator will provide fluoride therapy immediately after each dental examination. The examiner, children and children's parents will be blinded to the treatment allocation. A questionnaire survey will be conducted to study the children's oral health-related behaviours and socioeconomic backgrounds. Chi-square tests, t tests, regression analyses and survival analyses will be adopted for data analysis. They concluded as The effectiveness of 38% SDF in preventing ECC remains uncertain. If the results are as anticipated, care standards using 5% NaF for ECC prevention will be changed. In

addition, the results will be widely available and increase the adoption of SDF in other countries to reduce the global burden of ECC.

**Zohra Jabin, Vishnupriya V, Nidhi Agarwal, Iffat Nasim, Meena Jain, Ankur Sharma [2020]<sup>[56]</sup>** studied Effect of 38% silver diamine fluoride on control of dental caries in primary dentition: A Systematic review. Silver diamine fluoride (SDF) has been extensively researched and proven effective for caries prevention and arrest in children. Limited studies support its effectiveness in primary dentition at 38%. This systematic review examines the effectiveness of 38% silver diamine fluoride on control of dental caries in primary dentition. Multiple search engines and databases were searched in accordance with predefined inclusion-exclusion criteria. Quality assessment was done using Centre for Evidence-Based Medicine worksheets. Scientific works of literature were searched in October 2019 for articles. Four studies were identified that addressed the effectiveness of 38% SDF on deciduous dentition in children. All the four studies selected were controlled clinical trials. The cumulative results of the studies showed that 38% SDF application is efficacious and safe for the control of dental caries in primary teeth. Its advantages over different other techniques or placebo have been demonstrated. Based on this systematic review, 38% SDF is one of the best treatment approaches in control of dental caries in primary dentition.

**Nassar Seifo, Mark Robertson, Jeanette MacLean, Katharine Blain, Sarah Grosse, Roderick Milne, Clement Seeballuck and Nicola Innes [2020]<sup>[57]</sup>** studied The use of silver diamine fluoride (SDF) in dental practice. Silver diamine fluoride (SDF) is a clear, odourless liquid indicated for desensitisation of non-cariou tooth lesions and molar incisor hypomineralisation. It is also useful for arresting carious

lesions in adults and children who are high caries-risk and/or have difficult-to-control, progressing carious lesions, those who are unable to tolerate invasive treatment, elderly populations, and those who are medically compromised or have additional care and support needs. SDF may be used to manage lesions that are too extensive to restore but not associated with pain and/or infection. This can be important particularly where extractions might be contra-indicated for medical or behavioural reasons. This paper summarises the global evidence for the effectiveness and safety of SDF, describes what it is, its mechanisms of action and presents recommendations on how to use it. There are details on indications/contra-indications and risks/benefits to be considered in the use of SDF also discussion of how to approach SDF's side effect of black staining of carious tooth tissue.

## **MATERIALS AND METHOD**

The present randomized control study was carried out in the rural schools of municipal city of Maharashtra adopted by the Department of Pedodontics and Preventive Dentistry, for a study period of 9 months to compare the effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish with 38% silver diamine fluoride in arresting caries in children. The study was carried out after obtaining ethical clearance from the institutional ethics committee. Trail was also registered under Clinical trial registry India (CTRI/2020/02/023626). Children with the age range of 3 to 6 years were selected for the study based on the inclusion and exclusion criteria. Parents of the selected child were explained the purpose and methodology of the study in local vernacular language and a signed informed consent was obtained.

## **SAMPLE SIZE**

Statistician consultation was done to calculate the sample size for the study.

The minimum number of subjects based on results of previous studies.

Total samples = 160 teeth ; 80 teeth in each group

Sample size was calculated by using g power 3.1

Using formula 
$$n = \left[ \frac{z_1 \sqrt{2p(1-p)} + z_2 \sqrt{p_1(1-p_1) + p_2(1-p_2)}}{(p_1 - p_2)^2} \right]^2$$

Where,

P1 = probability of variable in sample -1 = 0.285 [ value <1]

P2= probability of variable in sample -2 = 0.5 [value <1]

P = arithmetic average of p1 and p2 = 0.3925

1- $\alpha$  = set level of confidence = 0.95

1- $\beta$  = set level of power of test = 0.8

Z1 = z value associated with set level of alpha = 1.9599

Z2 = z value associated with set level of beta =0.8416

n = minimum sample size =80

## **SAMPLING:**

Screening of all the children in school aged 3-6 years was done from which 80 children were selected for study having following criteria.

**INCLUSION CRITERIA:**

- Healthy children of 3-6 years age.
- Have at least 2 teeth with untreated carious lesions.
- Primary teeth with active carious lesion corresponding to International Caries Detection and Assessment System for caries lesion activity assessment (ICDAS II) code 2-5.

**EXCLUSION CRITERIA:**

- Uncooperative children.
- Children with severe form of hypoplasia of fluorosis.
- Medically compromised

**Materials:**

1. Sterile disposable gloves, mouth mask and head cap [**color plate I (1)**]
2. Diagnostic instrument: Mouth mirror. Probe, Explorer, Tweezer, Cotton holder, Waste receiver [**color plate I(2)**]
3. Suction tips, Sterile cotton rolls, Sterile cotton pellet [**color plate I(2)**]
4. Petroleum jelly [**color plate III**]
5. 25% silver nitrate solution [ **color plate IV**]
6. 5% sodium fluoride varnish [**color plate V**]
7. Silver Diamine Fluoride (Fagamine® Tedequim SRL Argentina [**color plate VI**]

Sr. No.	Instruments, equipment's and materials	Disinfections and sterilization protocol followed
1	Diagnostic instruments including mouth mirror, probe, explorer, tweezers, cotton holder, waste receiver	<p>a) <b>Cleaning</b> : Removal of gross debris by scrubbing them with water and soap</p> <p>b) <b>Disinfection</b> using Korsolex ® Rapid for 20 minutes as per product manual.</p> <p>c) <b>Rinsing</b> using distilled water</p> <p>d) <b>Drying</b>: the instruments were dried using autoclavable towel followed by inspection for cleanliness</p> <p>e) <b>Packing</b>: The instruments were then packed in autoclavable pouches for their sterilization</p> <p>f) <b>Sterilization</b>: By Autoclaving at 121°C at 15 psi pressure for 15 minutes</p>
2	Cotton pellet and cotton rolls	Autoclaved at 121°C at 15 psi pressure for 15 minutes.

### BASELINE EXAMINATION:

Examination of children was carried out and the demographic data of each child was recorded by a single calibrated investigator who selected and treated the subjects.

Rinsing / washing the instrument with distilled water, before drying or packing and sterilization was to remove the mechanical debris. At baseline oral hygiene status of children was recorded using **plaque index (Silness and Loe)**. The buccal and lingual surfaces of 6 index teeth (55, 51, 63, 71, 75, and 83) was examined. The presence or

absence of visible plaque on the caries surface was also be recorded. caries experience was recorded using **International Caries Detection and assessment System criteria II<sup>[58]</sup>** have been used for coronal primary caries detection and was recorded in the customized case record proforma.

The tooth status (decayed, missing, filled surfaces (dmfs) score), tooth discolouration, and hyper-mobility was also be recorded. Teeth with a caries lesion extending into the pulp or signs suggesting that the teeth were nonvital, such as tooth discolouration, hyper-mobility or abscess, was not included in this study. The caries was diagnosed at the cavitation level. **The carious lesion was gently explored with the straight probe in the center of the lesion.** Great care was taken to avoid tooth damage during the probing. A lesion was recorded as active if softness is detected upon gentle probing. If the dentine surface was hard to probing, it was classified as an arrested caries. All surfaces i.e., buccal, lingual, mesial, distal, and occlusal for posterior teeth of each tooth was assessed. Active caries at the baseline that become arrested in the follow-up examinations were used as the main treatment outcome.

A designated experienced outreach dentist was the examiner throughout the 9 months study. The selected children have even number of caries. If children have odd number of caries then that odd one was excluded from study. At baseline and during follow examination caries activity status of children was recorded using International Caries Detection And Assessment System Criteria II code 2-5. It was used for occlusal caries detection and that was recorded in the customized case record proforma. Then the teeth was randomized.

**Recommended training program by ICDAS committee:**

**Theoretical training:** Slide presentation and discussions explaining the ICDAS codes and protocol for examination

**Practical training:** For 2 days, this included examination of a set of subjects providing balanced numbers of tooth surface with ICDAS codes 1-5. The examination findings of all the examiners were reviewed to identify the difference in interpretation. Examination was repeated until agreement is reached among the examiner. This exercise was conducted by a senior examiner.

**Reliability assessment:** carried out using live subjects presenting with carious lesions with severity ranging between 1 and 5 (ICDAS).

**RANDOMIZATION:**

Then the selected children were randomly divided into 2 groups, for randomization convenience sampling technique was used.

Group 1 received topical application of silver nitrate followed by sodium fluoride varnish and

Group 2 received topical application of Silver diamine fluoride

<b>Group</b>	<b>Group 1</b>	<b>Group 2</b>
Treatment plan	Topical application of 25% Silver nitrate followed by 5% sodium fluoride varnish	Topical application of 38% Silver diamine Fluoride

## **PROCEDURE:**

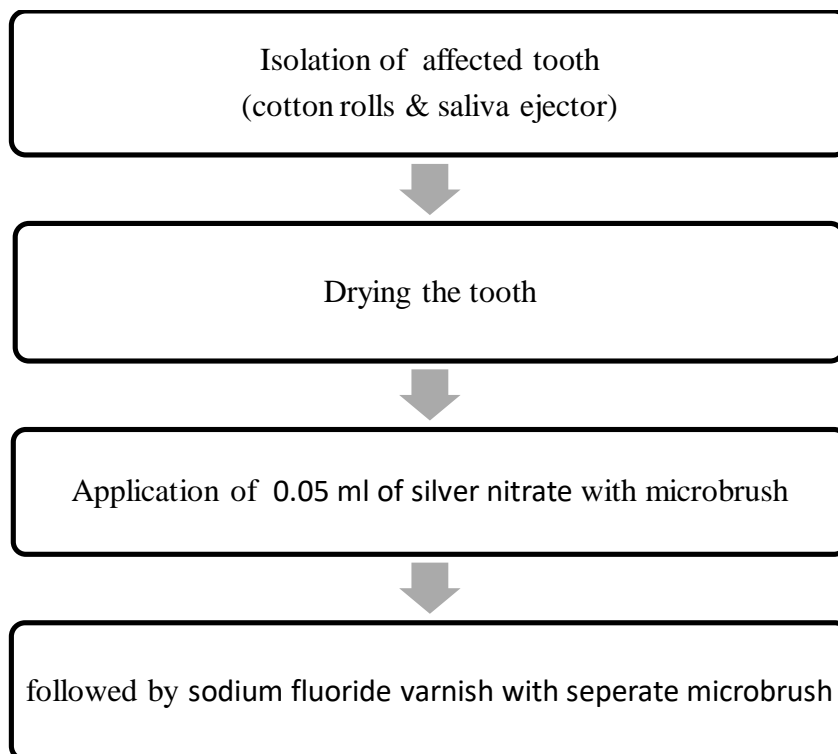
During treatment of caries in both techniques, excavation of caries or removal of unsupported enamel was not done as mentioned by the manufacturer. Cotton rolls and saliva ejector were used to isolate the teeth from saliva in both the techniques.

### **Group 1:**

The children allocated to group 1 were treated with **SN followed by sodium fluoride**. The **SN followed by sodium fluoride** was applied to the affected area as follows:

#### **Steps in application of SN:**

1. The Affected area was isolated with a cotton rolls and saliva ejector
2. Then lesion/tooth surface was dried completely.
3. Small amount of silver nitrate solution was dispensed in a disposable dish
4. Then solution of silver nitrate was applied to the affected teeth using a micro brush
5. Each tooth was received 0.05 ml of silver nitrate measured by micropipette
6. Then sodium fluoride varnish application using separate micro brush.



**Group 2:**

The children allocated to **group 2** received topical application of **38 %silver Diamine fluoride** to the affected carious primary molars. The procedure was carried out as given below:

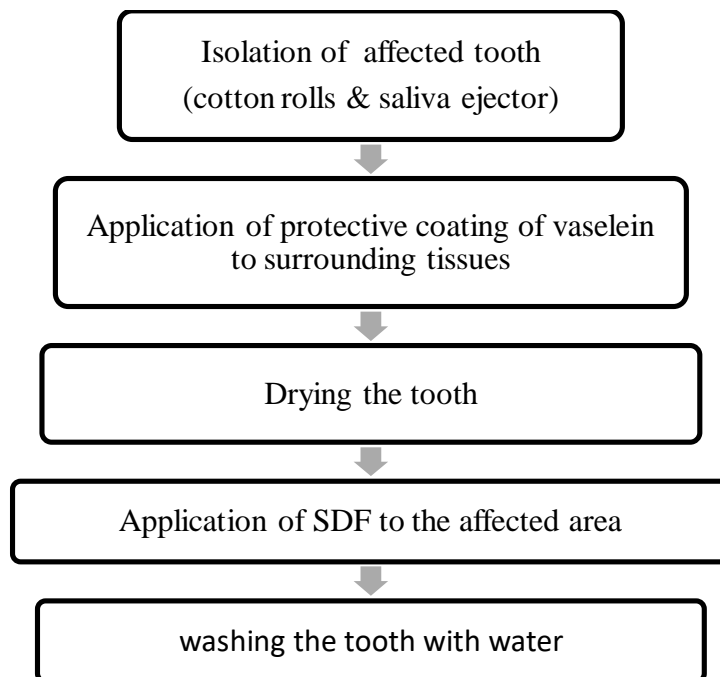
The affected area was isolated with a cotton rolls and saliva ejector. A protective coating of vaseline was applied to the surrounding tissue to prevent temporary staining that can occur if soft tissues come into contact with SDF. During the application of vaseline to surrounding gingival tissues, care was taken, not to coat the surfaces of caries lesions. The tooth surface was then dried with gentle flow of compressed air. Just before starting the procedure, small amount of SDF solution dispensed in a disposable dish, into which disposable micro brush was dipped and dabbed on the side of the plastic dappen dish to remove excess liquid. Then the SDF was applied directly to the affected tooth surface and excess was removed with gauze, cotton roll, or cotton pellet

to minimize systemic absorption. Application time was kept to one minute if possible. (And in very young and difficult to manage patients application time was further reduced). The teeth were then washed with copious amount of water.

Subjects and their parents/guardians from both the groups were given oral hygiene instruction, diet counseling, and instructions on how to floss proximal areas daily.

Because of the nature of the study, the investigator who performed the treatment and the subjects were not blinded to the group. However, the examiners who evaluated were blinded regarding the type of treatment performed in each group.

**Steps in application of SDF:**



**Clinical assessment criteria during follow up visit**

Reapplication of both the material {silver nitrate and silver diamine fluoride} will be done in second and third week after baseline. Follow up will be carried out at 3, 6 and 9 months.

During follow up examination, the teeth were assessed clinically using visual / tactile inspection by a trained blind examiner who was blind to the type of treatment. The **ICDAS II criteria for lesion activity assessment (Table)<sup>[58]</sup>** were used to classify the active and inactive carious lesions in both the groups. The active caries was recorded with a blunt probe that when applied with light force; easily penetrate the dentin, whereas arrested caries was recorded if dentin could not be penetrated. <sup>[59]</sup>

ICDAS Code	Characteristics of lesion	
	Active Lesion	Inactive Lesion
1, 2, 3	Surface of enamel is whitish / yellowish opaque with loss of luster; feels rough when tip of the probe is moved gently across the surface, Lesion is in a plaque stagnation area, i.e. pits and fissure, near the gingival and approximal surface below the contact point.	Surface of enamel is whitish, brownish or black. Enamel may be shiny and feels hard and smooth when the tips of probe are moved gently across the surface. For smooth surfaces. The caries lesion is typically located at some distance from the gingival margin.
4	Probably active	
5 or 6	Cavity feels soft or leathery on gently probing the dentin	Cavity may be shiny and feels hard on gentle probing the dentin

## **FOLLOW UP EXAMINATION:**

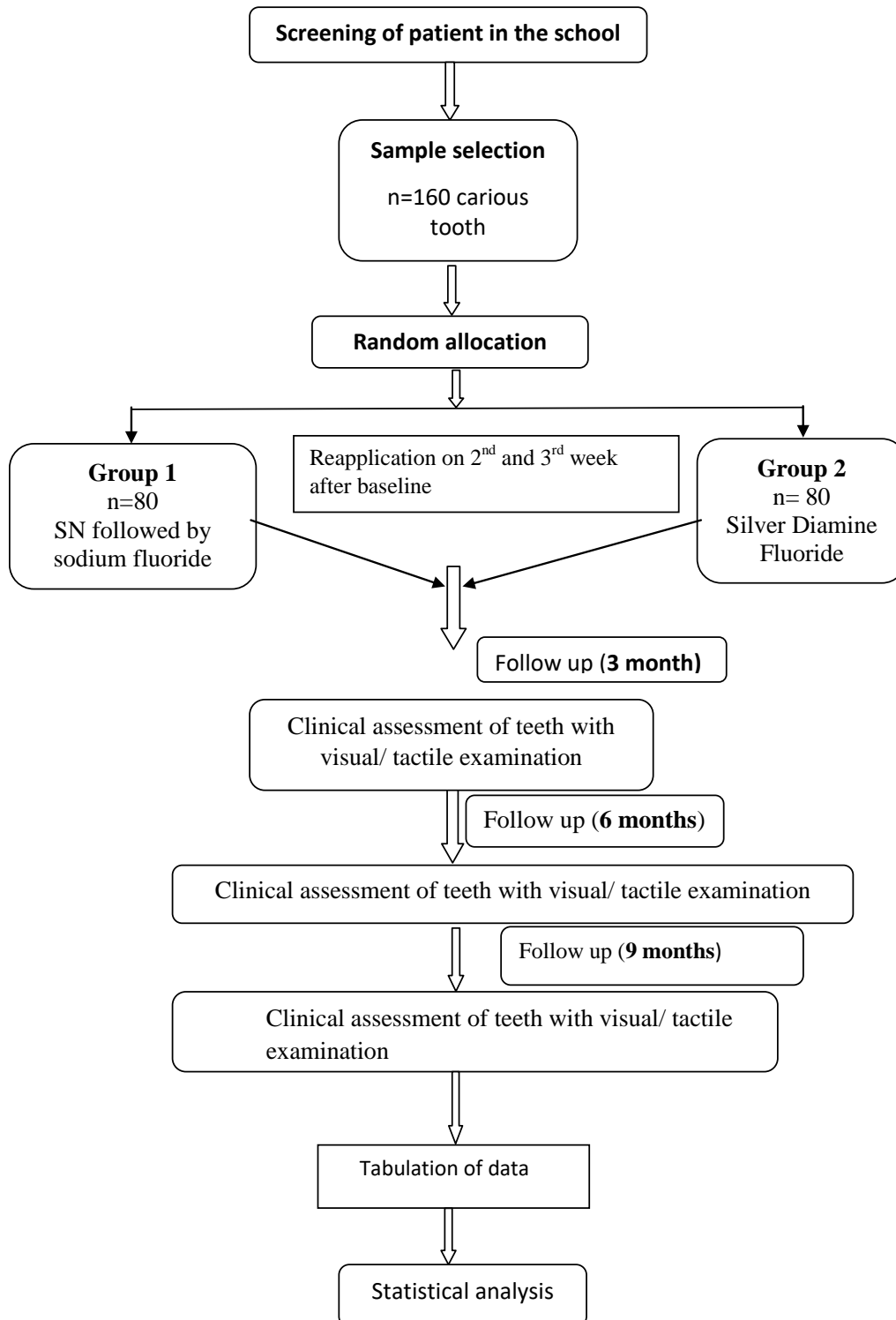
The follow up examination was carried out after three months, six months and nine months.

**3, 6, 9 months follow up visit:** Clinical assessment of teeth using visual/ tactile inspection. The **ICDAS II criteria for lesion activity assessment (Table)** were used to classify the active and inactive carious lesions in both the groups.

The representative clinical photographs of case no 20 from group 1 starting from baseline to follow up (3 month,6 month and 9 month) have been annexed in **color plate VII and VIII.**

The representative clinical photographs of case no 7 from group 2 starting from baseline to follow up (3 month, 6 month and 9 month) have been annexed in **color plate IX and X.**

**Procedures and Protocol:**



**COLOR PLATE I**



**Sterile disposable gloves, head cap and mouth mask**

**COLOR PLATE II**



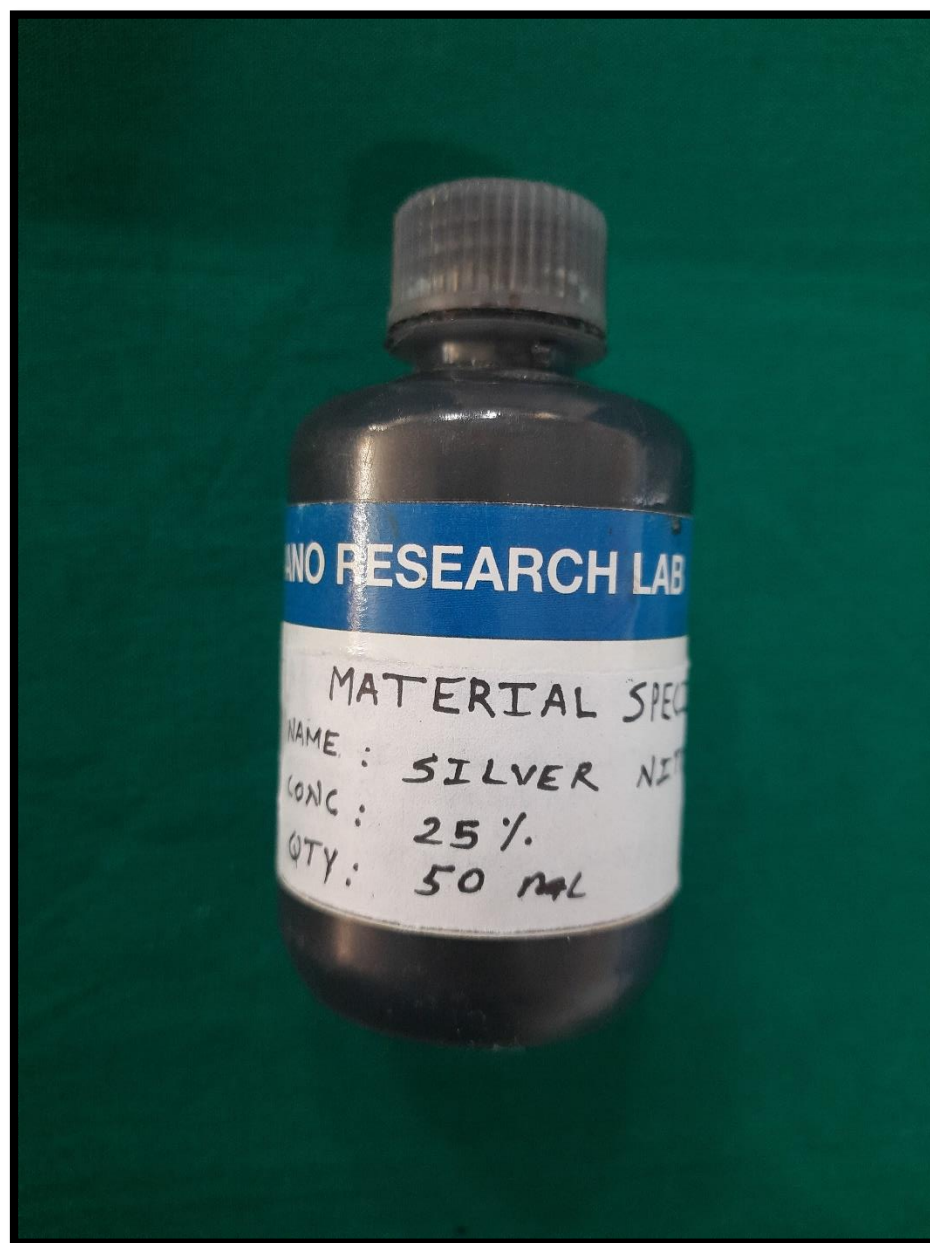
**Diagnostic instrument, cotton holder, waste receiver, suction tip, sterile cotton roll, sterile cotton palette**

**COLOR PLATE III**



**Petroleum jelly , disposable dish and micro brush**

## COLOR PLATE IV



**silver nitrate ( Nano Research Lab Jamshedpur, India)**

**COLOR PLATE V**



**Sodium fluoride**

**COLOR PLATE VI**



silver diamine fluoride (Fagamine® Tedequim SRL Argentina)

**COLOR PLATE VII**

**CLINICAL PHOTOGRAPH FROM CASE NUMBER 20 FROM  
GROUP I**



**Preoperative photograph showing carious lesion with 75**



**1<sup>st</sup> follow up ( after 3 months )**

**COLOR PLATE VIII**



**2<sup>nd</sup> follow up ( after 6 months)**



**3<sup>rd</sup> follow up (after 9 months)**

**COLOR PLATE IX**

**CLINICAL PHOTOGRAPH OF CASE NO 7 FROM GROUP II**



**Preoperative photograph carious lesion with 74**



**1<sup>st</sup> follow up (after 3 months)**

**COLOR PLATE X**



**2<sup>nd</sup> follow up ( after 6 months)**



**3<sup>rd</sup> follow up ( after 9 months)**

## **RESULTS**

Statistical analysis of assessment of effectiveness of 38% silver diamine fluoride vs 25% silver nitrate followed by 5% sodium fluoride varnish among children was carried out to find the significant difference between those values. Analysis of the data was done by using descriptive and inferential statistics both.

Descriptive statistics are used to describe the basic features of the data in a study. They provide simple summaries about the sample and the measures. Together with simple graphics analysis, they form the basis of virtually every quantitative analysis of data.

Descriptive statistics are typically distinguished from inferential statistics. With descriptive statistics are simply describing what is or what the data shows. With inferential statistics, are trying to reach conclusions that extend beyond the immediate data alone. For instance, we use inferential statistics to try to infer from the sample data

what the population might think. Or, we use inferential statistics to make judgments of the probability that an observed difference between groups is a dependable one or one that might have happened by chance in this study. Thus, we use inferential statistics to make inferences from our data to more general conditions; we use descriptive statistics simply to describe what's going on in our data.

The software used in the analysis were SPSS 24.0 and Graph Pad Prism 7.0 version and  $p < 0.05$  is considered as level of significance.

### **The statistical tests used for the analysis of the result were:**

#### **1. Chi square Test**

##### **Inferential Statistics :**

##### **Chi square t test**

Several proportions can be compared using a 2 by k chi-square test. For example, a random sample of people can be subdivided into k age groups and counts made of those individuals with and those without a particular attribute. For this sample, a 2 by k chi-square test could be used to test whether or not age has a statistically significant effect on the attribute studied. This is a test of the independence of the row and column variables, it is equivalent to the chi-square independence tests for 2 by 2 and r by c chi-square tables.

$$\chi^2 = \sum_{i=1}^r \sum_{j=1}^c \frac{(O_{ij} - E_{ij})^2}{E_{ij}}$$

- where, for r rows and c columns of n observations, O is an observed frequency and E is an estimated expected frequency. The expected frequency for any cell is estimated as the row total times the column total then divided by the grand total (n).

The study sample comprised of 80 children, which included 38 male and 42 female children in the age range of 3 to 6 years. The selected children were randomly allocated to group 1 to receive SN application and group 2 to receive SDF application. The duration of study was 9 month. At the end of 9 month follow up, there was no any lose to follow up children as the study was done in school.

Inter and Intra group comparison has been done by using chi square test.

### **Distribution of patients according to age in years**

Each 18.8% of the patients in two groups were 3 years of age, each 28.8% in two groups were of 4 years and 5 years, each 23.8% were of 6 years of age and mean age of the patients of group 1 and group 2 was  $4.57 \pm 1.05$ . [Table I, Graph I]

### **Distribution of patients according to gender**

Each 47.5% of the patients in two group were males and each 52.5% of the patients in two groups were females. [Table 2, Graph 2]

### **Distribution of patients according to ICDAS Code**

ICDAS code 3 was present in each 25% of the patients of two group, code 4 was present in each 35% patients of two groups and code 5 was present in each 40% patients of two groups. [Table 3, Graph 3]

### **Intragroup comparison of lesion activity according to ICDAS code in group 1**

64 Lesion activity according to ICDAS code was inactive from baseline to 3 months in 67.5% patients and active in 32.5% patients of Group 1. By using chi square

test statistically significant difference was found in lesion activity from baseline to 3 months in patients of Group 1 ( $\chi^2=11.52, p=0.0007$ ).

Lesion activity according to ICDAS code was inactive from baseline to 6 months in 82.5% patients and active in 17.5% patients of Group 1. By using chi square test statistically significant difference was found in lesion activity from baseline to 6 months in patients of Group 1 ( $\chi^2=87.12, p=0.0001$ ).

Lesion activity according to ICDAS code was inactive from baseline to 9 months in 90% patients and active in 10% patients of Group 1. By using chi square test statistically significant difference was found in lesion activity from baseline to 9 months in patients of Group 1 ( $\chi^2=128, p=0.0001$ ). [Table 4, Graph 4]

### **Intragroup comparison of lesion activity according to ICDAS code in group 2**

Lesion activity according to ICDAS code was inactive from baseline to 3 months in 73.75% patients and active in 26.25% patients of Group 2. By using chi square test statistically significant difference was found in lesion activity from baseline to 3 months in patients of Group 2 ( $\chi^2=46.08, p=0.0001$ ).

Lesion activity according to ICDAS code was inactive from baseline to 6 months in 87.5% patients and active in 12.5% patients of Group 2. By using chi square test statistically significant difference was found in lesion activity from baseline to 6 months in patients of Group 2 ( $\chi^2=115.5, p=0.0001$ ).

Lesion activity according to ICDAS code was inactive from baseline to 9 months in 95% patients and active in 5% patients of Group 2. By using chi square test

statistically significant difference was found in lesion activity from baseline to 9 months in patients of Group 2 ( $\chi^2=162, p=0.0001$ ). [Table 5, Graph 5]

### **Intergroup comparison of lesion activity according to ICDAS code in two groups**

Lesion activity at 3 months according to ICDAS code was inactive in 67.5% patients of Group 1 and 73.8% patients of Group 2 and active in 32.5% patients of Group 1 and 26.3% patients of Group 2. By using chi square test statistically no significant difference was found in lesion activity in patients of two Groups ( $\chi^2$ -value=0.75, p-value=0.38).

Lesion activity at 6 months according to ICDAS code was inactive in 82.5% patients of Group 1 and 87.5% patients of Group 2 and active in 17.5% patients of Group 1 and 12.5% patients of Group 2. By using chi square test statistically no significant difference was found in lesion activity in patients of two Groups ( $\chi^2$ -value=0.78, p-value=0.37).

Lesion activity at 9 months according to ICDAS code was inactive in 90% patients of Group 1 and 95% patients of Group 2 and active in 10% patients of Group 1 and 5% patients of Group 2. By using chi square test statistically no significant difference was found in lesion activity in patients of two Groups ( $\chi^2$ -value=1.44, p-value=0.22). [Table 6, Graph 6]

## **DISCUSSION**

Dental caries is the oral disease most commonly seen in infant. Carious lesions usually progress more rapidly in primary teeth than in permanent teeth due to the differences in tooth morphology and dietary habits.<sup>[60,61]</sup> Dental caries in primary dentition is known to be the sign of high caries risk in permanent dentition; it is therefore important to identify those children affected with caries and control the development and progression of these lesions in primary dentition. Preschool children are too young to cope with lengthy dental procedures and hence they often receive dental treatment under general anesthesia from pedodontiat. However, treatment under general anesthesia has some of the disadvantages like: 1) depressed protective reflexes 2) depressed vital signs of patients 3) requires special equipment's and 4) poses a life-threatening risk to some young children. Hence, conventional dental care is unaffordable, unapproachable or not available in many communities. <sup>[62]</sup> However, studies shows that the atraumatic restorative treatment has a very good success rate in

treating dentinal caries in young children. Variety of fluoride <sup>[63-66]</sup> and nonfluoride <sup>[67]</sup> based chemotherapeutic agents were developed and tested for their preventive and arresting effect on dental caries.

Many human infections are directly caused by or exacerbated by biofilms.<sup>[18]</sup> Dental caries is a prime example of a biofilm mediated disease. The bacteria responsible for caries produce a complex extra-cellular matrix that can complicate treatment.<sup>[68]</sup> Thus, all potential therapeutics or treatments for caries must be tested against biofilms to ensure that they can penetrate it to eradicate the bacteria within.

Since the 1800s, silver (Ag) has been used in dentistry for its anticaries, antimicrobial properties. In the 1960s, silver was advocated to be combined with fluoride as an anticaries agent presumably for a combined beneficial effect.<sup>[69]</sup> Silver containing materials, such as silver nitrate, Silver diamine fluoride, Nano silver fluoride has been introduced that can arrest caries and prevent future progression of the lesion without the need of caries excavation prior to their application.<sup>[51]</sup> In present study, 38% concentration of SDF was used which contains approximately 253,870 ppm silver and 44,800 ppm fluoride ions.<sup>[51]</sup> Use of high concentration (38%) SDF is recommended due to its higher caries arresting ability. The reason for higher caries arrest rate could be the synergic effect of silver ions and fluoride ions. Silver ions inhibit biofilm growth and fluoride ion enhances mineral formation. Fluor hydroxyapatite is the last product form after SDF application which reduced solubility. They also inhibit collagen enzymes activity helps in reduction of collagen degradation. In addition, the alkaline property of this reagent could alter the microenvironment around the carious lesion in which the enzymes could be inactivated.<sup>[70]</sup>

SDF was approved by the U.S. Food and Drug administration [FDA] in summer 2014 as a desensitizing agent and it became commercially available in the spring of 2015. It has been used off-label as a caries arresting medicament, since 38% SDF promises to outperform fluoride varnish for caries arrest and to become an invaluable tool for caries prevention and management [71,27] with caries lesion arrest rates upwards of 70%.<sup>[72]</sup> **Yee et al (2009)** <sup>[24]</sup>, **Duangthip et al (2018)** <sup>[73]</sup>, **Fung et al (2016, 2018)**<sup>[74,75]</sup> in their study observed that the 38 % is more effective than 12 % in arresting active caries in primary teeth. In a systematic review of **Gao et al. (2016)** <sup>[37]</sup> overall caries arrest rate of 38% SDF was 65.9% which suggest that 38% SDF is capable of efficiently arresting the caries process. However, SDF has the disadvantage of staining dental tissue black due to oxidation process of ionic silver contained in its formulation and slightly painful reversible lesion on oral mucosa caused by unintentional contact of SDF solution, which may disappear within 48 Hours. **Heloisa Branca**<sup>[54]</sup> et.al. in their systematic review they concluded that when SDF compared to no treatment, placebo or FV appears to effectively prevent dental caries in the entire dentition. And another systematic review of **Jabin Zohra et.al. (2020)** <sup>[56]</sup> said that silver diamine fluoride having a concentration of 38% is one of the best treatment approaches in control of dental caries in primary dentition.

The another material used in this study was silver nitrate followed by sodium fluoride varnish which is gaining popularity due to its excellent anti- bacterial and remineralising property (**Gao et al. 2018**).<sup>[17]</sup> This may be the basic mechanisms of the caries-arresting effect of SN. One of the studies in United State used the combined application of 25% silver nitrate solution followed by 5% sodium fluoride varnish as a non-invasive treatment of caries for children.<sup>[16]</sup> In their study more than 5000 children

were treated with this protocol. Their results showed that almost all carious lesions were arrested after treatment. The hardness of the lesion surface is commonly used as a diagnostic criterion for arrested caries which one felt by tactile sensation. (**Braga et al. 2009**).<sup>[76]</sup> Studies revealed an increase in microhardness with a highly remineralized zone rich in calcium and phosphate in the arrested lesions (**Chu and Lo 2008; Mei et al. 2013**).<sup>[23,30,31]</sup> Applying a 25% AgNO<sub>3</sub> solution followed by a 5% NaF varnish follows the same principle for caries arrest. An in vitro study of SN followed by NaF indicated that this method could remineralized inter- and intratubular demineralized dentine and prevent the exposure of collagen fibers on dentine surfaces (**Zhao et al. 2017**).<sup>[40]</sup> A US community dental care program for children reported that this method could arrest active caries in almost all carious lesions (**Duffin 2012**).<sup>[16]</sup> AgNO<sub>3</sub> solution and NaF varnish are readily available in many countries. SN treatment protocols aim to stabilize the carious lesion by arresting caries.

In present study, children in 3- 6year age group having at least 2 active carious lesion on primary molar teeth were selected. The children in 3-6 age groups were included because, these children tend to be less co-operative and they are too young to cope with lengthy dental treatment. Also, conventional restorative treatment is technique sensitive which may be difficult to manage in children with unfavorable behavior. However, studies showed that the atraumatic restorative treatment has a very good success rate in treating dental caries in young children. The 25% SN and 38 % SDF are non- invasive materials which are safe and effective approach to deal with such young patients and hence both these materials were used in this study for arresting active caries in primary molars of children. Active carious lesions were included in this study, which permits proper evaluation of therapeutic effects of these non-invasive

techniques apart from their preventive property. Being Non- invasive technique i.e. without caries excavation **Chu et al (2002)**<sup>[18]</sup> who suggested that excavating the carious tissues before SDF application has no effect on their ability to arrest caries and had no significant beneficial effect. Similar finding was observed in study done by **Chun-Hung Chu [2015]**<sup>[34]</sup>, **Sophia Khan[2017]**<sup>[41]</sup>, **Gao ss et.al. 2019**<sup>[83]</sup> who said that both these materials used were effective in treating caries without caries excavation in apprehensive young children with intense dental fear and obtained good cooperation from young children. Hence in the present study caries excavation was not carried out in both the groups<sup>[53]</sup>. However, only one study by **Fusayama et al (1979)**<sup>[77]</sup> suggested that caries removal prior to fluoride treatment is advantageous because the bacterial load in the caries lesion is reduced. In present study, according to result obtained, it can be suggested that, the use of both 38 % SDF and 25% SN without caries removal in children of 3- 6 year age group has the advantage of being simple and good cooperation from young children has been obtained.

Till date, maximum studies conducted on dental caries had used DMFT(S)/ dmft(s) index to measure the prevalence of caries which allowing the recording of cavitated lesions only. However, the use of WHO's DMF index for caries recording will continue in future because of its worldwide acceptance, convenience and the possibility to compare the past dental data with new one, but also there is need to record non cavitated lesions. Various caries recording criteria have been used in the past based on histological picture, caries activity and descriptors, such as the iceberg diagrams, which described caries as a continuum from enamel, through dentin, to the pulp. The need of an evidence-based system which would permit standardized caries detection and diagnosis in differing environments and situations which leads to the development

of International Caries Detection And Assessment System (ICDAS).<sup>[84]</sup> Thus in the present study for detecting carious lesion and for lesion activity assessment, ICDAS II system was used in this study. The training programme was carried out to assess and record the carious status of child's teeth according to recommended training program by ICDAS committee. It was a 2 day training programme which included theoretical and practical training. Reliability assessment was carried out by examining the 15 patients presenting with carious lesions with severity ranging between 1- 5 (ICDAS) and the caries activity of same patients was also assessed during follow up visits by both the examiner. Second examiner was a senior dentist with experience in using the ICDAS, and has high degree of intra- examiner reliability ( $\alpha = 0.81$ ). Hence, in this study ICDAS II system was found to be effective in predicting the depth of carious lesion correctly as well as in assessing the activity of carious lesions truthfully by using both visual and tactile sensation during probing. **Santos et al (2014)<sup>[79]</sup>, Duangthip et al (2018)<sup>[80]</sup>, Mattos Silveira et al (2014)<sup>[81]</sup>** have successfully used the same criteria for assessment of lesion activity. **Ekstrand et al (2007)<sup>[82]</sup>** also reported the effectiveness of this system in their systematic review.

Second assessor was blinded and there is no to minimal risk of bias because caries excavation was not carried out in any of the group, blackening and hardening of lesion occurred in both the groups. Since all the arrested caries lesions appear similar, the examiner would not be able to guess the group assigned.

In the present study effectiveness of SN and SDF in arresting dental caries in children was compared. Based on the result obtained after 9 months of evaluation of

both the groups, the caries arresting efficacy of SN was comparable to those of SDF in primary molar teeth. Both the groups had almost equal no of active lesions (8 in SN group and 4 in SDF group) at the end of study, the difference was not statistically significant. At the end of 9 month, the follow up of the inactive lesions suggested that arrested caries in SN group were 90% and in SDF group were 95% which were not statistically significant, (p= 0.22). **Gao ss et.al. 2019<sup>[83]</sup>** have reported similar findings to that of the present study using SN and SDF. Overall success rate was slightly higher in SDF group as compared to SN group; however the difference was not statistically significant. **Zhao.IS (2017) <sup>[40]</sup>** conducted an in vitro antimicrobial study and reported that, the use of AgNO<sub>3</sub> solution and NaF varnish is effective in inhibiting dentine demineralization and dentine collagen degradation. They said that Silver Nitrate would be the better alternative to Silver Diamine Fluoride.

In present study, SDF presented good result in arresting active caries in short period of time i.e. 73.25% caries arrested at the 3 months of follow up period and it increased to 87% at 6 month and 95% at 9 month follow up, whereas in SN group only 67.5% of lesions were inactive at 3 month follow up which later increased to 82 % at 6 months and 90% at 9 month. So in present study it was observed that SN took longer time to arrest the caries as compared to SDF. At the end of 9 month follow up, it was observed that the staining caused by SDF application started to fade away in some of the cases. Similar finding was observed in 6 month follow up study done by **Tirupathi et al (2019)<sup>[51]</sup>** for SDF.

No incidence of serious adverse effect/ systemic illness related to SDF and SN application occurred during the whole study period. Hence, both SDF and SN can be

considered safe to be used in children. SDF has the capability to stain gingival tissue adjacent to the lesion which are reversible. A temporary henna-appearing stain was appear when silver nitrate solution comes into contact with skin. The skin pigmentation is temporary and will disappear within one to two weeks because the silver does not penetrate into the dermis. Silver nitrate stains were comparatively lighter than stains of silver diamine fluoride on the tooth surface.[Gao SS]<sup>17</sup> However, in present study gingival staining related to SDF and SN both application was prevented by application of petroleum jelly to the adjacent tissue.

A protocol based on the University of California, San Francisco (UCSF) for the treatment of carious lesions with SDF was designed, which included a one minute long, direct exposure of the compound to the lesion followed by a wash, using saline.<sup>[39]</sup> To equally judge the effectiveness of both AgNO<sub>3</sub> and SDF under similar conditions, they opted to treat each lesion with each silver compound using a similar protocol.

### **Advantages of SN**

1. Silver nitrate application does not require an expensive infrastructure, such as piped water and electricity.
2. Para-dental staff such as dental hygienists and therapists can be trained to provide the treatment under a dentist's supervision.
3. Because of the low cost of the material and relatively short time required, this protocol should be affordable in most communities.
4. Last but not least, this treatment protocol is non-invasive, and the risk of cross-infection is low

### **Limitation of study**

1. The sample size in the present study was limited to 80 patients. A larger sample size would be desirable so as to substantiate the results.
2. Long term analysis is needed to determine the stability of the outcomes and to improve the clinical assessment of the results.

## **SUMMARY AND CONCLUSION**

The present randomized controlled study was undertaken to evaluate and compare the efficacy of silver nitrate [SN] and Silver Diamine Fluoride [SDF] in arresting dental caries in 80 children of aged 3-6 years old. Based on inclusion and exclusion criteria the selected children were randomly allocated into two groups: Group 1- SN; Group 2- SDF group. At baseline, application of both study materials i.e SN and SDF was carried out and follow up examination was undertaken after 3 months, 6 months and 9 months. During follow up visits, the teeth were assessed clinically using ICDAS II criteria for lesion activity by independent examiners. After collection of data the master chart was prepared and sent for statistical analysis.

Results of 9 months study showed that, number of inactive lesions in SDF group were greater as compared to SN group but the difference was not statistically significant.

1. Application of SN does not require complex training of dental health professional similar to SDF.
2. Thus combined application of silver nitrate solution followed by sodium fluoride varnish can be used to arrest dental caries.
3. Application of silver nitrate followed by sodium fluoride is simple, non-invasive, painless, and low-cost. Also it can be a favorable policy for treating dental caries among young children, elderly populations, and people with special needs. Thus silver nitrate could be used as a potential alternative to SDF.

As there are limited studies about 25% silver nitrate followed by 5% sodium fluoride treatment, more randomized clinical trials should be conducted to provide stronger evidence for using silver nitrate solution followed by sodium fluoride varnish as an alternative to 38% silver diamine fluoride.

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## Table and Graphs

**Table 1: Distribution of patients according to age in years**

Age Group(yrs)	Group 1	Group 2	$\chi^2$ -value
3 yrs	15(18.8%)	15(18.8%)	0.00 p=1.00,NS
4 yrs	23(28.8%)	23(28.8%)	
5 yrs	23(28.8%)	23(28.8%)	
6 yrs	19(23.8%)	19(23.8%)	
Total	80(100%)	80(100%)	
Mean $\pm$ SD	4.57 $\pm$ 1.05	4.57 $\pm$ 1.05	
Range	3-6 yrs	3-6 yrs	

**Table 2: Distribution of patients according to gender**

Gender	Group 1	Group 2	$\chi^2$ -value
Male	38(47.5%)	38(47.5%)	0.00 p=1.00,NS
Female	42(52.5%)	42(52.5%)	
Total	80(100%)	80(100%)	

**Table 3: Distribution of patients according to ICDAS Code**

ICDAS Code	Group 1	Group 2	$\chi^2$ -value
3	20(25%)	20(25%)	0.00 p=1.00,NS
4	28(35%)	28(35%)	
5	32(40%)	32(40%)	
Total	80(100%)	80(100%)	
Mean $\pm$ SD	4.15 $\pm$ 0.79	4.15 $\pm$ 0.79	
Range	3-5	3-5	

**Table 4: Intragroup comparison of lesion activity according to ICDAS code in group 1**

Success/Failure	Group 1		$\chi^2$ -value	p-value
	Inactive	Active		
Baseline-3 months	54(67.5%)	26(32.5%)	11.52	0.0007,S
Baseline-6 months	66(82.5%)	14(17.5%)	87.12	0.0001,S
Baseline-9 months	72(90%)	8(10%)	128	0.0001,S

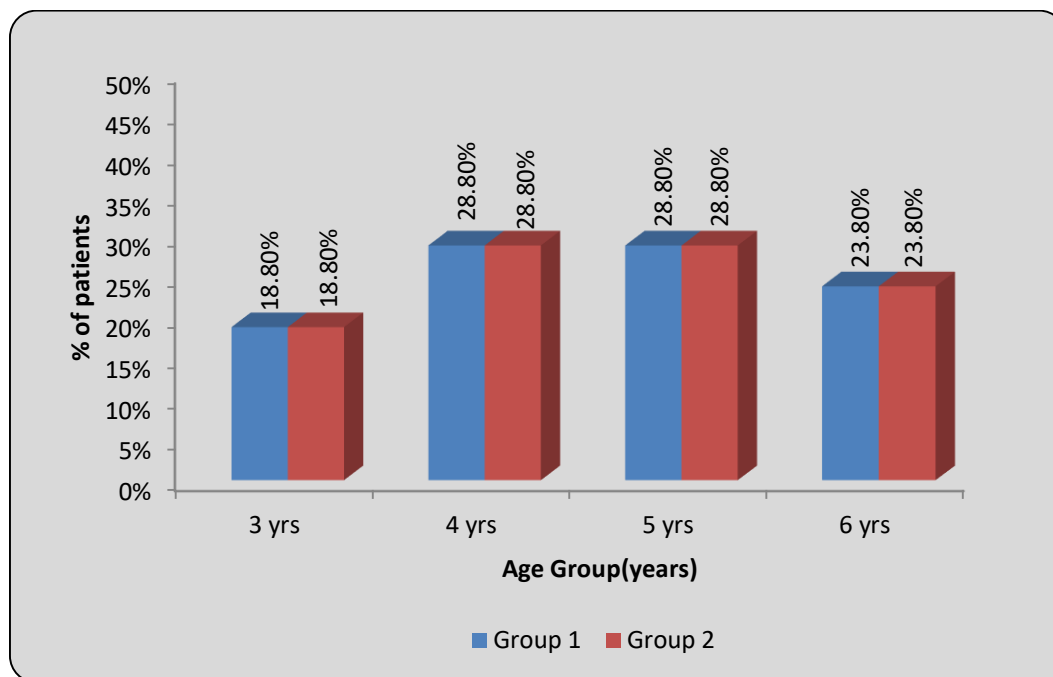
**Table 5: Intragroup comparison of lesion activity according to ICDAS code in group 2**

Success/Failure	Group 2		$\chi^2$ -value	p-value
	Inactive	Active		
Baseline-3 months	59(73.75%)	21(26.25%)	46.08	0.0001,S
Baseline-6 months	70(87.5%)	10(12.5%)	115.5	0.0001,S
Baseline-9 months	76(95%)	4(5%)	162.0	0.0001,S

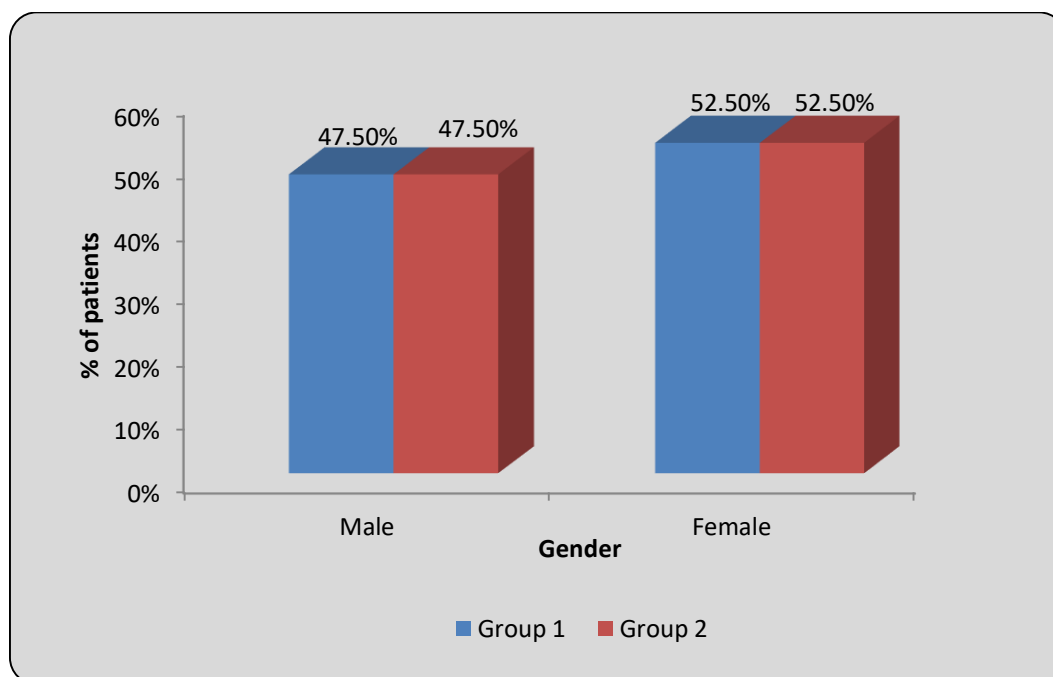
**Table 6: Intergroup comparison of lesion activity according to ICDAS code in two groups**

Months		Group 1	Group 2	X2-value	p-value
3 months	Inactive	54(67.5%)	59(73.8%)	0.75	0.38,NS
	Active	26(32.5%)	21(26.3%)		
6 months	Inactive	66(82.5%)	70(87.5%)	0.78	0.37,NS
	Active	14(17.5%)	10(12.5%)		
9 months	Inactive	72(90%)	76(95%)	1.44	0.22,NS
	Active	8(10%)	4(5%)		

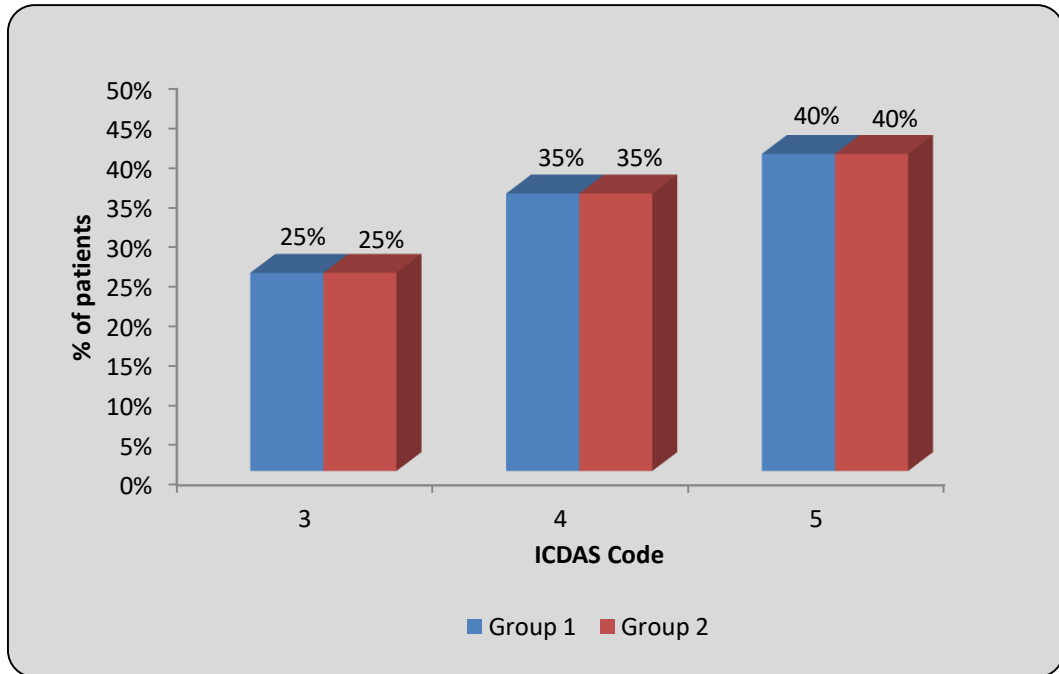
**Graph 1: Distribution of patients according to age in years**



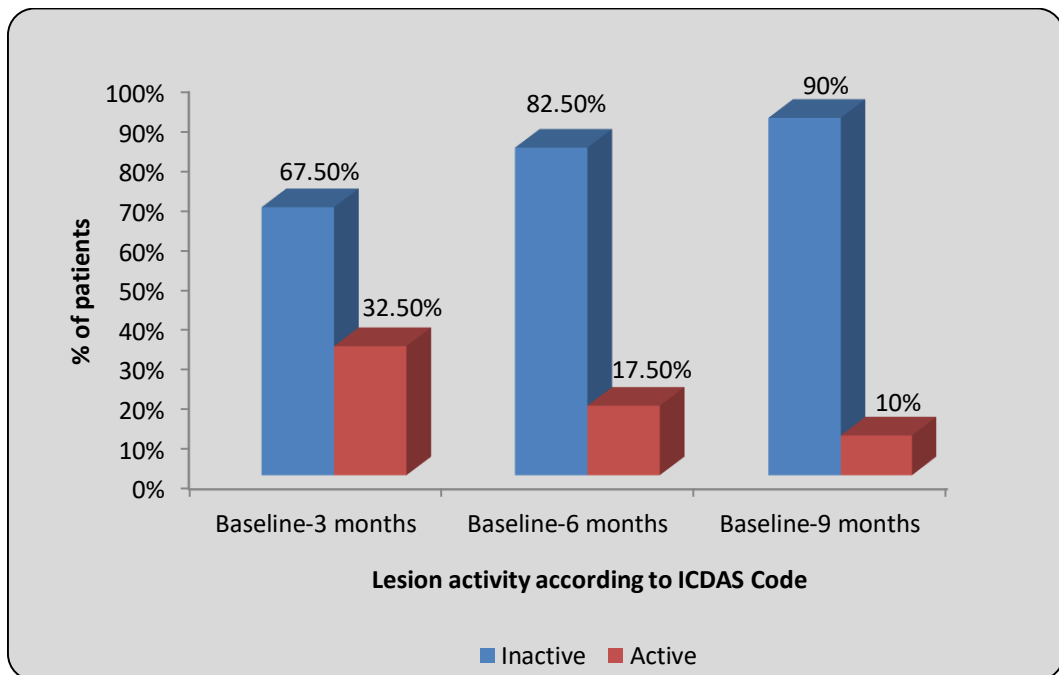
**Graph 2: Distribution of patients according to gender**



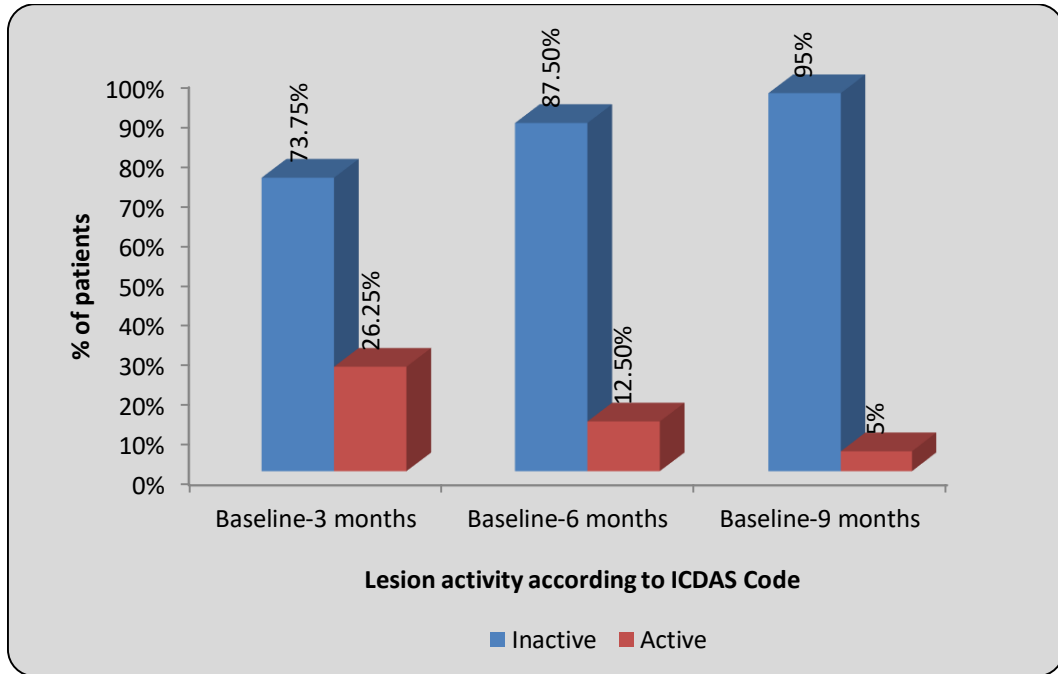
**Graph 3 : Distribution of patients according to ICDAS Code**



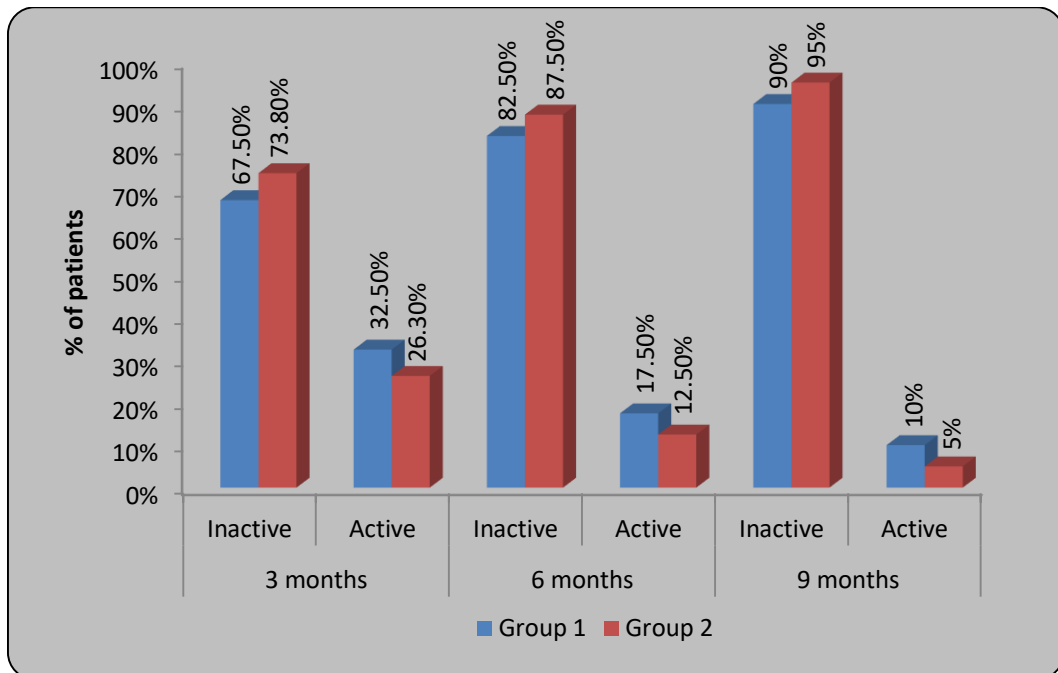
**Graph 4: Intragroup comparison of lesion activity according to ICDAS code in group 1**



**Graph 5 : Intragroup comparison of lesion activity according to ICDAS code in group 2**



**Graph 6: Intergroup comparison of lesion activity according to ICDAS code in two groups**



**Annexure – I**

**Comparison of the effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish with 38% silver diamine fluoride in arresting caries in children - a randomized control study.**

**EXAMINATION PROFORMA/CASE RECORD FORM**

**Date of examination**

Identification No-

Day -

Date -

Group –

Baseline / follow up 3/6/9 -

**General information:**

**Name of child** \_\_\_\_\_

**Gender-**

1=M, 2=F

Day      Month      Year

**Date of Birth-**

Age in years-

**Name and Address of parent:**

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**Contact No. of Parent:** .....

**Chief Complaint:**

**H/O Present illness:**

**Past Medical History:**

**Past Dental History:**

**Frequency of tooth brushing per day:** 1) Once

2) Twice













3) After every meal













**Intra-Oral Examination:**

1. **Teeth present( FDI)** –

2. **Dental caries status** –

- **defs index** –

<b>16</b>	<b>55</b>	<b>54</b>	<b>53</b>	<b>52</b>	<b>51</b>	<b>61</b>	<b>62</b>	<b>63</b>	<b>64</b>	<b>65</b>	<b>26</b>
											

											
<b>46</b>	<b>85</b>	<b>84</b>	<b>83</b>	<b>82</b>	<b>81</b>	<b>71</b>	<b>72</b>	<b>73</b>	<b>74</b>	<b>75</b>	<b>36</b>

**Total score =**

<b>d</b>	<b>E</b>	<b>f</b>	<b>s</b>	<b>Defs # activesurface</b>	<b>d</b>	<b>E</b>	<b>f</b>	<b>s</b>	<b>defs # arrested surface</b>

<b>Primary teeth Crown</b>	<b>Permanent teeth Crown</b>	<b>Status</b>	<b>Treatment</b>
A	0	Sound	0= none
B	1	Decayed	P= Preventive, caries arresting care
C	2	Filled, with decay	F= Fissure sealant
D	3	Filled, no decay	1= One surface filling
E	4	Missing, as a result of caries	2= Two or more surfaces filling
—	5	Missing, any other reason	3= Crown for any reason
F	6	Fissure sealant	4= Veneer or laminate
G	7	Crown	5= Pulp care and restoration
—	8	Unerupted tooth (crown) or exposed root	6= Extraction
			7= Need for other care (specify)

T	T	Trauma (fracture)	8= Need for other care (specify)
—	9	Not recorded	9= not recorded

**Coronal primary caries detection (ICDAS II):**

<b>Tooth</b>	<b>16</b>	<b>55</b>	<b>54</b>	<b>53</b>	<b>52</b>	<b>51</b>	<b>61</b>	<b>62</b>	<b>63</b>	<b>64</b>	<b>65</b>	<b>26</b>
<b>Code</b>												

<b>Tooth</b>	<b>46</b>	<b>85</b>	<b>84</b>	<b>83</b>	<b>82</b>	<b>81</b>	<b>71</b>	<b>72</b>	<b>73</b>	<b>74</b>	<b>75</b>	<b>36</b>
<b>Code</b>												

**Criteria:**

<b>Code</b>	<b>Description</b>
0	Sound
1	First visual change in enamel (seen only after prolonged air drying or restricted to within the confines of pit or fissure)
2	Distinct visual changes in enamel
3	Localized enamel breakdown (without clinical visual signs of dentinal involvement)
4	Underlying dark shadow from dentin
5	Distinct cavity with visible dentin
6	Extensive Distinct cavity with visible dentin

**Activity predictor :**

<b>ICDAS CODE</b>	<b>Active lesion</b>	<b>Inactive lesion</b>
1,2 or 3	Surface of enamel is whitish/ yellowish opaque with loss of luster, feels rough when tip of probe is moved gently across the surface. Lesion is in a plaque stagnation area i.e. pit and fissure , near the gingival and approximal surface below the contact point.	Surface of enamel is whitish , brownish or black. Enamel may be shiny and feel hard and smooth when tip of probe is moved gently across the surface . for smooth surface lesion is typically located at some distance from gingival margin .

4	Probably active	
5 or 6	Cavity feel soft or leathery or gently probing the dentin	Cavity may be shiny and feel hard on gently probing the dentin .

- **Diagnosis**
- **Treatment plan:**

### Coronal primary caries Activity predictor (ICDAS II): follow up – 3 months

<b>Tooth</b>	<b>16</b>	<b>55</b>	<b>54</b>	<b>53</b>	<b>52</b>	<b>51</b>	<b>61</b>	<b>62</b>	<b>63</b>	<b>64</b>	<b>65</b>	<b>26</b>
<b>Code</b>												

<b>Tooth</b>	<b>46</b>	<b>85</b>	<b>84</b>	<b>83</b>	<b>82</b>	<b>81</b>	<b>71</b>	<b>72</b>	<b>73</b>	<b>74</b>	<b>75</b>	<b>36</b>
<b>Code</b>												

ICDAS CODE	Active lesion	Inactive lesion
1,2 or 3	Surface of enamel is whitish/ yellowish opaque with loss of luster, feels rough when tip of probe is moved gently across the surface. Lesion is in a plaque stagnation area i.e. pit and fissure , near the gingival and approximal surface below the contact point.	Surface of enamel is whitish , brownish or black. Enamel may be shiny and feel hard and smooth when tip of probe is moved gently across the surface . for smooth surface lesion is typically located at some distance from gingival margin .
4	Probably active	
5 or 6	Cavity feel soft or leathery or gently probing the dentin	Cavity may be shiny and feel hard on gently probing the dentin .

### Coronal primary caries Activity predictor (ICDAS II): follow up – 6 months

<b>Tooth</b>	<b>16</b>	<b>55</b>	<b>54</b>	<b>53</b>	<b>52</b>	<b>51</b>	<b>61</b>	<b>62</b>	<b>63</b>	<b>64</b>	<b>65</b>	<b>26</b>
<b>Code</b>												

<b>Tooth</b>	<b>46</b>	<b>85</b>	<b>84</b>	<b>83</b>	<b>82</b>	<b>81</b>	<b>71</b>	<b>72</b>	<b>73</b>	<b>74</b>	<b>75</b>	<b>36</b>
<b>Code</b>												

ICDAS CODE	Active lesion	Inactive lesion
1,2 or 3	Surface of enamel is whitish/ yellowish opaque with loss of luster, feels rough when tip of probe is moved gently across the surface. Lesion is in a plaque stagnation area i.e. pit and fissure , near the gingival and approximal surface below the contact point.	Surface of enamel is whitish , brownish or black. Enamel may be shiny and feel hard and smooth when tip of probe is moved gently across the surface . for smooth surface lesion is typically located at some distance from gingival margin .
4	Probably active	
5 or 6	Cavity feel soft or leathery or gently probing the dentin	Cavity may be shiny and feel hard on gently probing the dentin .

### Coronal primary caries Activity predictor (ICDAS II): follow up – 9 months

<b>Tooth</b>	<b>16</b>	<b>55</b>	<b>54</b>	<b>53</b>	<b>52</b>	<b>51</b>	<b>61</b>	<b>62</b>	<b>63</b>	<b>64</b>	<b>65</b>	<b>26</b>
<b>Code</b>												

<b>Tooth</b>	<b>46</b>	<b>85</b>	<b>84</b>	<b>83</b>	<b>82</b>	<b>81</b>	<b>71</b>	<b>72</b>	<b>73</b>	<b>74</b>	<b>75</b>	<b>36</b>
<b>Code</b>												

ICDAS CODE	Active lesion	Inactive lesion
1,2 or 3	Surface of enamel is whitish/ yellowish opaque with loss of luster, feels rough when tip of probe is moved gently across the surface. Lesion is in a plaque stagnation area i.e. pit and fissure , near the gingival and approximal surface below the contact point.	Surface of enamel is whitish , brownish or black. Enamel may be shiny and feel hard and smooth when tip of probe is moved gently across the surface . for smooth surface lesion is typically located at some distance from gingival margin .
4	Probably active	
5 or 6	Cavity feel soft or leathery or gently probing the dentin	Cavity may be shiny and feel hard on gently probing the dentin .

### Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

I acknowledge the “Specially designed proforma”, and also the doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to let my child’s oral examination to be taken as required. I agree to take part in this project. I shall co-operate with the doctors, in all respects. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation. I have been informed of my right to opt out of this research project at any time without giving any reason for doing so. I hereby record my consent for participation in the said project.

.....  
Parent’s/guardian’s name                      Signature/thumbprint                      Date                      Time

.....  
Investigator’s name                      Signature                      Date                      Time

If illiterate a literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

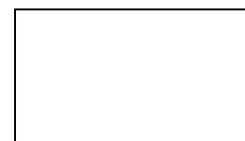
Name of witness \_\_\_\_\_

Thumb print of participant

Signature of witness \_\_\_\_\_

Date \_\_\_\_\_

Day/month/year



**Statement by the researcher/person taking consent**

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

**“Comparision of the effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish with 38% silver diamine fluoride in arresting caries in children - a randomized control study.”**

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of Researcher/person taking the consent\_\_\_\_\_

Signature of Researcher /person taking the consent\_\_\_\_\_

Date \_\_\_\_\_

Day/month/year

**(Confidential)**  
**Informed Consent Form**

**“Comparision of the effectiveness of 25% silver nitrate followed by 5% sodium fluoride varnish with 38% silver diamine fluoride in arresting caries in children - a randomized control study.”**

Mr./Master/Mrs./Miss. \_\_\_\_\_

Resident of: \_\_\_\_\_

\_\_\_\_\_ aged \_\_\_\_\_

years,

Exercising my free will/choice, without any pressure/lure of incentive in any form, hereby give my consent for the project to be conducted by -----.

I acknowledge the receipt of “patient’s information sheet”, and also that the doctor has informed me about this research project suitably and sufficiently to my satisfaction. I agree to take part in this project and will not mix any other projects during the period of this trial. I permit to publishing the results of my participation in this study. I shall not be given any reimbursement or compensation.I hereby record my consent for participation in the said questionnaire.

_____	_____	_____	_____
Patient’s name	Signature/thumbprint	Date	Time

_____	_____	_____	_____
Principal	Investigator Signature	Date	Time

**GROUP 1- SN**

General Examination			Preoperative		Postoperative		
ID number	Gender	Age	Tooth number	ICDAS Code	1st Follow Up	2nd Follow Up	3rd Follow Up
					ICDAS Code	ICDAS Code	ICDAS Code
1	F	3	54	5	Inactive	Inactive	Inactive
2	F	3	64	5	Active	Active	Active
3	F	4	55	4	Inactive	Inactive	Inactive
4	M	5	75	3	Active	Active	Inactive
5	F	6	85	5	Inactive	Inactive	Inactive
6	M	3	65	5	Active	Inactive	Inactive
7	M	4	85	5	Inactive	Inactive	Inactive
8	F	5	84	4	Inactive	Inactive	Inactive
9	M	5	74	3	Inactive	Inactive	Inactive
10	F	5	75	4	Inactive	Inactive	Inactive
11	M	6	65	4	Inactive	Inactive	Inactive
12	F	3	65	4	Inactive	Inactive	Inactive
13	M	6	85	3	Inactive	Inactive	Inactive
14	F	3	85	3	Inactive	Inactive	Inactive
15	F	6	84	5	Active	Inactive	Inactive
16	F	4	74	5	Active	Active	Active
17	M	5	75	5	Inactive	Inactive	Inactive
18	M	6	55	4	Inactive	Inactive	Inactive
19	M	5	54	3	Inactive	Inactive	Inactive
20	F	5	55	5	Inactive	Inactive	Inactive
21	M	5	54	4	Active	Inactive	Inactive
22	F	6	64	4	Active	Inactive	Inactive
23	M	6	84	4	Active	Inactive	Inactive
24	F	6	75	4	Active	Inactive	Inactive
25	F	4	65	4	Active	Inactive	Inactive
26	F	3	84	5	Active	Active	Inactive
27	F	4	55	3	Active	Active	Active
28	M	3	65	5	Inactive	Inactive	Inactive
29	M	3	54	5	Inactive	Inactive	Inactive
30	M	5	55	5	Inactive	Inactive	Inactive
31	M	5	65	3	Active	Active	Inactive
32	F	4	85	3	Inactive	Inactive	Inactive
33	F	4	84	4	Inactive	Inactive	Inactive
34	M	4	75	5	Active	Inactive	Inactive
35	M	4	74	4	Inactive	Inactive	Inactive
36	F	4	74	4	Active	Active	Active
37	M	6	75	4	Inactive	Inactive	Inactive
38	F	6	85	4	Active	Active	Inactive
39	M	5	84	5	Inactive	Inactive	Inactive
40	F	4	84	5	Inactive	Inactive	Inactive
41	M	4	85	5	Inactive	Inactive	Inactive
42	F	3	85	5	Inactive	Inactive	Inactive
43	M	3	75	3	Inactive	Inactive	Inactive
44	F	3	75	5	Inactive	Inactive	Inactive
45	M	6	74	3	Inactive	Inactive	Inactive
46	F	5	74	4	Inactive	Inactive	Inactive

47	M	4	65	5	Inactive	Inactive	Inactive
48	F	6	84	3	Active	Inactive	Inactive
49	F	5	85	4	Active	Active	Active
50	F	4	65	5	Inactive	Inactive	Inactive
51	F	4	64	5	Inactive	Inactive	Inactive
52	F	4	54	5	Inactive	Inactive	Inactive
53	M	5	55	5	Inactive	Inactive	Inactive
54	M	5	65	3	Inactive	Inactive	Inactive
55	M	6	64	4	Inactive	Inactive	Inactive
56	F	5	65	3	Inactive	Inactive	Inactive
57	F	4	85	3	Inactive	Inactive	Inactive
58	M	4	75	3	Active	Active	Inactive
59	M	5	85	4	Inactive	Inactive	Inactive
60	F	6	75	5	Active	Active	Active
61	M	5	85	3	Inactive	Inactive	Inactive
62	M	4	75	4	Active	Active	Active
63	F	5	85	5	Active	Inactive	Inactive
64	F	6	84	4	Inactive	Inactive	Inactive
65	M	4	75	4	Inactive	Inactive	Inactive
66	M	5	74	4	Inactive	Inactive	Inactive
67	M	6	75	4	Inactive	Inactive	Inactive
68	F	5	74	5	Inactive	Inactive	Inactive
69	F	4	85	5	Inactive	Inactive	Inactive
70	F	6	64	4	Inactive	Inactive	Inactive
71	F	3	64	5	Active	Inactive	Inactive
72	M	3	65	4	Active	Active	Active
73	F	5	55	5	Inactive	Inactive	Inactive
74	M	3	84	3	Inactive	Inactive	Inactive
75	F	4	55	5	Inactive	Inactive	Inactive
76	M	6	54	3	Inactive	Inactive	Inactive
77	F	5	65	3	Inactive	Inactive	Inactive
78	M	6	65	3	Active	Inactive	Inactive
79	F	4	55	5	Inactive	Inactive	Inactive
80	M	3	85	4	Active	Active	Inactive

GROUP 2- SDF							
General Examination			Preoperative		Postoperative		
ID number	Gender	Age	Tooth number	ICDAS Code	1st Follow Up	2nd Follow Up	3rd Follow Up
					ICDAS Code	ICDAS Code	ICDAS Code
1	F	3	64	5	Inactive	Inactive	Inactive
2	F	3	54	5	Active	Active	Active
3	F	4	65	4	Inactive	Inactive	Inactive
4	M	5	85	3	Active	Active	Inactive
5	F	6	75	5	Inactive	Inactive	Inactive
6	M	3	55	5	Active	Inactive	Inactive
7	M	4	75	5	Inactive	Inactive	Inactive
8	F	5	74	4	Inactive	Inactive	Inactive
9	M	5	64	3	Inactive	Inactive	Inactive
10	F	5	85	4	Inactive	Inactive	Inactive
11	M	6	55	4	Inactive	Inactive	Inactive
12	F	3	85	4	Inactive	Inactive	Inactive
13	M	6	55	3	Inactive	Inactive	Inactive
14	F	3	75	3	Inactive	Inactive	Inactive
15	F	6	64	5	Inactive	Inactive	Inactive
16	F	4	64	5	Active	Active	Active
17	M	5	85	5	Inactive	Inactive	Inactive
18	M	6	75	4	Inactive	Inactive	Inactive
19	M	5	64	3	Inactive	Inactive	Inactive
20	F	5	85	5	Inactive	Inactive	Inactive
21	M	5	64	4	Active	Inactive	Inactive
22	F	6	74	4	Active	Inactive	Inactive
23	M	6	54	4	Inactive	Inactive	Inactive
24	F	6	65	4	Inactive	Inactive	Inactive
25	F	4	55	4	Active	Inactive	Inactive
26	F	3	74	5	Active	Inactive	Inactive
27	F	4	65	3	Active	Active	Active
28	M	3	55	5	Inactive	Inactive	Inactive
29	M	3	55	5	Inactive	Inactive	Inactive
30	M	5	65	5	Inactive	Inactive	Inactive
31	M	5	75	3	Inactive	Inactive	Inactive
32	F	4	65	3	Inactive	Inactive	Inactive
33	F	4	54	4	Inactive	Inactive	Inactive
34	M	4	85	5	Active	Inactive	Inactive
35	M	4	64	4	Inactive	Inactive	Inactive
36	F	4	84	4	Active	Active	Inactive
37	M	6	65	4	Inactive	Inactive	Inactive
38	F	6	75	4	Active	Active	Inactive
39	M	5	64	5	Inactive	Inactive	Inactive
40	F	4	54	5	Inactive	Inactive	Inactive
41	M	4	65	5	Inactive	Inactive	Inactive
42	F	3	75	5	Inactive	Inactive	Inactive
43	M	3	85	3	Inactive	Inactive	Inactive
44	F	3	65	5	Inactive	Inactive	Inactive
45	M	6	54	3	Inactive	Inactive	Inactive
46	F	5	54	4	Inactive	Inactive	Inactive

47	M	4	75	5	Inactive	Inactive	Inactive
48	F	6	64	3	Active	Inactive	Inactive
49	F	5	75	4	Active	Inactive	Inactive
50	F	4	55	5	Inactive	Inactive	Inactive
51	F	4	74	5	Inactive	Inactive	Inactive
52	F	4	64	5	Inactive	Inactive	Inactive
53	M	5	75	5	Inactive	Inactive	Inactive
54	M	5	55	3	Inactive	Inactive	Inactive
55	M	6	74	4	Inactive	Inactive	Inactive
56	F	5	55	3	Inactive	Inactive	Inactive
57	F	4	75	3	Inactive	Inactive	Inactive
58	M	4	55	3	Active	Active	Inactive
59	M	5	65	4	Inactive	Inactive	Inactive
60	F	6	85	5	Active	Active	Active
61	M	5	75	3	Inactive	Inactive	Inactive
62	M	4	65	4	Active	Active	Inactive
63	F	5	65	5	Inactive	Inactive	Inactive
64	F	6	54	4	Inactive	Inactive	Inactive
65	M	4	85	4	Inactive	Inactive	Inactive
66	M	5	64	4	Inactive	Inactive	Inactive
67	M	6	55	4	Inactive	Inactive	Inactive
68	F	5	54	5	Inactive	Inactive	Inactive
69	F	4	54	5	Inactive	Inactive	Inactive
70	F	6	74	4	Inactive	Inactive	Inactive
71	F	3	54	5	Active	Inactive	Inactive
72	M	3	55	4	Active	Inactive	Inactive
73	F	5	75	5	Inactive	Inactive	Inactive
74	M	3	74	3	Inactive	Inactive	Inactive
75	F	4	65	5	Inactive	Inactive	Inactive
76	M	6	64	3	Inactive	Inactive	Inactive
77	F	5	85	3	Inactive	Inactive	Inactive
78	M	6	85	3	Active	Inactive	Inactive
79	F	4	65	5	Inactive	Inactive	Inactive
80	M	3	75	4	Active	Active	Inactive