"COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE"

DISSERTATION

Submitted to

BABU BANARASI DAS UNIVERSITY,

LUCKNOW, UTTAR PRADESH

In the partial fulfillment of the requirements for the degree

of

MASTER OF DENTAL SURGERY

In

PEDIATRIC & PREVENTIVE DENTISTRY

By

Dr. NEEDHI SINGH

Under the guidance of

Dr. MONIKA RATHORE

PROFESSOR & HEAD

Department of Pediatric & Preventive Dentistry

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES, LUCKNOW

YEAR OF SUBMISSION: 2023

BATCH: 2020-2023 **Enrollment No.:12003270337**

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I hereby declare that this dissertation entitled " **COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE** " is a bonafide and genuine research work carried out by me under the guidance of **Dr. MONIKA RATHORE,** Professor & Head, Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences and **Dr. RAJIV GUPTA,** Dean, College of Pharmacy as Co-Guide in Department, BabuBanarasi Das University, Lucknow, Uttar Pradesh.

Date: 22/2/23

Place: Lucknow

Needhi

Dr. NEEDHI SINGH

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Date:

Dr. MONIKA RATHORE
Professor & Head
Department of Pediatric and
Preventive Dentristry.
BBDCODS, BBDU
Lucknow

CERTIFICATE BY THE CO-GUIDE

This is to certify that the dissertation entitled " **COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE** " is a bonafide work done by **Dr. NEEDHI SINGH** under the supervision of **Dr. RAJIV GUPTA** as Co-Guide, Dean, College of Pharmacy, Babu Banarasi Das University, Lucknow, Uttar Pradesh.

22.02.2023

Dr. RAJIV GUPTA

Dean,

College of Pharmacy,

BBDU

Lucknow

ENDORSEMENT BY THE HOD

This is to certify that the dissertation entitled **"COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE "**is a bonafide work done by **Dr. NEEDHI SINGH** under the supervision of **Dr. MONIKA RATHORE**, Professor & Head, Department of Pedaitric and Preventive Dentistry, BabuBanarasi Das College Of Dental Sciences, BabuBanarasi Das University, Lucknow, Uttar Pradesh.

Dr. MONIKA RATHORE

Professor & Head

Department of Pediatric and

Preventive Dentistry,

BBDCODS, BBDU

Lucknow

ENDORSEMENT BY THE HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE "**is a bonafide work done by **Dr. NEEDHI SINGH** under the supervision of **Dr. MONIKA RATHORE**, Professor & Head, Department of Pedaitric and Preventive Dentistry, BabuBanarasi Das College Of Dental Sciences, BabuBanarasi Das University, Lucknow, Uttar Pradesh.

Dr. PUNEET AHUJA
Principal
BBDCODS, BBDU
Lucknow

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Dr. NEEDHI SINGH

ACKNOWLEDGEMENT

First and foremost I would like to bow before the **Almighty** for his grace, spiritual guidance and showering blessing on me with his bountiful nature and giving me the opportunity to undertake this work and the strength and ability for its successful completion.

I would like to thank my guide, **Dr. Monika Rathore**, M.D.S. Head of Department, Department of Pediatric and Preventive Dentistry, BBDCODS, BBDU. Without her assistance and dedicated involvement in every step throughout the process, this paper would have never been accomplished. I would like to thank you very much for your support and understanding at every step.

It has been a privilege and honor to work under the guidance and sharp vigil of my respected teacher **Dr. Neerja Singh,** M.D.S. Professor, Department of Pediatric and Preventive Dentistry, BBDCODS, BBDU whose unfailing support was invaluable to me.

I would like to pay sincere thanks to my teachers **Dr. Subash Singh,** M.D.S. Reader, and **Dr. Somya Govil**, M.D.S Reader being my support system. Their zeal for perfection, passion, unflinching courage and conviction has always inspired me to do more.

I would like to pay sincere thanks to my teachers **Dr. Mansi Semwal** ,M.D.S, Reader**, Dr. Monisha Moses**, M.D.S, Senior Lecturer, **Dr. Anu Bhatt,** M.D.S, Senior Lecturer, **Dr. Sharlin Ahmad,** M.D.S. Senior Lecturer and **Dr. Khyati Kaushal**, M.D.S, Senior Lecturer for their insightful comments and suggestions.

I must also thank my colleagues at the Department **Dr. Raunaq**, **Dr. Akash, Dr. Bibhav** and **Dr. Saheli** for giving me the retreat to have this dissertation rushed to the printer.

I express my heartfelt thanks to my seniors **Dr. Shama**, **Dr. Ritika**, **Dr. Malika**, **Dr. Vishaka** and **Dr. Madina** you deserve endless gratitude for your endless support. They always stood beside me and always answered my call whenever I needed them and this was no expectation.

For many memorable evenings out and in, I must thank everyone above as well as my juniors **Dr. Ajay**, **Dr. Ayushi, Dr. Sarwani**, **Dr. Sadia**, and **Dr. Ninapyari**.

Getting through my dissertation required more than academic support, and I have many, many people to thank for listening to and, at times, having to tolerate me over the past three years. I cannot begin to express my gratitude and appreciation for their friendship. **Dr. Snigdha**, **Dr. Aishwariya**, **Dr. Charu** and **Dr. Rimjhim**, have been unwavering in their personal and professional support during the time I spent in Lucknow.

Most importantly, none of this could have happened without my family. **Papa**, **Maa**, **Dr. Shashank** and my **In-laws**, you all offered me encouragement through phone calls– despite my own limited devotion to correspondence. To my brother, **Karan**– it would be an understatement to say that, as a family, we have experienced some ups and downs in the past three years. Every time I was ready to quit, he did not let me and I am forever grateful. This dissertation stands as a testament to his unconditional love and encouragement.

I would like to express my gratitude to **Dr Ashish** who helped me with all statistical analysis work, and non-teaching staff **Mr Inderpal** and **Mr. Vaibhav** for their help. My appreciation goes to each and every person who have directly or indirectly helped me during my dissertation in any form.

-Dr. Needhi Singh

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ABSTRACT

Background: Dental caries is considered to be a concern for public health, while being largely preventable, it remains to be one of the most common chronic disease impacting people globally. Conventional restoration for ECC in young children is challenging because of their uncooperative behavior. Silver fluoride treatment is viewed as the first step in slowing down the caries progression in a population where it is very severe. Silver diamine fluoride has an intense antibacterial effect on cariogenic bacteria and can inhibit the growth of multi-species cariogenic biofilms on tooth surface. The most prominent and lasting side effect has been the characteristic irreversible black staining of teeth after silver diamine fluoride application. The application of a layer potassium iodide (KI) over silver diamine fluoride forms a yellow silver iodide precipitate and prevents black staining of teeth.

Aim: To determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children.

Materials and Methods: The present split mouth randomised control trial was conducted in 24 subjects were randomly divided into equal half in two groups Group I (SDF) and Group II (SDF+KI). The study was conducted to evaluated and compare the efficacy of silver diamine fluoride with and without potassium iodide. 38% silver diamine fluoride with and without potassium iodide was applied on the tooth surface after which the tooth was restored with resin modified glass ionomer cement. Color assessment of the restored surface was done at different time interval. To determine the efficacy of silver diamine fluoride with and without potassium iodide CFU count was done of the carious surface prior the application and immediately after the application.

Results: A statistical significant difference in color assessment (<0.001) was noted in both groups at different time interval, CFU count comparison between the two groups was statistically significant (<0.001) at different time interval. The intergroup comparison between both the group in terms of feeding practice and frequency was non-significant (p=1.00). The intergroup comparison between both the group in terms of oral hygine practice and tooth brushing frequency was non-significant (p=1.00) at different

time interval. The intergroup comparison between both the group for sugar and snacks consumption was non-significant (p=1.00) at different time interval.

Conclusion: Silver diamine fluoride with and without potassium iodide was equally effective in arresting the progression of carious lesion. Potassium iodide solution was effective in reducing black discoloration produced by silver diamine fluoride on the infected dentinal surface. The application of potassium iodide enhanced the antimicrobial activity of silver diamine fluoride.

INTRODUCTION

Early childhood caries (ECC) is the single most common chronic childhood disease, and its progress is a global health problem.[1] ECC is defined as the presence of one or more decayed, missing, or filled tooth surfaces in any primary tooth in a child at 71 months of age or younger.[2] Early childhood caries is caused by a variety of factors, major factor is a time-specific interaction between microbes and carbohydrates on a tooth surface.[3] Diet and feeding habits are crucial in the development of caries and the spread of infection.[4,5]

Dental caries flourish due to the presence of various microorganism in plaque. Hence daily plaque removal by brushing, flossing, and rinsing is recommended to reduce dental caries and periodontal disease.[6] Fluoride helps to promote remineralization and inhibit demineralization of the crystaline structures inside of tooth, which together is the primary caretaker to prevent dental cavities.[7] In order to reduce children dental caries, the International Association of Pediatric Dentistry (IAPD) recommends brushing at least twice a day with fluoride toothpaste that contains at least 1000 ppm F.

The mother, who is often a child's primary caretaker, she may transmit on caries-causing microorganisms to a child, which may lead to M. streptococcus colonisation in the child's oral cavity.[8] Emphasis should be laid on prediction of dental caries and caries risk analysis rather than detection of dental caries that needs to be restored.

A mixture of ammonia and silver ions with fluoride is known as silver diamine fluoride (SDF). SDF is a liquid agent consisting of 24.4%–28.8% silver and 5.0–5.9% fluoride.[9] 38% SDF can reduce the rate of dentine and enamel demineralization and prevent the spread of common cariogenic bacteria.[10,11] Silver diamine fluoride protects collagen in demineralized dentin from degeneration.

Fluoride and silver ions are released when fluoride and silver mix in an ammonia solution. Silver is a bacterial inhibitor. Silver kills germs by several mechanisms, making it difficult for bacteria to acquire resistance to it.[12] The bacterial enzyme glycosyltransferase is similarly rendered inactive by silver, preventing the development of biofilm. Bacterial adherence and the thickness of biofilms on tooth surfaces are caused by the glucan that is produced by glycosyltransferases. Additionally, silver stops collagenases from degrading dentine collagen by inhibiting their proteolytic activity. The addition of silver to hydroxyapatite results in the formation of silver-containing hydroxyapatite in enamel and dentine, which also lessens bacterial adherence.[13,14] As a remineralization agent, fluoride is widely recognised. By exchanging fluoride ions for hydroxyl ions and/or growing crystals of fluorapatite from saliva, fluoride can react with hydroxyapatite to create fluoride-substituted hydroxyapatite.[15] High concentrations of fluoride have antibacterial effects on microorganisms that cause caries. By attaching to bacterial enzymes, fluoride ions can prevent acidogenic bacteria from metabolising carbohydrates and absorbing sugar.[16,17,18]

According to research, silver has an antimicrobial impact whereas fluoride is useful in promoting the remineralization of enamel and dentine tissues.[19] Silver fluoride treatment is viewed as the first step in slowing down the caries progression in a population where the disease is ubiquitous and very severe. Silver diamine fluoride has an intense antibacterial effect on cariogenic bacteria and can inhibit the growth of multispecies cariogenic biofilms on tooth surface, is a promising therapeutic option.[20]

A significant drawback of silver diamine fluoride treatment is black discoloration on teeth, which can be unpleasant.[21] Applying a solution of potassium iodide immediately after the application of silver diamine fluoride has been recommended as a remedy.[22] In order to prevent discolouration, Ngo et al.(2002) proposed supplementing SDF with potassium iodide.[23] Potassium iodide is a salt that forms white or clear hexahedral crystals and contains 76% iodine and 23% potassium. Potassium iodide is very soluble

in water and has photosensitive and mildly hygroscopic characteristics.[24] It was proposed that the caries arresting effect of silver diamine fluoride could be maintained while the carious lesion's discoloration could be prevented.[25] The silver ions from the silver diamine fluoride solution reacts with the iodide ions from the potassium iodide solution to form silver iodide.[26] Recent numerous in vitro studies have demonstrated that the use of KI alone reduced biofilm development and qualitatively reduced dentine discoloration.[27,28]

Primary mechanism of the caries-arresting effect of silver diamine fluoride is its microbicidal effect on cariogenic biofilm.[29,30] Silver diamine fluoride elemental silver content is primarily responsible for its antibacterial properties.[31] The antibacterial efficacy of iodide ions (I) in aqueous potassium iodide is greater than that of iodine solutions, which have previously been used as an antiseptic for treating wounds and wound infections.[32,33]

However, after extensive research, limited data is available on the comparison of the silver formulations with or without potassium iodide used for treatating early childhood caries. Thus, the present study was conducted with an aim to determine and compare caries preventive efficacy and staining potential of silver diamine fluoride therapies with and without potassium iodide in children.

AIM

To determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children.

OBJECTIVES

1) To evaluate and compare effectiveness of silver diamine fluoride with and without potassium iodide in arresting progression of early childhood caries

2) To evaluate and compare staining potential of silver diamine fluoride with and without potassium iodide.

3) To evaluate and compare antimicrobial activity of silver diamine fluoride with and without potassium iodide on carious lesions in dentin

REVIEW OF LITERATURE

Klein U, Kanellis M J, Drake D(1999)[34] conducted an in-vitro study on eighty-five extracted permanent teeth to compare four chemotherapeutic regimens used for inhibiting carious lesion progression: silver nitrate; silver fluoride/stannous fluoride; silver diammine fluoride; and chlorhexidine. Streptococci mutans and Lactobacilli was used to generate carious lesions on the tooth surface. Six weeks later, lesions treated with silver fluoride/stannous fluoride or silver diammine fluoride; application demonstrated 29% and 19% less lesion progression, respectively. Silver diammine fluoride and chlorhexidine did not differ significantly. They concluded that silver fluoride/stannous fluoride and silver nitrate may be useful in slowing down carious lesion depth progression.

Chu CH, Lo E C M, Lin H C(2002)[35] conducted a prospective controlled clinical trial to investigate the effectiveness of sodium fluoride and silver diamine fluoride applications in arresting dentinal caries. Three hundred seventy-five children, aged between 3-5 years, with carious upper anterior teeth where included in the study. Silver diamine fluoride was found to be effective in arresting dentinal caries in primary anterior teeth in pre-school children.

Llodra J C, Rodriguez A, Ferrer B, Menardia V, Ramor T, Morato M(2005)[36] conducted a study to determine the efficacy of a 38% SDF solution for caries reduction in primary teeth of six year old school children. They concluded that silver diamine fluoride solution was effective for caries reduction in primary teeth in school children.

G M Knight et al (2005)[37] conducted a study to determine the efficacy and permeability of *S. mutans* in silver diamine fluoride followed by potassium iodide application, silver

diamine fluoride and potassium iodide. Forty dentinal disc were prepared for the study. After two weeks the optical density of the growth medium chambers was measured to determine bacterial penetration and growth. *S. mutans* migrated through all dentine discs. The samples treated with silver diamine fluoride and silver diamine fluoride followed by potassium iodide had significantly lower optical densities when compared with control group. The range of optical densities was least amongst demineralized samples treated with silver diamine fluoride followed by potassium iodide.

HH Hamama, CK Yiu, MF Burrow(2015)[38] conducted an in vitro study on forty-five dentine discs prepared from caries-free maxillary premolars. The aim of the study was to evaluate and compare the antimicrobial effect of silver diamine fluoride with and without potassium iodide; silver diamine fluoride with and without chlorhexidine; silver diamine fluoride with and without carisolv and silver diamine fluoride with and without papacrine on the viability of intratubular bacteria. Silver diamine fluoride with potassium iodide exhibited a potent antibacterial effect, it represented a significantly higher percentage of dead bacteria, when compared with chlorhexidine, Carisolv and Papacarie . They concluded that silver diamine fluoride with potassium iodide product is effective in reducing the numbers of S. mutans in dentinal tubules infected with this organism**.**

Garg S, Sarda A, Chan DCN(2015)[39] explained the clinical procedure for using potassium iodide to reverse silver diamine fluoride staining. They found that application of potassium iodide aids in reducing the stain caused by silver diamine fluoride, but the restorative margins may still be at risk of staining.

Miller MB, Lopez LA, Quock R(2016)[40] conducted an in-vitro study on twenty extracted teeth with frank cavitated carious lesions that was prepared with a spoon excavator to remove superficial soft carious dentin in order to assess perceptible differences in staining of restorations in silver diamine fluoride treated teeth, with or

without the subsequent application of potassium iodide. They found no significant differences between silver diamine fluoride with or without potassium iodide, and they even stated that subsequent application of potassium iodide after silver diamine fluoride on caries-affected teeth may improve aesthetic appearance.

Zhao IS, Mei ML, Burrow MF, Lo EMC, Chu CH(2017)[41] conducted an in vitro study on thirty extracted premolars to determine the effect of silver diamine fluoride with and without potassium iodide treatment on secondary caries prevention and tooth discolouration on glass ionomer cement restoration. The colour of the restoration was assessed using CIELAB system at different time points. Silver diamine fluoride followed by potassium iodide treatment reduced secondary caries formation on glassionomer cement restoration, but was not as effective as silver diamine fluoride treatment alone, perceptible staining on the restoration margin was observed, the intensity of discolouration was less than that of silver diamine fluoride treatment alone.

Nguyen V, Neill C, Felsenfeld J, Carolyn P(2017)[42] conducted a study to evaluate the effect of silver diamine fluoride with and without potassium iodide on healthy and carious tooth structure on forty-five extracted molars. Visual examination and color measurements were used to evaluate the change in color. They found that both treatments were effective in arresting active caries lesions. Silver diamine followed by potassium iodide had little to no discoloration on the tooth surface .

Maribasappa K, Dena A, Hien N (2017)[43] conducted an *in vivo* study to evaluate and compare the efficacy of silver diamine fluoride with and without potassium iodide and 2% chlorhexidine on bacteria present in deep carious lesions. The median colony-forming unit (CFU) counts per mg of dentin in silver diamine fluoride group showed remarkable decrease in bacterial counts, in silver diamine fluoride followed by

potassium iodide group decrease was observed but was not as effective when compared with silver diamine fluoride alone, while least reduction was seen in chlorhexidine gluconate (CHX) group and they concluded that silver diamine fluoride with and without potassium iodide showed more antibacterial activity than 2% chlorhexidine.

Fung MHT, Duangthip D, Wong MCM, Lo ECM, Chu C H(2018)[44] conducted a thirty-month randomized controlled trial to compare the effectiveness of two concentrations (12% or 38%) of silver diamine fluoride in arresting cavitated dentin caries in primary teeth . Children between 3-4 years with atleast 1 active carious lesion were included in the study.They concluded that silver diamine fluoride at a concentration of 38% is more effective than that of 12% in arresting active caries in primary teeth.

Clemens J, Gold J, Chaffin J(2018)[45] conducted a study to accesse the effectiveness of 38% silver diamine fluoride in arresting active dental caries lesions. Thirty-two children aged between 2-5 years with one hundred and eighteen active caries lesions in primary teeth where included in the study. Children were evaluated at 3-week and 3-month recall to access color and consistency changes in lesions. 100 lessions were found to be arrested at first recall and remaining lesions were arrested on second visit. They even stated that silver diamine fluoride was effective in arresting active caries lesions in primary teeth in young children and was well accepted by parents.

Milgrom P et al (2018)[46] conducted a double blinded randomized control trial study to investigate the effectiveness and safety of 38% silver diamine fluoride in arresting caries lesions in which sixty-six pre school children with more than one active carious lesions were included. Silver diamine fluoride (38%) or placebo (blue-tinted water), was applied topically to the lesion. Dental plaque was collected from all children, and microbial

composition was assessed by RNA sequencing from 2 lesions and 1 unaffected surface of each subject before intervention and at follow-up at 3 month visits for each children . They concluded no consistent changes in relative abundance of caries-associated microbes, was seen. Topical 38% silver diamine fluoride was found to be effective and safe in arresting cavities in preschool children.

Fung M H T, Duangthip D, Wong M C M, Lo E C M, Chu C H(2018)[47] conducted a thirty months randomized control trial to compare the effectiveness of two concentrations (12% or 38%) of silver diamine fluoride in arresting cavitated dentin caries in primary teeth in children between 3-4 years of age. A total of 888 children with 4,220 decayed tooth surfaces received silver diamine fluoride application. They concluded that silver diamine fluoride at a concentration of 38% is more effective than that of 12% in arresting active caries in primary teeth.

Yu O Y et al(2018)[48] conducted an in vitro study to evaluate the remineralising effect of the adjunctive application of 38% silver diamine fluoride solution with and without 5% sodium fluoride varnish on artificial enamel caries lesions on forty eight demineralized enamel specimen. The surface morphology and fluoride content of the specimens were studied via scanning electron microscopy (SEM)/energy dispersive spectroscopy (EDS). The lesion depth and crystal characteristics were assessed using micro-computed tomography and X-ray diffraction (XRD) respectively. They concluded adjunctive application of silver diamine fluoride with sodium fluoride varnish had a similar remineralising effect to that of silver diamine fluoride alone on enamel caries.

Vinson L A, Gilbert P R, Sanders B J, Moser E, Gregory R(2018)[49] conducted an in vitro study to determine the bactericidal potential of 38% silver diamine fluoride alone, potassium iodide, and silver diamine fluoride with potassium iodide against three bacterial species commonly found in root canal samples (*Enterococcus*

faecalis, Actinomyces naeslundii and *Parvimonas micra*). The bactericidal potential of SDF was 100% against *A. naeslundii* and *P. micra* and the least against 99.97% *E. faecalis*. Silver diamine fluoride with potassium iodide showed a 100% bactericidal effect against *P. micra,* and similar result againts *E. faecalis* and *A. naeslundii.* The bactericidal effect of potassium iodide was found to be least against all the three micro organism. Silver diamine fluoride had the best bactericidal effect against the examined bacteria.

Patel J, Anthonappa R P, King N M(2018)[50] conducted an in vitro study on extracted carious primary molars with an aim to evaluate the staining potential of silver diamine fluoride and the influence of the potassium Iodide application on the degree of black staining over time. Following silver dimaine fluoride application, the onset of black staining occurred within 2 minutes and increased in value for up to 6 hours post-application. The use of potassium iodide immediately after silver diamine fluoride application resulted in no noticeable staining of the carious dentine or surrounding enamel.

Ana L V et al. (2019)[51] conducted a blinded randomized control trial to determine and compare the efficacy of silver diamine fluoride and atraumatic restoration treatment in arresting dentine caries in primary molars. Time required for treatment, adverse effects, parental aesthetic perception, anxiety and oral health related to quality of life (OHRQoL) was evaluated. The study was conducted in sixty-eight children between 2-5 years age. A examiner evaluated the outcome at the 3, 6, and 12-month follow-up points. The time required to treat with SDF was lower than the ART. There was no difference in the percentage of adverse events, aesthetic perception, and the change in anxiety. There was a less impact on oral health related to quality of life after ART treatment. They concluded that silver diamine fluoride arrests secondary caries lesions.

Duker M V, Hayashi J, Chan D C, Tagami J, Sadr A(2019)[52] conducted an in vitro study to evaluate the microtensile bond strength (MTBS) of resin composite to demineralized dentin treated with silver diamine fluoride with and without potassium iodide on thirty caries free molars. They concluded that silver diamine fluoride can be applied on demineralized dentin before bonding without compromising the bond strength of a universal adhesive used with phosphoric acid etching. The bonding was found to be significantly weakened when potassium iodide was applied to prevent discolouration.

Gupta J, Thomas M S, Radhakrishna M, Srikant N, Ginjupalli K(2019)[53] conducted an in vitro study to compare the alteration in bond strength and microleakage while using silver diamine fluoride followed by potassium iodide and chlorhexadine as cavity cleansers in resin-modified glass ionomer cement (RMGIC) restorations on freshly extracted molars. They concluded that the application of silver diamine fluoride followed by potassium iodide and chlorhexadine was useful against *S. mutas.* Although silver diamine fluoride followed by potassium iodide group showed the least microleakage among the groups, it was not statistically significant.

Bathsheba T, Rithvitou H, Callum D (2020)[54] conducted a study to compare the caries arrest rate and colour change of carious lesion in primary teeth using silver fluoride or silver diamine fluoride with and without potassium iodide. This study demonstrated that both silver fluoride and silver diamine fluoride can effectively arrest carious lesions on primary teeth. The use of potassium iodide was associated with poor caries control but better aesthetic outcomes was seen.

Liu B I et al (2020)[55] conducted an in vitro study to investigate micro-ecological changes in dental plaque on deep caries of deciduous teeth after topical silver diamine fluoride treatment. Unstimulated saliva collection and initial plaque sampling were done before tooth extraction, then caries lesion was topically treated with 38% silver diamine

fluoride in vitro. After intervention, each tooth was stored respectively in artificial saliva at 37 °C. Repeated plaque collections were done at 24 hour and 1 week post-intervention. They concluded that silver diamine fluoride has extensive antimicrobial effect on dental plaque, which may reduce carbohydrate metabolism in dental plaque and help promote new balance of the plaque flora.

Detsomboonrat P, Thongmak P, Lertpayab P, Aiemsri W, Sooampom SC(2021)[22] conducted a study to determine the ideal potassium iodide concentration for efficiently reducing black staining following application of silver diamine fluoride on twenty four extracted teeth. Silver diamine fluoride with 7.5% potassium iodide, 10% potassium iodide, 15% potassium iodide, 20% potassium iodide, and silver diamine fluoride plus saturated potassium iodide. They observed that the teeth in the 20% potassium iodide group had the highest Δ mean gray value compared with other groups immediately after potassium iodide application, whereas a reduction in black staining in the saturated potassium iodide group appeared 1 day after potassium iodide application.

Haiat A, Ngo HC, Samaranayake L P, Fakhruddin KS(2021)[56] conducted a systematic review to determine antimicrobial efficacy of silver diamine fluoride with potassium iodide combination on cariogenic microbes and reducing the discoloration associated with the application of silver diamine fluoride. Twelve studies were included in the analysis, seven of which have investigated the antimicrobial efficacy of silver diamine fluoride with potassium iodide, and the rest have examined the anti-staining potential of potassium iodide. The findings from the reviewed articles revealed promising antimicrobial potential of silver diamine fluoride with potassium iodide on cariogenic microbes associated with dentine caries.

Marroguim B B, Ismael Y, Callaway A, Tennert C, Wolf T G(2021)[57] conducted a in vitro study to determine the bactericidal potential of 38% silver diamine fluoride,

potassium iodide, and silver diamine fluoride with potassium iodide against three bacterial species commonly found in root canal samples (Enterococcus faecalis, Actinomyces naeslundii and Parvimonas micra). They concluded that silver diaime fluoride had an effective bactericidal effect against the examined bacteria.

Kamble A N, Chimata V K, Katge F, Nanavatei K K, Shetty S K(2021)[58] conducted a study to evaluate and compare the effect of potassium iodide and glutathione on tooth discoloration after application of 38% silver diamine fluoride on thirty primary molars. Teeth were prepared and divided into three groups. Final restoration was done using glass ionomer cement. Visual examination and color assessments was done using spectrophotometer and were recorded at three time interval points, that is, day one, one week, and four weeks. Spectrophotometer results showed that silver diamine fluoride exhibited the greatest amount of discoloration at all time intervals, while silver diamine fluoride with glutathione was effective in decreasing the discoloration.

Vennela E et al(2021)[59] conducted a in vitro study to compare the staining potential of silver diamine fluoride versus silver diamine fluoride and potassium iodide under tooth-colored restorations on forty extracted carious primary teeth. Images were captured after initial applications on day 1 and day 14 after restoration. They concluded restorations after silver diamine fluoride application attained dark stain eventually, whereas with the application of silver diamine fluoride followed by potassium iodide,the restorations showed the least staining.

Chhattani B et al (2021)[60] conducted an in vivo study in nineteen children having >1 caries lesion to evaluate and differentiate the efficacy of 38% silver diamine fluoride, chlorhexidine varnish, and fluoride varnish on carious primary teeth. Thirty-eighty percent silver diamine fluoride or fluoride varnish and chlorhexidine varnish were topically applied on the lesion. The primary outcome measured was the arrest of carious lesion as per the Nyvad criteria after a follow-up of 14–21 days. Dental biofilm sample

was obtained from each child and subsequently assessed for microbial composition before and after treatment. Protein analysis was done after microbial analysis by sodium dodecyl sulfate-polyacrylamide gel electrophoresis method. They concluded that 38% silver diamine fluoride was more effective than 2% chlorhexedine varnish and fluoride varnish in arresting dentin carious lesions in young children.

Alsagob E et al (2022)[61] conducted an in vitro study among sixty infected teeth which was divided into five groups to determine whether immediate or delayed restoration application is associated with less discoloration. Delayed restoration with either composite or glass ionomer cement showed least color change. They concluded that under laboratory conditions, delaying application of restoration for two weeks after silver diamine fluoride to samples of caries-infected teeth significantly reduced discoloration.

Sulyanto R M et al(2022)[62] conducted a case control study to examine the mechanisms by which silver diamine fluoride may impact the oral microbiota on carious lesions of primary teeth with or without silver diamine fluoride treatment. Microbial viability testing and next-generation sequencing method was used to compare untreated or silver diamine fluoride-treated carious surface biofilm and subsurface carious dentin. They concluded silver diamine fluoride does not significantly alter the carious surface biofilm microbial community composition, it promotes a shift in community membership deeper within dentin tubules.

Lee K E, Erdenebulgan M, Kang C M, Jug H I, Song J S(2022)[63] conducted an in vitro study to evaluate and compared the efficacy of 38% SDF with potassium iodide, 38% silver diamine fluoride and 5% sodium fluoride varnish for enamel remineralization of sixty bovine incisors. Silver diamine fluoride with potassium iodie caused no significant difference in discoloration between the silver diamine fluoride and sodium fluoride groups. They concluded that silver diamine fluoride is effective for dental enamel remineralization even with potassium iodide, which reduces discoloration.

Aly M M, Yousry Y M(2022)[64] conducted a split mouth randomized controlled trial on thirty carious primary canine to evaluate the potential discolouration and carious lesion arresting effect of silver diamine fluoride and silver diamine fluoride/potassium iodide in the treatment of carious primary teeth. They concluded from the study both silver diamine fluoride and silver diamine fluoride with potassium iodide was effective in arresting carious lesions in primary teeth but in terms of the discolouration potential, the use of potassium iodide significantly reduced the discolouration caused by silver diamine fluoride immediately post-operatively but marked discolouration was recorded in the subsequent follow-up visits, compromising the aesthetic outcome.

MATERIALS & METHODS

The present study was conducted in the Department of Pediatric and Preventive Dentistry, BBDCODS, BBDU, Lucknow. The aim of the study was to evaluate and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children. The study was conducted on children with early childhood caries between the age group of 3-5 years of both gender. The study was conducted in collaboration with College of Pharmacy, BBDU, Lucknow.(ANNEXURE VIII)

Materials:

38% Silver diamine fluoride (FAgamin®) (Fig 1)

20% potassium iodide solution (Fig 2)

Resin modified glass ionomer cement (GC Gold Lable 2 Lc) (Fig 3)

CPI Probe (GDC Germany) (Fig 4)

Spoon Excavator (GDC Germany) (Fig 4)

Mouth Mirror (GDC Germany) (Fig 4)

Gloves (Fig 5)

Petroleum jelly (Fig 5)

Paper pad (Fig 5)

Applicator tip (Fig 5)

Fig 1: 38% Silver

Fig 2: 20% Potassium iodide solution

Fig 3: Resin modified glass ionomer cement (GC Gold Lable 2 Lc)

Fig 4: Diagnostic Instruments (CPI probe, Mouth mirror, Spoon excavator)

Fig 5: Petroleum jelly, curing light, applicator tip

The study was conducted in the Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences (BBDCODS), after obtaining ethical approval from the Institutional ethical committe. (ANNEXURE II)

Study Sample Size:

Sample size estimation was done by using GPower software (version 3.0). Sample size was estimated for Paired t test.

A minimum total sample size of 96 was found to be sufficient for an alpha of 0.05, power of 95%, 0.50 as effect size.

t tests - Means: Difference between two dependent means (matched pairs)

Analysis: A priori: Compute required sample size

Input: Tail(s) = One

Effect size dz = 0.5

α err prob = 0.05

Power (1-β err prob) = 0.95

Output: Noncentrality parameter δ = 3.3541020

Critical t = 1.6802300

Df = 88

Total sample size = 96

Actual power = 0.9512400

Eligibility Criteria:

Inclusion criteria

- Healthy children with early childhood caries belonging to both genders .
- Subjects with active carious lesion according to ICDAS code 3 or above on primary tooth.
- Subjects for whom consent was obtained from the parents.

Exclusion Criteria

- Teeth showing symptoms such as discoloration, pulp exposure and abscess or fistula were considered non vital.
- Teeth where isolation was not possible.
- Subjects with systemic disease/ history of medication for more than 3 months.

Sampling Method: Simple random sampling method

Randomization was done on the basis of coin toss method. All participants opting for heads were included in Group I (SDF) and participants opting for tails were included in Group II (SDF+KI).

Study Design

This split mouth randomised control trial was conducted in 24 children with 96 affected tooth. Subjects were equally divided into two groups. The study was conducted to evaluated and compare the efficacy of silver diamine fluoride with and without potassium iodide. 38% silver diamine fluoride with and without potassium iodide was applied on the tooth surface after which the tooth was restored with resin modified glass ionomer cement. Color assessment of the restored surface was done at different time interval by visual method. Antimicrobial efficacy of SDF with and without potassium iodide was evaluated.

Clinical examination:

Children were clinically examined for detection of early childhood caries. Assessment of caries was done according to ICDAS II criteria and ICDAS radiographic scoring criteria (Annexure X). The patient was seated in erect position on the dental chair and then examination for early childhood caries was done. Probing of the lesion was done with a CPI probe to evaluate the extent of the lesion. Lesions with ICDAS II code 3 and above were included for the study. Radiographs were taken for each tooth and lesion with radiolucency limited to the middle 1/3 of the dentine were included. The activity of the carious lesion was recorded by CPI probe. If the lesion was found to be soft on probing it was to be considered as an active lesion and was included in the study and if hard, it was to be considered as inactive lesion and was not included in the study.[65]

Formation of 20% Potassium iodide solution:

20% potassium iodide solution was formulated in the college of pharmacy, BBD University by pharmacocopial method. The solution was stored in a amber color bottle to protect the solution from external light.

Swab Sample Collection:

Swab sample was collected from active carious lesion before the intervention, immediately after intervention and 14 days after the intervention. The sample was collected from the dentinal surface of each carious surface using a spoon excavator and the sample was stored in tube containing saline. The tube was stored in a ice box for transportation purpose to maintain an optimal temperature between 15'C-20'C. Collected sample was sent to a laboratory for microbial analysis within 2 hours.

Microbial Analysis

The microbial analysis was done by counting the colony forming units.

Aerobic culturing technique

10 µL of the BHI broth was inoculated using micropipette on 5% Columbia sheep blood agar plates. The inoculated loop was heated on the blue flame of Bunsen flame, till it became red hot and was allowed to cool down at room temperature. With the help of the loop streaking was carried out on the agar plates and was placed in the incubator at 34˚C for 24 hours. The bacterial growth was counted as CFUs using the manual counting method.

$$\text{Calculation of colonies in 2mL (2000µL) of BHI Broth} = \frac{\text{Number of CFUs} \times 2000\mu l}{10\mu L}$$

The results obtained were tabulated on an excel sheet and sent for statistical analysis

Silver diamine fluoride application:

Three way syringe was used to clean the tooth surface with sterile distilled water and tooth was air dried with the same. Exposed gingival tissue and the lip was taking care not to contaminate the treatment site or stain the gingival surface. Isolation was done using cotton rolls to prevent moisture contamination before intervention. Infected soft dentine was excavated using a sharp spoon excavator (GDC Germany) before the application of silver diamine fluoride(FAgamin®).

- **Group I**: one drop of silver diamine fluoride(FAgamin®) was dispensed on the non-absorbant mixing pad and applied on the tooth surface using a applicator tip for about 15-30 sec.
- **Group II**: one drop of silver diamine fluoride (FAgamin®) and two drops of formulated 20% potassium iodide solution was applied on tooth surface using a applicator tip for about 15-30 sec.

After the application of 38% silver diamine fluoride (FAgamin®) with and without potassium iodide the child was asked verbally to ensure no adverse events like (irritation, redness, burning sensation etc on the gingival surface or the oral mucosa) has taken place. The child was asked twice for any symptoms, once immediately after the procedure and second time one hour post intervention.

Restoration of the tooth:

In each group half subjects received resin modified glass ionomer cement(GC Gold Lable 2 Lc) restoration on the same day immediately after the application of silver diamine fluoride(FAgamin®) with and without potassium iodide and the remaining half of the subjects from both the groups received restoration two weeks after intervantion for evaluation of staining potential of silver diamine fluoride with and without potassium iodide. Restoration was done 14 days after application of silver diamine fluoride with and without 20% potassium iodide to get the dentinal sample for microbial analysis.

Colour Assessment

Child was made to sit in an upright position under dental operatory light. Color assessment of the tooth surface and the restoration after the application of silver diamine fluoride with and without potassium iodide was done by two examiners.

Colour Assessment was done by visual method[45]

Color assessment of restored tooth surface was done at baseline immediately after intervention, 14 days after the intervention, 2 months after intervention and 6 months after intervention.

Any change in the color of the restored surface was noted by both examiner and final record was noted.

There was perfect inter observer agreement between Observer 1 and Observer 2 for the color assessment of the lesion at all time interval. (Table 8-11)

Lession Assessment

A radiograph was taken 6 months after intervention to evaluate the tooth surface restored with resin modified glass ionomer cement after application of silver diamine fluoride with or without 20% potassium iodide. The ICDAS radiographic grading system was used to determine the extent of radiolucency. (ANNEXURE X)

Fig 6: Early Childhood caries

Fig 7: Coating of the gingiva with petroleum jelly

Fig 8: Application of SDF with and without KI

Fig 9: Tooth surface restored with Resin modified glass ionomer cement immediately after intervention

Fig 10: Tooth surface restored with resin modified glass ionomer cement 14 days after intervention

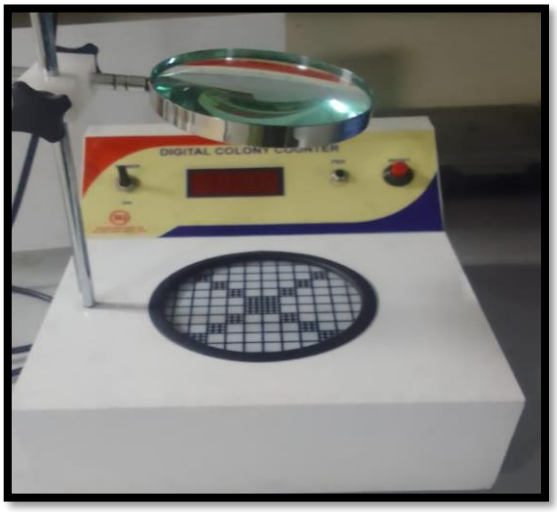


Fig 11: Colony forming unit counter

Fig 12: Microbe culture on agar plate

Table 1: Color asssessment of restored tooth surface in both the groups at different time intervals

Time interval	Groups	White	Grey	Black	Chi Square value	P value
Baseline	SDF	0(.0%)	16(69.6%)	7(30.4%)	38.213	0.001
	SDF+KI	21(91.3%)	2(8.7%)	0(.0%)		
14 days	SDF	0(.0%)	0(.0%)	23(100%)	39.657	0.001
	SDF+KI	20(87.0%)	3(13.0%)	0(.0%)		
2 months	SDF	0(.0%)	0(.0%)	23(100%)	36.458	0.001
	SDF+KI	9 (39.1%)	14 (60.9%)	0(.0%)		
6 months	SDF	0 (.0%)	0 (.0%)	21 (100%)	40.231	0.001
	SDF+KI	3 (14.3%)	16(76.2%)	2 (9.5%)		

In SDF group 69.6% of tooth surface were grey whereas 30.4% were black none of the restored tooth were black at baseline. In SDF+KI group 91.3% tooth surface were white, 8.7% were grey and none of the tooth surface attained black stain at baseline. The intergroup difference in the color of lesion at baseline was statistically significant

14 days after intervention 100% of restored tooth surface in SDF group turned black. All restored tooth surface in this group remained black even 2 months after intervention and 6 months after intervention. The intergroup difference in the color of lesion was statistically significant at all time interval.

In SDF+KI group 87% restored surface were white whereas 13% of restored tooth turned grey but none of the tooth surface were black 14 days after intervention . 2 months after intervention there was increase in the intensity of discoloration 60.9% restored surface were grey whereas 39.1% of restored tooth were white but none of the restored tooth surface were black . 6 months after intervention 76.2% restored surface

were grey whereas 14.3% of restored tooth were still white whereas 9.5% of the restored surface turned black 6 months after intervention.

Table 2: Distribution of subjects according of feeding practice and frequency in both group

Group	Feeding Practice		Feeding Frequency				Night Time feeding		Age when subjects Stopped Bottle Feeding		
	Bottle feeding	Breast & Bottle feeding	<1 time/ day	2-3 times/ day	3-4 times/ day	> 4 times/ day	Yes	No	between 12-18 months	>18 months	Still continuing
SDF	20 (89.3 %)	2 (11.7 %)	7 (30.4 %)	2 (8.7%)	8 (34.8 %)	6 (26.1 %)	23 (100%)	0 (0%)	8 (34.8 %)	9 (39.1%)	6 (26.1 %)
SDF+ KI	21 (91.3 %)	4 (9.7 %)	2 (8.7%)	6 (26.1 %)	8 (34.8 %)	7 (30.4 %)	23 (100%)	0 (0%)	9 (39.1 %)	8 (34.8%)	3 (13.1 %)
P value	1.00		1.00				1.00		1,00		

At baseline majority subjects in SDF and SDF+ KI were bottle fed 89.3% and 91.3% respectively. On the basis of feeding frequency in SDF group majority subject where fed 3-4 times per day (34.8%) followed by once daily (30.4%) and more than 4 times per day (26.1%). In SDF+KI group majority subject were feeding 3-4 times / day (34.8%) followed by more than 4 times / day (30.4%) and 2-3 times per day (26.1%). 100% of subjects in both the groups had night time bottle feeding habit.

The intergroup comparison between both the group was non-significant and the analysis was done using Chi square test

Table 3: Distribution of subjects according to sugar and snack consumption in both the groups

Groups	Baseline			2 months			6 months		
	<1 time/day	1-2 time/day	>2 times/day	<1 time/day	1-2 time/day	>2 times/day	<1 time/day	1-2 time/day	>2 times/day
SDF	6 (26.0%)	0 (0%)	17 (74.0%)	11 (48.6%)	10 (42.7%)	2 (8.7%)	15 (65.2%)	8 (34.8%)	0 (0%)
SDF+KI	3 (13.0%)	0 (0%)	20 (87.0%)	16 (69.6%)	5 (21.7%)	2 (8.7%)	14 (60.9%)	9 (39.1%)	0 (0%)
P value	1.00			1.00			1.00		

At baseline, 74% of subjects in the SDF group and 87% of subjects in the SDF+KI group consumed snacks more than twice a day. 2 months after intervention the frequency of eating snacks more than twice a day decreased to 8.7% in both SDF and SDF+KI group. Whereas 48.6% of the SDF group and 69.6% of the SDF+KI group consumed snacks less than once each day. Six months after the intervention, none of the individuals consumed snacks more than twice a day. Snacks were consumed less than once per day by 65.2% of the SDF group and 60.9% of the SDF+KI group. Whereas 34.8% of the SDF group and 39.1% of the SDF+KI group consumed snacks 1-2 times each day.

The intergroup comparison between both the group was non-significant and the analysis was done using Chi square test

Table 4: Distribution of subjects according to oral hygine practice in both group at different time interval

Oral hygine practice						
	Baseline		**2 months**		**6 months**	
Groups	Does not brush	Tooth brush	Does not brush	Tooth brush	Does not brush	Tooth brush
SDF	4 (17.3%)	19 (82.6%)	0 (0%)	23 (100%)	0 (0%)	23 (100%)
SDF+KI	6 (26.1%)	17 (73.9%)	0 (0%)	23 (100%)	0 (0%)	23 (100%)
P value	1.00		1.00		1.00	

Frequency of Tooth Brushing									
	Baseline			**2 months**			**6 months**		
Group	Does not Brush	Once	Twice	Does not Brush	Once	Twice	Does not Brush	Once	Twice
SDF	4 (17.3%)	14 (60.8%)	3 (13.0%)	0 (0%)	17 (73.9%)	6 (26.1%)	0 (0%)	15 (65.2%)	8 (34.8%)
SDF+KI	6 (26.1%)	13 (58.5%)	4 (15.4%)	0 (0%)	16 (69.6%)	7 (30.4%)	0 (0%)	15 (65.2%)	8 (34.8%)
P value	1.00			1.00			1.00		

At baseline, 82.6% subject in SDF group and 73.9%subject in SDF+KI group used tooth brush as cleaning aid. The rest of the participants in SDF group (17.3%) and in SDF+KI group (26.1%) were not using any intraoral cleaning aid. At 2 months and 6 months follow up in both the groups all subjects (100%) started using toothbrush.

Based on the frequency of tooth brushing 60.8% subjects in SDF group and 58.5% subjects in SDF+KI group where brushing once daily, while 17.3% subject in SDF group and 26.1% subjects in SDF+KI group where not brushing. 2 months after intervention all subjects started brushing 73.9% in SDF group and 69.6% in SDF+KI group where brushing once daily and 26.1% in SDF group and 30.4% in SDF+KI group

started brushing twice daily. 6 months after intervention 34.8% subjects in both groups started brushing twice daily while 65.2% in both groups where still brushing once daily.

The intergroup comparison between both the group was non-significant and the analysis was done using Chi square test

Table 5: Mean CFU score at different time interval in both the groups

Time interval	Groups	Mean	Standard deviation	P value
Baseline	SDF	280.00	70.47	0.867
	SDF+KI	307.69	76.67	
Immediately after Intervention	SDF	240.71	55.64	0.001
	SDF+KI	210.76	53.69	
14 days after intervention	SDF	190.12	47.12	0.001
	SDF+KI	146.23	37.21	

All the measurements of CFU in units of 10^5

At baseline in SDF group the mean CFU count was (280.00), wand in the SDF+KI group, it was (307.69). CFU counts reduced in both groups immediately after the intervention. The mean CFU count in SDF group was (240.71) and in SDF+KI group it was (210.76). 14 days after intervention mean CFU count was less in the SDF+KI group (146.23) compared to the SDF group (190.12). The intergroup comparison between the two groups was statistically significant immediately after intervention and 14 days after intervention.

Immediately after intervention and 14 day after intervention mean CFU count were less in SDF+KI group.

Table 6: Change in mean dmft score in both groups at different time interval

Groups	Baseline	2 Months	6 Months	Mean Change At 2 Months	Mean change At 6 Months
SDF	7.95±2.47	8.56±2.82	9.56±3.72	0.61±1.03	1.61±1.95
SDF+KI	8.08±2.48	8.21±3.24	9.13±4.14	0.13±0.87	1.05±1.32
P value				0.001	0.001

At baseline the dmft score for SDF and SDF+KI group was 7.95±2.47 and 8.08±2.48 respectively. Increase in dmft score for both the group was noted at 2 months and 6 months. The mean change in dmft score for SDF group was 0.61±1.03 at 2 months and 1.61±1.95 at 6 month. In SDF+KI group it was 0.13±0.87 2 months after the intervention and after 6 months mean dmft was 1.05±1.32.

The intergroup comparison between two groups was statistically significant at all time interval.

Table 7: Change In Mean Sugar Score at Different Time Interval in the both groups

Time interval	Groups	Mean	SD	SE	P value
Baseline	SDF	18.69	8.818	1.838	0.802
	SDF+KI	19.34	8.700	1.814	
2 months	SDF	18.69	5.880	1.226	0.900
	SDF+KI	18.91	5.830	1.215	
6 months	SDF	21.08	5.830	1.215	0.899
	SDF+KI	21.30	5.684	1.185	

The mean sugar score at baseline in the SDF group was 18.69 and in the SDF+KI group 19.34. 2 months after intervention the mean sugar consumption score reduced in SDF+KI group (18.91) whereas in SDF group it was unchanged. 6 months after intervention mean sugar consumption score increased in SDF group 21.08 and 21.30 in SDF+KI group.

The intergroup comparison between two groups was statistically non-significant.

Table 8: Comparison between change in CFU count and feeding habit at baseline and immediately after intervention

	Feeding Practice		Feeding Frequency				Night Time feeding		Stopped Bottle Feeding		
Change in CFU Score	**Breast & Bottle feeding**	**Bottle feeding**	**> 4 times/day**	**3-4 times/day**	**2-3 times/day**	**<1 time/day**	**Yes**	**No**	**between 12-18 months**	**>18 months**	**still continuing**
SDF (40)	38.21±14.70	40.26±14.96	34.12±13.95	37.37±14.53	40.57±14.98	45.12±15.31	33.01±12.84	45.58±16.90	38.49±14.80	43.26±15.60	36.17±13.71
SDF+KI (96.98)	95.85±19.85	97.9±20.10	91.76±18.10	95.01±19.68	98.21±20.10	102.76±20.46	90.65±17.99	103.22±22.05	96.13±19.95	100.9±20.75	93.81±18.86
P value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001

Independent t test at p value less than 0.05 is significant

There was a significant correlation between feeding habit and change in CFU score from baseline to soon after intervention. Subjects who were bottle fed had higher CFU change in both the SDF and SDF+KI groups, 40.26±14.96 and 97.9±20.10, respectively. In both SDF and SDF+KI groups, higher change in CFU was seen in participants who were fed less than once per day, 45.12±15.31 and 102.76±20.46, respectively. Subjects that were fed at night exhibited a more change in CFU count in both the SDF and SDF+KI groups, 45.58±16.90 and 103.22±22.05. Subjects who stopped feeding at 18 months exhibited more change in CFU counts in both the SDF and SDF+KI groups, 43.26±15.60 and 100.9±20.75, respectively. CFU were reduced more in the SDF+KI group than in the SDF group.

The intergroup comparison between both the group was significant and the analysis was done using Independent t-test

Table 9: Comparison between change in CFU count and feeding habit at baseline and 14 days after intervention

	Feeding Practice		Feeding Frequency				Night Time feeding		Stopped Bottle Feeding		
Change in CFU Score	**Breast & bottle feeding**	**Bottle feeding**	**> 4 times/day**	**3-4 times/day**	**2-3 times/day**	**<1 time/day**	**Yes**	**No**	**Between 12-18 months**	**>18 months**	**Still continui**
SDF (90)	88.72± 23.22	90.77±2 3.48	84.63±2 2.47	87.88±2 3.05	91.08±2 3.50	95.63±23 .83	83.52±2 1.36	96.09±2 5.42	89.00±2 3.32	93.77±2 4.12	86.68±2 2.23
SDF+KI (161.46)	160.38 ±39.33	162.43± 39.59	156.29± 38.58	159.54± 39.16	162.74± 39.61	167.29±3 9..94	155.18± 37.47	167.75± 41.53	160.66± 39.43	165.43± 40.23	158.34± 38.34
P value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001

Independent t test at p value less than 0.05 is significant

Significant correlation was seen between feeding habit and change in CFU score from baseline to 14 days after intervention. Subjects who were bottle fed had higher change in CFU count in SDF and SDF+KI groups, which was 90.77±23.48 and 162.43±39.59, respectively. In both SDF and SDF+KI groups, higher change in CFU count was seen in participants who were fed less than once per day, 95.63±23.83 and 167.29±39.94, respectively. Subjects that were not fed at night exhibited a more change in CFU count in both the SDF and SDF+KI groups, 96.09±25.42 and 167.75±41.53. Subjects who stopped feeding at 18 months exhibited more change in CFU counts in both the SDF and SDF+KI groups, 93.77±24.12 and 165.43±40.23, respectively. CFU were reduced more in the SDF+KI group than in the SDF group.

The intergroup comparison between both the group was significant and the analysis was done using Independent t-test

Table 10: Comparison between CFU count snacks consumption and Oral hygine practice at baseline and post intervention (Immediate and 14 days)

	Sugar and Snack consumption			Oral hygine practice		Tooth Brushing Frequency		
Change in CFU Score	**<1 time/day**	**1-2 time/day**	**>2 times/day**	**Does not brush**	**Tooth brush**	**Does not Brush**	**Once**	**Twice**
SDF (40)	34.5 ±13.69	39.13±14.65	44.16±16.17	35.47±13.56	43,12±16.09	35.47±13.81	39.41±14.93	42.98±15.78
SDF+KI (97.69)	92.23±21.84	96.77±22.80	101.8±24.32	93.11±21.71	100.76±24.24	93.11±21.96	97.05±23.08	100.62±23.93
P value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001
Change in CFU Score	**<1 time/day**	**1-2 time/day**	**>2 times/day**	**Does not brush**	**Tooth brush**	**Does not Brush**	**Once**	**Twice**
SDF (89.88)	85.1±22.21	89.64±23.17	94.67±24.69	85.98±21.43	93.63±22.08	85.98±22.33	89.92±23.45	93.49±24.30
SDF+KI (161.46)	156.7±38.32	161.24±39.28	166.27±40.80	157.58±38.19	165.23±40.72	157.58±38.44	161.52±39.56	165.09±40.41
P value	0.001	0.001	0.001	0.001	0.001	0.001	0.001	0.001

According to snacks/sugar consumption maximum change in CFU score was seen subjects who were consuming snacks more than 2 times per day. In both SDF and SDF+KI group 44.16±16.17 and 101.8±24.32 respectively from baseline to immediately after intervention and 94.67±24.69 in SDF group and 166.27±40.80 in SDF+KI group From baseline to 14 days after intervention.

Subjects who were using tooth brush in both SDF and SDF+KI group exhibited more change in CFU from base line to immediately after treatemnet and 14 days after intervention 43,12±16.09 AND 100.76±24.2, 93.63±22.08 and 165.23±40.72. Subject s who brushed twice daily in both groups showed more change in CFU count when comapred immediately and 14 days after intervention. 42.98±15.78 in SDF and 100.62±23.93 in SDF+KI immediately after intervention. . 93.49±24.30 in SDF and 165.09±40.41 in SDF+KI immediately after intervention

Statistical significant correlation was found between Sugar/snacks consumption and oral hygine practice. Mean change in CFU score for SDF+KI group was found to be more when compared with SDF group at baseline and immediately after intervention to 14 days after intervention.

Table 11: Progression of lesion in both group at different time interval

Time interval	Groups	RA3	RA4	Chi Square value	P value
Baseline	SDF	21(91.3%)	02 (8.7%)	0.224	1.000
	SDF+KI	20 (87%)	03 (13%)		
6 months	SDF	21(91.3%)	02 (8.7%)	0.224	1.000
	SDF+KI	20 (87%)	03 (13%)		

At baseline, 91.3% of the teeth in the SDF group had RA3 lesion score, whereas 8.7% had RA4. In the SDF+KI group, 87% of the tooth surfaces had RA3 scores, whereas 13% had RA4 scores.

Six months after intervention, no lesion progress was seen. in SDF group 91.3% of teeth remained in RA3 score and 8.7% of teeth were of RA4 . Similarly, no progression of lesion was seen in the SDF+KI group; 87% of teeth were RA3 and 13% were in RA4 category.

The intergroup difference in the progression of lesion at 6 months was statistically non-significant

Table 12: Inter examiner agreement for color assessment immediately after intervention

		Observer 2				
		White	Grey	Black	Kappa Agreement	P value
Observer 1	White	21 (100%)	0 (0%)	0 (0%)	1.000 (Perfect Agreement)	0.001
	Grey	0 (0%)	18 (100%)	0 (0%)		
	Black	0 (0%)	0 (0%)	7 (100%)		

Table13: Inter examiner agreement for color assessment 14 days after intervention

		Observer 2				
		White	Grey	Black	Kappa Agreement	P value
Observer 1	White	20(100.0%)	0 (.0%)	0 (.0%)	1.000 (Perfect Agreement)	0.001
	Grey	0 (.0%)	3 (100.0%)	0 (.0%)		
	Black	0 (.0%)	0 (.0%)	23(100.0%)		

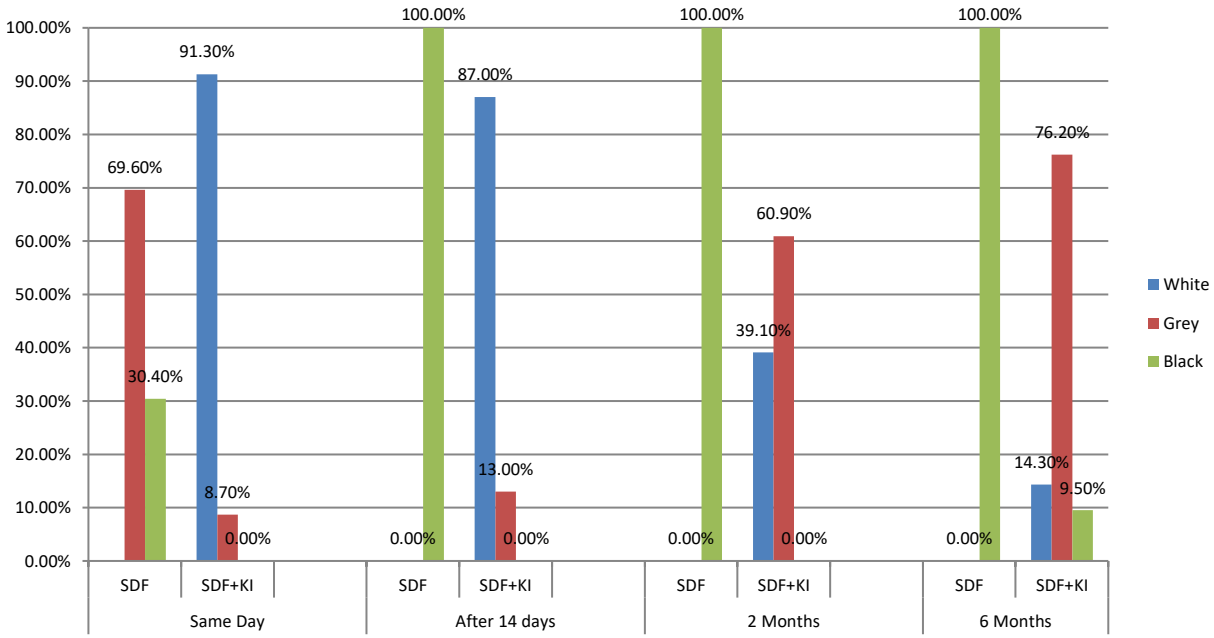
Table 14: Inter examiner agreement for color assessment two months after intervention

		Observer 2				
		White	Grey	Black	Kappa Agreement	P value
Observer 1	White	9 (100.0%)	0 (.0%)	0 (.0%)	1.000 (Perfect Agreement)	0.001
	Grey	0 (.0%)	14(100.0%)	0 (.0%)		
	Black	0 (.0%)	0 (.0%)	23(100.0%)		

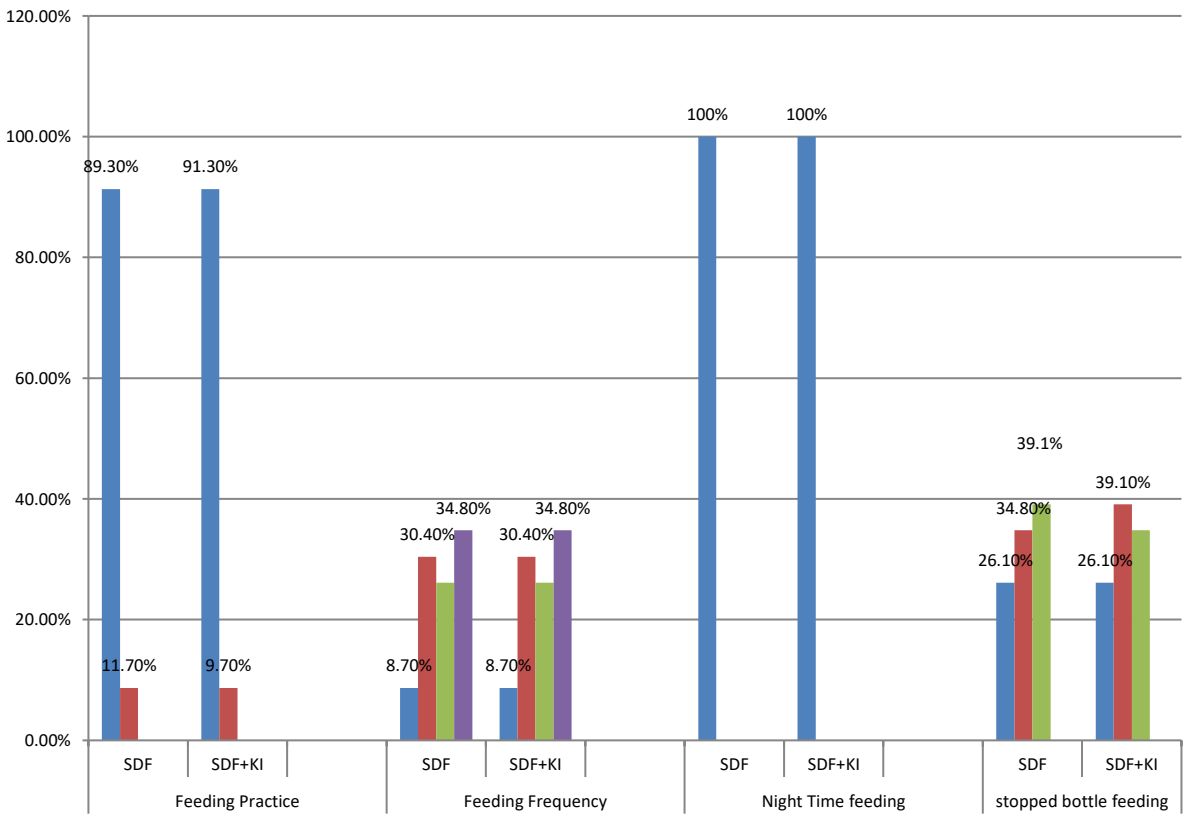
Table 15: Inter examiner agreement for color assessment six months after intervention

		Observer 2				
		White	Grey	Black	Kappa Agreement	P value
Observer 1	White	3 (100.0%)	0 (.0%)	0 (.0%)	1.000 (Perfect Agreement)	0.001
	Grey	0 (.0%)	16(100.0%)	0 (.0%)		
	Black	0 (.0%)	0 (.0%)	23(100.0%)		

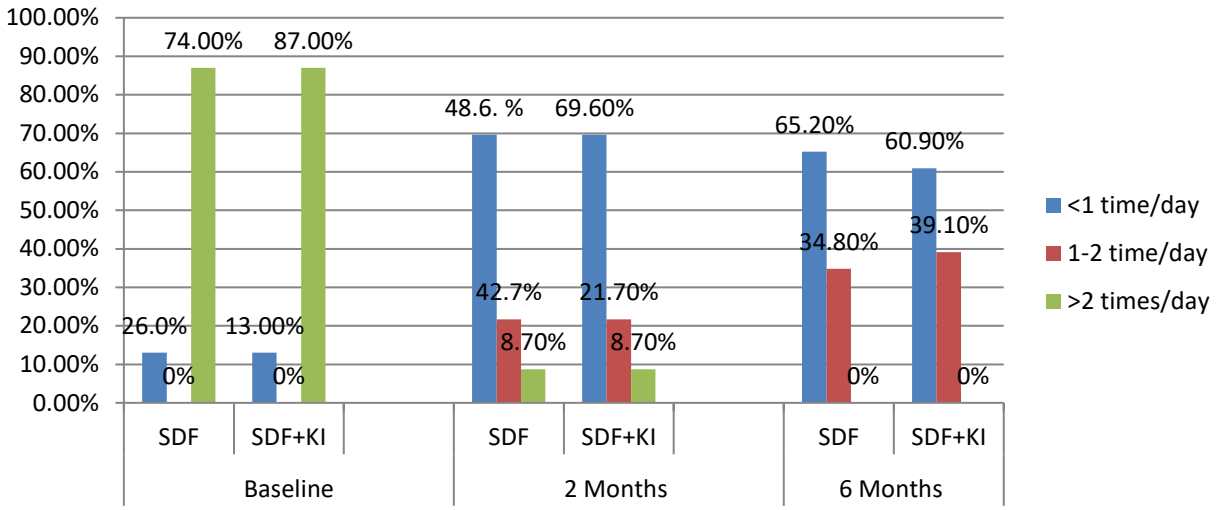
There was perfect inter observer agreement between observer 1 and observer 2 for the color assessment of the restored tooth surface at all time interval.



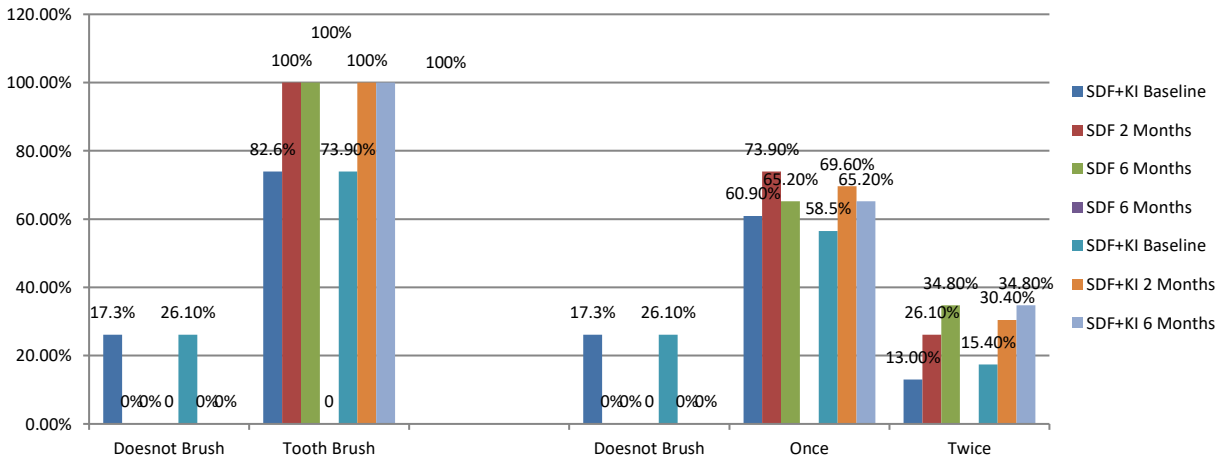
Graph 1: Color asssessment of the restored tooth surface in both groups



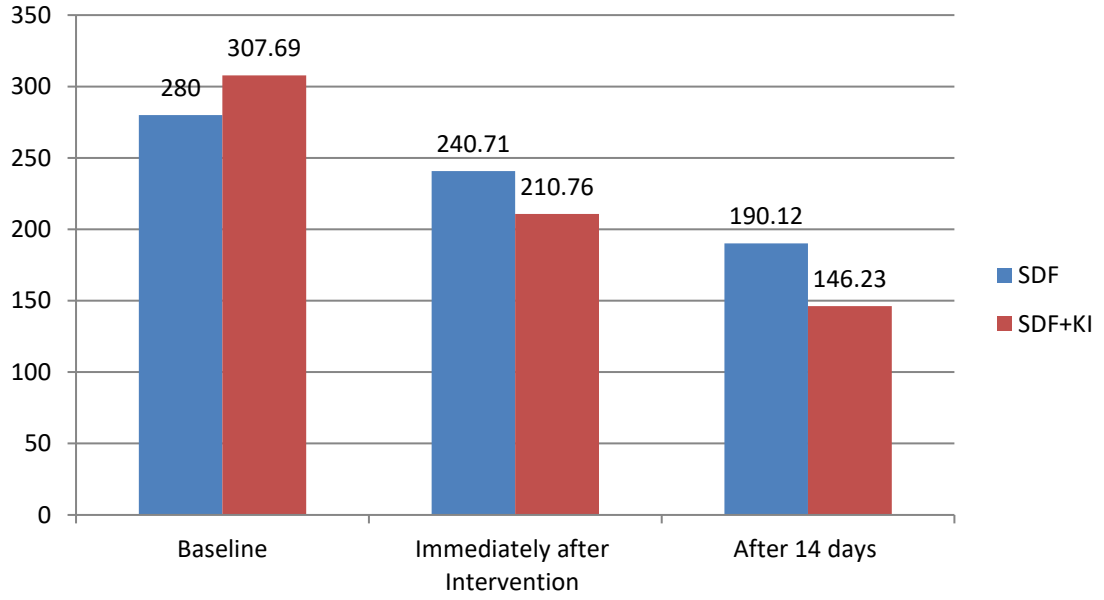
Graph 2: Distribution of subjects according of feeding habits in both groups



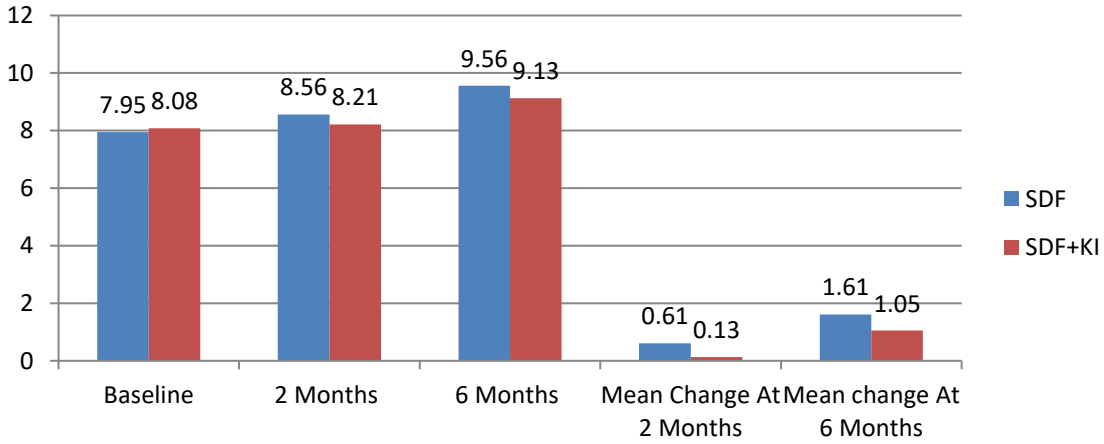
Graph 3: Distribution of subjects according to sugar and snack consumption in both groups



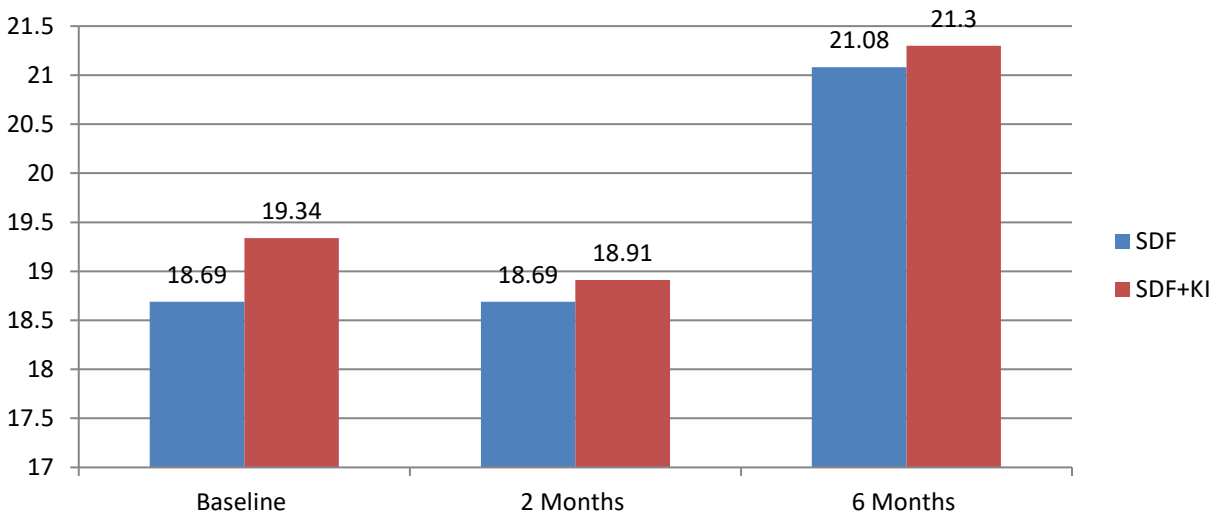
Graph 4: Distribution of subjects according to oral hygine practice in both groups



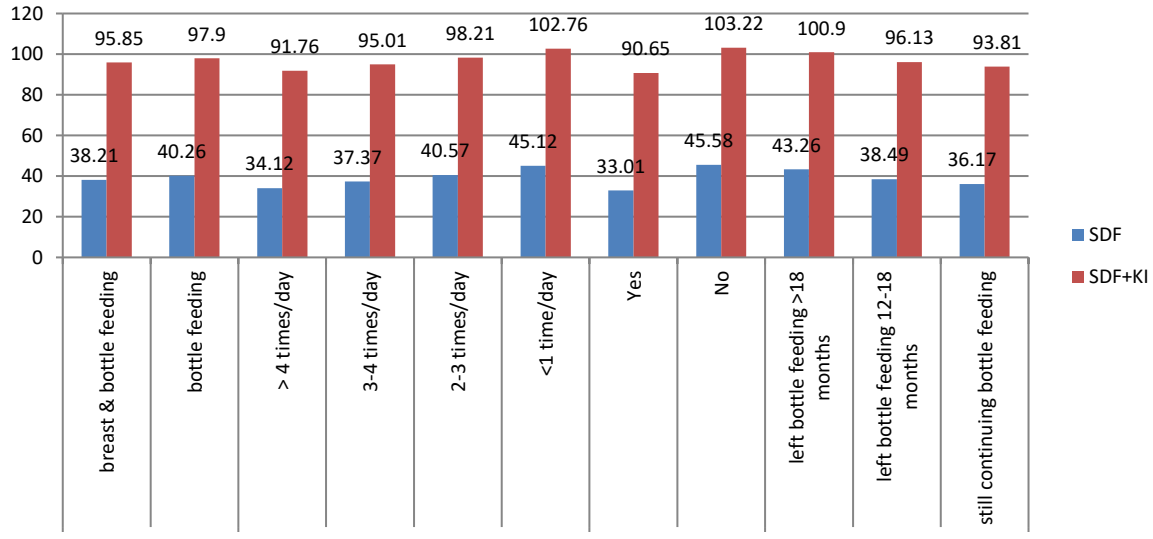
Graph 5: Change in mean CFU count in both groups



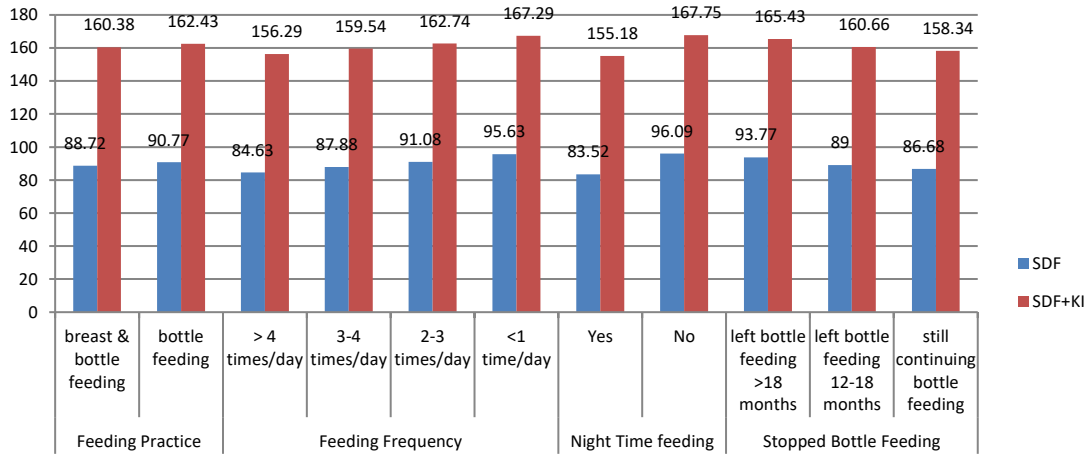
Graph 6: Change in mean dmft score in both groups



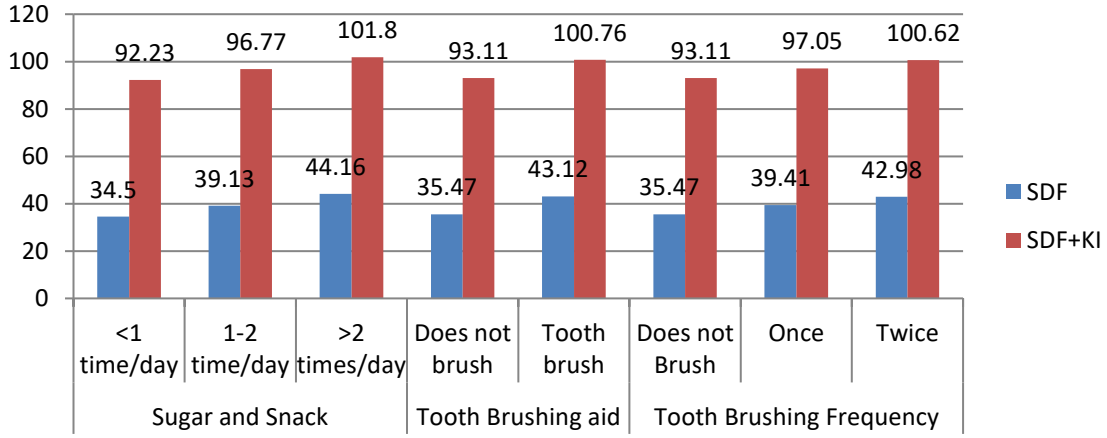
Graph 7: Change In Mean Sugar Score in both groups



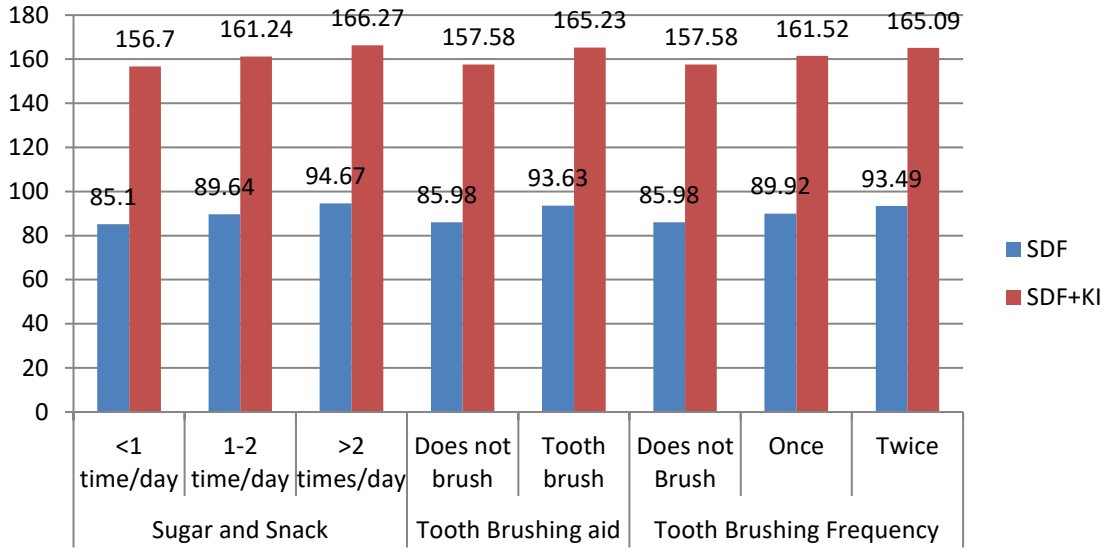
Graph 8: Correlation between CFU count and feeding habit at baseline and immediately after intervention



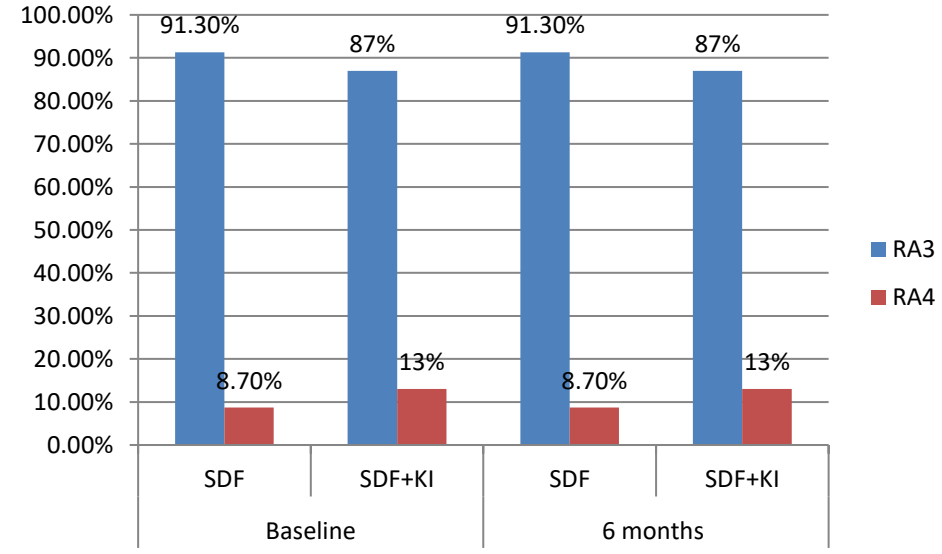
Graph 9: Correlation between CFU count and feeding habit at baseline and 14 days after intervention



Graph 10: Correlation between CFU count based on snacks consumption and oral hygine practice at baseline and immediately after intervention



Graph 11: Correlation between CFU count based on snacks consumption and oral hygine practice at baseline and 14 days after intervention



Graph 12: Progression of lesion in both group

DISCUSSION

This split mouth randomized contol trial was conducted to determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children between 3-5 years of age with early childhood caries, in the Department of Pediatric and Preventive Dentistry, BBDCODS, BBDU, Lucknow.

Silver diamine fluoride (SDF) has been used by dentists for a long time as an anti-caries agent in countries including Argentina, Australia, Brazil, China, and Japan.[66] Professor Misuho Nishino at Osaka University formulated a 38% silver diamine fluoride solution during her PhD studies in the 1960s.[67] Silver diamine fluoride is used to treat infected root canals, desensitize hypersensitive teeth, manage root caries, prevent pit and fissure caries, inhibit secondary caries, remineralize hypomineralized teeth, and prevent pit and fissure caries.[68,69,70] silver diamine fluoride was added to the WHO model list of essential medicines for adults and children in 2021.[71]

Silver diamine fluoride is colourless, alkaline in nature and has a pH between 9 and 10. It can be given a blue color to make application of silver diamine fluoride simple.[72] Silver fluoride is unstable, to create diamine silver fluoride [Ag(NH3)2+]F, ammonia is used. Compared to silver fluoride, diamine silver fluoride has a more stable linear structure. Silver diamine fluoride breaks down to silver under light irradiation, like the majority of silver compounds. Silver diamine fluoride must thus be kept in a bottle that is light-proof. In practical practise, it should be applied as soon as it is poured from the bottle.[68] 38% silver diamine fluoride solution includes 253,870 ppm silver and 44,800 ppm fluoride ions. 38% silver diamine fluoride solution is made up of 5% fluoride ions and 25% silver ions dissolved in an 8% ammonia solution.[73]

38% silver diamine fluoride is considered a standard care for arresting early childhood caries, but the significant drawback associated with silver diamine fluoride is the black stain on the surface of the tooth. Silver diamine fluoride is an effective supplementary therapy method for reducing caries in high-risk children, particularly in those who are

uncooperative, have medical conditions, or have logistical difficulties getting to a dentist who can provide them with comprehensive care.[74,75,76]

The present study was done with an aim to determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children. Based on the results obtained from the study 20% potassium iodide was found to be effective in significantly reducing black staining to a large extent after silver diamine fluoride application. **(Table 1 & Graph 1).** The formation of a layer of silver phosphate on the carious dentin is what causes the concerning black staining after silver diamine fluoride administration. Additionally, precipitates of silver sulphide can also occur, which contributes to the resultant staining.[77]

Similar findings were observed by **Zhao et al.(2017)**[78], **Patel et al.(2018)**[79], and **Zhao et al.(2019)**[80] they found statistically significant decrease in staining intensity when silver diamine fluoride was used in combination with potassium iodide. **Patel J et al.(2018)**[77] concluded that two minutes after silver diamine fluoride application, the black staining of carious dentine was clinically noticeable. They even stated that five minutes after application, the staining value gradually increased, and by four to six hours after treatment, the dentine and surrounding enamel developed a dark black stain. The stain's impact peaks 12 hours after application, and the tooth structure hardly continues to be stained beyond that.[77] However, **Miller et al.(2016)**[81] reported no change in the staining intensity between silver diamine fluoride and silver diamine fluoride with potassium iodide. Similarly **Li R et al.(2017)**[82] concluded that the dark staining was not reduced by the potassium iodide treatment. Different evaluation time points might be the cause of these varied outcomes. **Nguyen et al.(2017)**[83] observed that silver diamine fluoride with potassium iodide treated teeth showed little to no colour change over the course of 28 days, but the tooth surface restored with glass ionomer cement, resin modified glass ionomer cement and composite after the application silver diamine fluoride stained significantly with within hours**.**

Knight et al.(2005)[89] developed the new technique of using a saturated potassium iodide solution immediately after topical treatment of the dentine with silver diamine fluoride containing agents in order to resolve this significant staining. **Nguyen et al.(2017)**[87] and **Zhao et al.(2017)**[88], stated that silver diamine fluoride is used to arrest carious lesions, but when applied on the **anterior tooth or the margins of the restoration, it's** important **to** consider **the** possibility **of staining the enamel or** dentin.**Detsomboon rat P et al.(2022)**[22] concluded that in comparison to 15% potassium iodide soulution, the 20% potassium iodide group had the highest mean grey value. It was effective in reducing black staining.

According to the present study after silver diamine fluoride application maximum restored surface turned grey(69%) and (30%) of restored surface turned black, but 14 days after intervention (100%)of restored tooth surface turned black. Whereas in silver diamine fluoride followed by potassium iodide 91.35% of tooth surface were white immediately after intervention but the intensity of discoloration changed 14 days after intervention and 13% of restored surface turned grey and the intensity of discoloration increased in this group.(**Table 1 & Graph 1)** 20% potassium iodide was found to effective than other formulations of potassium iodide in a study conducted by **Detsomboonrat P et al.(2022)**[22]. Hence 20% potassium iodide solution was formulated by pharmacocopial method for the present study.

Our study was in accordance with **V. Nguyen(2016)**[84] they concluded that after the application of saturated solution of potassium iodide, the amount of black staining was significantly reduced; however, potassium iodide application had no long-term impact on the reduction of black staining after 7 days and 14 days. **Garg S et al.(2019)**[39] found that using saturated solution of potassium iodide after silver diamine fluoride significantly reduced staining immediately after restoration. However, some greying was observed during the 6-month follow-up. These results were consistent with the outcomes of present study. **Kamble AN et al.(2021)**[58] evaluated the effect of saturated solution of potassium iodide and gluthione after the application of silver diamine fluoride. They

concluded that silver diamine fluoride showed greatest amount of discoloration immediately after application, 1 week and 1 month after intervention but no change was noticed in silver diamine fluoride with potassium iodide and gluthione group. However **Primus et al.(2021)**[85] found no or minor colour change in silver diamine fluoride with saturated solution of potassium iodide treated teeth after 28 days, which contrasts with the current study results, which showed minimal discoloration in 38% silver diamine fluoride with potassium iodide group 2 months after intervention. **Aly MM et al.(2021)**[86] concluded from their study that using saturated solution of potassium iodide immediately post-operatively reduced the discoloration caused by silver diamine fluoride, but no statistically significant differences were seen at 1, 3, 6, and 12 months. Similarly in the present study 6 months after intervention majority of restored surface (76.2%) turned grey and 14.3% remained white. (**Table 1 & Graph 1**) It's possible that the silver iodide is photosensitive and darkens when exposed to flash photography light. It's likely that the silver ions from silver diamine fluoride and the iodide ions from potassium iodide combine to produce the yellowish-white substance known as silver iodide (AgI), which is insoluble in water. As a result, the use of potassium iodide can reduce silver diamine fluoride dark staining and solve the aesthetic issue.[50,51]

In the present study color assessment was done by visual method by two observer at different time interval**.** Two examiners assessed each lesion, in order to avoid individual judgmental error and low repeatability of results. Visual assessment method was used in present study, to assess the change in color of restored surfaces immediately after intervention, 14 days after intervention, two months after intervention and six months after intervention. Perfect inter observer agreement between both observers for the color assessment of the restored tooth surface was found. Visual method of color assessmet was used for present study as it was fesible and no additional arrmamtarium was required for this. **(Table 11-14)**

Similarly **Li et al.(2016)**[84] in their study used visual method for color assessment of the restored tooth surface. They had only one examiner who assessed each lesion, which resulted in individual judgmental error and repeatability of results. **Turton et**

al.(2021)[90] one examiner evaluated the efficacy of potassium iodide in reducing staining after silver diamine fluoride and silver fluoride (AgF) by visual colour assessment. At 6-month recall using a colour scale that includes 'yellow', 'light brown', 'dark brown', and 'black'.Majority of the teeth turned black after 6 months follow up. In contrast, the in-vitro investigations by **Nguyen et al.(2017)**[42] and **Zhao et al.(2019)**[91] used a colorimeter for colour assessment of the lesions using the CIELAB colour system. They found this approach highly precise and reliable in measuring tooth colour. **Patel et al.(2018)**[92], on the other hand, used digital image analysis programme to determine the mean grey value for colour evaluation and found it a reliable tool for assessing tooth color.

In the present study resin modified glass ionomer cement was used to restore the tooth surface after the application of 38% silver diamine fluoride with and with 20% potassium iodide. Resin modified glass ionomer cement has good mechanical property compared to glass ionomer cement. Significant staining on the margins of the restoration was seen after the application of 20% potassium iodide. Silver diamine fluoride releases free fluoride ions and silver ions when applied on the tooth surface. The release of silver precipitate causes black staining on the tooth or the restoration surface. However, no progression of lesion was seen on any of the restored surface. Due to the release of fluoride ions the progression of lesion was not enhanced. **(Table 11 & Graph 12)**

Li et al.(2019)[91] even stated that silver diamine fluoride followed by potassium iodide therapy prevented secondary caries formation on glass ionomer cement restorations, however it was less effective than silver diamine fluoride treatment alone. **Knight et al.(2006)**[93] evaluated the influence between silver diamine fluoride with potassium iodide and the adherence of dentin to glass ionomer cement and proposed that, so long as the silver diamine fluoride treated surface is washed with water, it would not affect the adhesive strength. **Zhao et al.(2019)**[80] concluded from their study that the adhesion of glass ionomer cement is unaffected by the immediate application of potassium iodide solution following silver diamine fluoride. Additionally, potassium iodide therapy reduce the discoloration induced by silver diamine fluoride on the demineralized dentine.

Adverse effects like staining of the mucosa, irritation to the soft tissue were also noted during the course of the study. Subjects were checked immediately and 1 hour post intervention. To prevent such events the underlying soft tissue was coated with petroleum jelly in none of the subject staining of the mucosa was seen. Staining was significantly observed adverse effect in both the groups.

Similarly, **Duangthip et al.(2018)**[114] found that silver diamine fluoride caries arrest therapy is safe for preschool children. Silver diamine fluoride does not cause acute or severe systemic disease. However, **Garg et al.(2019)**[39] stated that if soft tissue is not protected, adverse effects such as ulcerative gingivitis might arise, although the condition will resolve in 48 hours. They even stated >16mg of potassium iodide can result in adverse effects such as a metallic taste in the mouth, swollen glands, nausea, diarrhoea, vomiting, stomachache, and headache. If potassium iodide comes into contact with soft tissue, it can induce desquamation of the mucosa. In contrast, **Castillo et al.(2011)**[115] observed the occurrence of reversible localised gingival responses followed by silver diamine fluoride application.

The antibacterial activity of silver diamine fluoride was enhanced by the application of 20% potassium iodide, according to the current study. CFU count decreased immediately after intervention in both the silver diamine fluoride and silver diamine fluoride with potassium iodide group. The outcome from the current study demonstrated enhanced antibacterial efficacy of silver diamine fluoride with potassium iodide. Iodide is a highly effective topical antimicrobial agent. It penetrates into the microorganism and oxidizes key protein leading to cell death**.**[98] **(Table 5 & Graph 5)**

The amount of silver and fluoride ions in the 38 percent silver diamine fluoride solution used in this study was around 253,870 pm silver and 44,800 pm fluoride ions. Silver is known to interact with a variety of components present in bacterial cell walls, inducing cell lysis. The production of fructose and glucans, two essential polysaccharides for the development and growth of S. mutans biofilms, may be inhibited by silver, which can

also inactivate them. The enzyme activity of enolase and adenosine criphosphase (AT Pase) as well as the production of S. mutans biofilms can be inhibited by fluoride ions. These essential enzymes work in the process of glycolysis, which is a part of cellular respiration.[49]

Biofilm development and caries activity are often linked with microorganisms. The CFU counts wereis employed in present study to assess the material's efficacy. CFU is a cost-effective and industry-standard measurement of the number of viable bacterial cells in a sample used in microbiology. CFU was thus employed in the current study's microbiological examination.[60] .In several in vitro studies, the antibacterial properties of silver diamine fluoride in the management of caries have been shown to be highly efficient against bacteria.[60,88,74,99]

Our result were in accordance to study done by **Vinson L A et al.(2018)**[49] they found that saturated solution of potassium iodide possessed antibacterial activity. Similarly **I S Zhao et al.(2018)**[94] found that dentinal surfaces treated with SDF had significantly less growth of *Streptococcus mutans* than those without SDF treatment. Colony-forming unit (CFU) counts also showed decrease in count of *Actinomyces naeslundii* on the infected dentinal surface. **S Shah(2017)**[95] in their study stated that silver diamine fluoride is more effective in reducing S. mutans from the carious dentinal surface than silver nitrate or sodium fluoride. **Karched et al.(2019)**[43] in their study stated treatment of carious dentin with silver diamine fluoride and aqueous solution of potassium iodide reduced the total viable count of anaerobes greater than 95%, whereas mutans streptococci growth was completely inhibited.[43] **H Hammam(2015)**[38] concluded from their study that use of the silver diamine fluoride with saturated potassium iodide solution is effective in reducing the numbers of S. mutans in dentinal tubules infected with this organism.

Zhao IS(2017)[88] hypothetised that decreasing the concentration of silver ions and application of potassium iodide could reduce the antibacterial effectiveness of silver diamine fluoride however, the efficacy of 38% silver diamine fluoride was not affected. In contrast to our study, **Zhao IS et al.(2017)**[88], **Abdullah et al.(2020)**[96]and **Knight**

GM et al.(2005)[97], found that saturated solution of potassium iodide had no antibacterial effect on the microrganism causing dental caries.

According to the present study change in CFU score at different time interval was associated with feeding practice, oral hygine practice and sugar and snacks consumption in both silver diamine fluoride and silver diamine fluoride with potassium iodide group. Significant decrease in CFU count was seen in silver diamine fluoride with potassium iodide group when all the parameters were compared. The addition of 20% potassium iodide increases the efficacy of silver diamine fluoride by penetrating into the cell wall of the microorganism and causing lysis of the bacteria. This ultimate led to decrease in CFU count. (**Table8,9,10 & Graph 8,9,10**)

Yun M et al.(2019)[100`] stated children who started weaning at four to six months of age had a decreased probability of developing ECC than those who had food introductions later. According to **Yon Hyun Park(2022)**[101] nutrient supplements and the introduction of cow's milk were not significantly correlated with ECC experience. Night time breast-feeding was linked to an increased risk of developing dental caries, according to studies by **Kato T et al.(2015)**[103], **Peres KG et al.(2017)**[104] and **Du MQ et al.(2018)**[102].**Victoria et al.(2019)**[70] stated that extended breastfeeding for more than 12 months had been identified as a risk factor for ECC .

In the present study the subjects who were bottle fed for more than 3 times and had night time feeding habit in both silver diamine fluoride with and without potassium iodide showed decreased level of CFU count compared to breast feeding. Change in mean CFU count for silver diamine fluoride with potassium iodide group was more than silver diamine fluoride group when compared at different time interval. Statistical significant correlation was found between feeding practice, feeding frequency, night time feeding and age when the subjects stopped bottle feeding. (**Table8,9 & Graph 8,9**)

According to data compiled by **Tinanoff et al.(2019)**[98] from 72 international research conducted between 1998 and 2018. They found the mean ECC prevalence for children

aged 1, 2, and 3 was 17%, 36%, and 43%, respectively. **Boustedt K et al.(2020)**[99] concluded that frequency of tooth brushing and inappropriate brushing during the early years of preschoolers were important factors in the development of caries till the age of 5. In present study, regular dental checkup and tooth brushing was associated with arresting the progression of the lesion in both the groups. It would be incorrect to interpret these findings as indicating that tooth brushing frequency increased the risk of ECC or that neither was related to ECC experience.(**Table 10 & Graph 10**)

The change in colony forming unit was significantly associated with frequency of sugar and snacks consumption in between meal. However change in mean CFU count in silver diamine fluoride with potassium iodide group was comparatively higher than silver diamine fluoride group. The difference in both the groups was due to the presence of potassium iodide that causes the lysis of the bacteria. **(Table 10 & Graph 10)**

The worldwide nutritional revolution has resulted in an increase in children's consumption of processed meals high in carbohydrate and sugary drinks in recent decades.[105] The prevalence of ECC was positively correlated with per capita sugar intake globally, in middle income countries and high income countries but not in low income countries. Perhaps there is a dosage response relationship between sugar consumption and ECC, beyond which other variables, including access to healthcare or wholesome diets like fruits, vegetables, and milk, have a greater influence.[106]

According to **Skafida et al.(2018)**[107] and **Van Loveren(2019)**[108] both the quantity and frequency of sugar consumption are crucial factors in progression of ECC, however the frequency of sugar consumption may be more of a risk factor than the quantity of sugar. S**ilva et al.(2017)**[109], found 53.5% of 5-year-old children in Brazil had dental caries, and the progression of caries was associated with between-meal snacking.

Similar results were obtained from the present study in addition to traditional risk indicators for early childhood caries- poor oral hygine, sugar intake and snacking between meal was associated with development of early childhood caries in young

children in subsequent recall visits. In our study, the mean CFU score raised periodically in subjects who continued to consume snacks in between meal while receiving proper diet counselling.

In the present study strong association was observed between oral hygine practice, snack and sugar consumption and dmft score at different time interval. At baseline the dmft score for silver diamine fluoride and silver diamine fluoride with potassium iodide group was 7.95±2.47 and 8.08±2.48 respectively. Increase in dmft score for both the group was noted at 2 months and 6 months. The mean dmft score for silver diamine fluoride group was 0.61±1.03 and 1.61±1.95 and for silver diamine fluoride with potassium iodide group it was 0.13±0.87 and 1.05±1.32. The increase in dmft score could be due to the consumption of more snacks and sugar. (**Table 6,7 & Graph 6,7**)

In the present study the progression of leasion was seen at different time interval after the application of silver diamine fluoride with and without potassium iodide. Both silver diamine fluoride and silver diamine fluoride with potassium iodide were equally effective in arresting the progression of carious lession**.** Silver diamine fluoride releases free fluoride ions when applied on the tooth surface. Due to the release of fluoride ions the progression of lesion was not enhanced. **(Table 11 & Graph 12)**

Similar findings were obtained by **Knight et al.(2006)**[93] concluded that saturated solution of potassium iodide immediately after applying silver diamine fluoride, minimized the staining of the carious lesion, while the caries arresting effect of silver diamine fluoride is not affected. **Jaana Gold(2020)**[110] stated 38% silver diamine fluoride is a promising treatment for arresting the progression of carious lesions in young children. **Mei et al.(2013)**[111] in their in vitro study, found an increase in the mineral density and hardness of carious dentin, which was consistent with dentin remineralization. According to **Mabangkhru S(2020)**[112] at 12 month follow up, 38% silver diamine fluoride was found to be more effective than 5% NaF varnish in preventing dentin carious lesions in young children. In contrast, **Li et al.(2017)**[113] found

that silver diamine fluoride with potassium iodide therapy prevented secondary caries formation, although it was not as effective as silver diamine fluoride treatment alone.

The current study had a few drawbacks, including a small sample size and the colour evaluation of the restored surface, which might have been done using a light measuring device rather than simply observing it visually. Whereas, with regards to the strength of the study, it was an in vivo split mouth design study comparing the effectiveness of silver diamine fluoride with and without potassium iodide.

SDF topical application is simple, safe, inexpensive, and has the potential to both arrest and prevent dental caries in primary teeth, they may have a significant impact on reducing the burden of untreated dental disease in children. Both silver diamine fluoride and silver diamine fluoride with 20% potassium iodide were effective in arresting the progression of carious lesions in children with early childhood caries, the use of potassium iodide greatly reduced the discoloration of the restored surface. Marked discoloration was seen at the margins of restoration. Although silver diamine fluoride combined with potassium iodide is a reliable method to arrest the progression of dental caries, additional factors such as oral hygiene practice and frequency of snacking have been linked to the formation of new carious lesions.

CONCLUSIONS

The present split mouth randomized control trial was conducted in the Department of Pediatric and Preventive Dentistry, Babu Banarasi Das College of Dental Sciences, BBDU, Lucknow.

The following conclusions were drawn from the observations done during the course of the study:

1) Both 38% Silver diamine fluoride and 38% silver diamine fluoride with 20% potassium iodide were equally effective in arresting the progression of carious lesion.

2) 20% Potassium iodide solution was effective in reducing black discoloration produced by silver diamine fluoride on the infected dentinal surface. However the margins of the restored surface turned grey two months after intervention.

3) Antimicrobial activity of 38% silver diamine fluoride was enhanced by addition of 20% potassium iodide.

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ANNEXURE I

BABU BANARASI DAS COLLEGE OF DENTAL SCIENCES (FACULTY OF BBD UNIVERSITY), LUCKNOW

INSTITUTIONAL RESEARCH COMMITTEE APPROVAL

The project titled **"Comparative Evaluation of Staining Potential and Antimicrobial Activity of Silver Diamine Fluoride with and Without Potassium Iodide"** submitted by **Dr Needhi Singh** Post graduate student from the **Department of Pediatric and Preventive Dentistry** as part of MDS Curriculum for the academic year 2020-2023 with the accompanying proforma was reviewed by the Institutional Research Committee present on **12th October 2021** at BBDCODS.

The Committee has granted approval on the scientific content of the project. The proposal may now be reviewed by the Institutional Ethics Committee for granting ethical approval.

Prof. Vandana A Pant
Co-Chairperson

Prof. B. Rajkumar
Chairperson

ANNEXURE II

Babu Banarasi Das University
Babu Banarasi Das College of Dental Sciences,
BBD City, Faizabad Road, Lucknow – 226028 (INDIA)

Dr. Lakshmi Bala
Professor and Head Biochemistry and
Member-Secretary, Institutional Ethics Committee

Communication of the Decision of the IXth Institutional Ethics Sub-Committee

IEC Code: 13 **BBDCODS/04/2022**

Title of the Project: Comparative Evaluation of Staining Potential and Antimicrobial Activity of Silver Diamine Fluoride with and Without Potassium Iodide.

Principal Investigator: Dr Nidhi Singh **Department:** Pediatric and Preventive Dentistry

Name and Address of the Institution: BBD College of Dental Sciences Lucknow.

Type of Submission: New, MDS Project Protocol

Dear Dr Nidhi Singh,

The Institutional Ethics Sub-Committee meeting comprising following four members was held on 07th April, 2022.

1.	Dr. Lakshmi Bala Member Secretary	Prof. and Head, Department of Biochemistry, BBDCODS, Lucknow
2.	Dr. Amrit Tandan Member	Prof. & Head, Department of Prosthodontics and Crown & Bridge, BBDCODS, Lucknow
3.	Dr. Rana Pratap Maurya Member	Reader, Department of Orthodontics, BBDCODS, Lucknow
4.	Dr. Akanksha Bhatt Member	Reader, Department of Conservative Dentistry & Endodontics, BBDCODS, Lucknow

The committee reviewed and discussed your submitted documents of the current MDS Project Protocol in the meeting.
The comments were communicated to PI thereafter it was revised.

Decisions: The committee approved the above protocol from ethics point of view.

Forwarded by:

Lakshmi Bala

(Dr. Lakshmi Bala)
Member-Secretary
IEC

Member-Secretary
Institutional Ethic Committee
BBD College of Dental Sciences
BBD University
Faizabad Road, Lucknow-226028

(Dr. Puneet Ahuja)
Principal
BBDCODS

PRINCIPAL
Babu Banarasi Das College of Dental Sciences
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURE III

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105
(INDIA)

Consent Form (English)

Title of the Study: **COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE.**

Subject's Full Name…….

Date of Birth/Age ……
Address of the Subject…….
Phone no. and e-mail address……
Occupation: Student / Self Employed / Service / Housewife/Other (Please tick as appropriate)
Annual income of the Subject……
Name and of the nominees(s) and his relation to the subject..... (For the purpose of compensation in case of trial related death).

1. I confirm that I have read and understood the Participant Information Document dated ……..for the above study and have had the opportunity to ask questions. **OR** I have been explained the nature of the study by the Investigator and had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and given with free will without any duress and that I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.

3. I understand that the sponsor of the project, others working on the Sponsor‘s behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. However, I understand that my Identity will not be revealed in any information released to third parties or published.

4. I agree not to restrict the use of any data or results that arise from this study provided sucha use is only for scientific purpose(s).

5. I permit the use of stored sample (tooth/tissue/blood) for future research. **Yes [√] No [ ]**

6. I agree to participate in the above study. I have been explained about the complications andside effects, if any, and have fully understood them. I have also read and understood the participant/volunteer’s Information document given to me.

Signature (or Thumb impression) of the Subject/Legally AcceptableRepresentative:……..
Signatory‘s Name……. Date …….
Signature of the Investigator…… Date……..
Study Investigator‘s Name..... Date……..
Signature of the witness…… Date……..
Name of the witness……
Received a signed copy of the PID and duly filled consent form Signature/thumb impression of the subject or legally
Date……

Acceptable representative

ANNEXURE IV

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

PARTICIPANT INFORMATION DOCUMENT

1. **Study Title**

   COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE.

2. Invitation Paragraph

You are being invited to take part in a research study. Before you decide it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends, relatives and your treating physician/family doctor if you wish. Ask us for any clarifications or further information. Whether or not you wish to take part is your decision.

3. What is the purpose of the study?

To determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children.

4**. Why have I been chosen?**

You have been chosen for this study as you are fulfilling the required criteria for this study.

5. **Do I have to take part?**

Your participation in the research is entirely voluntary. If you do, you will be given this information sheet to keep and will be asked to sign a consent form. During the study you are still free to withdraw at any time and without giving a reason.

6. **What will happen to me if I take part?**

The participant will be benefited as the required dental treatment will be carried out once the local anaesthesia is effective. This will also help the patients to get the treatment done without pain, fear and anxiety.

7**. What do I have to do?**

This study requires treatment to be carried out only after the parent has given consent, and assent from the patient for the administration of local anaesthesia. Children of both the gender (male and female) with an age group of 5-16 years, requiring dental treatment categorized as ASA I and Frankl III and IV will be included in the study.

8. What is the procedure that is being tested?

This study is being carried out to determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and without potassium iodide in children. Children with early childhood caries of both gender ICDAS II score 3 or above will be selected for the study. Pre and post operative colony forming unit count will be done for each sample.

9. What are the interventions for the study?

Children with early childhood caries ICDAS II score 3 and above requiring treatment.

10. What are the side effects of taking part?

Although there are no reports of serious side effects of the procedure, but the participant may have dark stain on the tooth.

11. What are the possible disadvantages and risks of taking part?

There are no disadvantages of taking part in this study.

12. What are the possible benefits of taking part?

The participant will be benefited as this is an invasive technique and the chair side time is also very less.

13. What if new information becomes available?

If additional information becomes available during the course of the research you will be told about these and you are free to discuss it with your researcher, your researcher will tell you whether you want to continue in the study. If you decide to withdraw, your researcher will make arrangements for your withdrawal. If you decide to continue in the study, you may be asked to sign an updated consent form.

14. What happens when the research study stops?

Nothing will happen to the participants.

15. What if something goes wrong?

The problems/complaint will be handled by the HOD or the IRC. If something serious happens the institute will take care of the problems.

16. Will my taking part in this study be kept confidential?

Yes it will be kept confidential.

17. What will happen to the results of the research study?

The results of the study will be used to determine and compare caries preventive efficacy and staining potential of silver diamine fluoride with and

without potassium iodide in children. Your identity will be kept confidential in case of any report/publications.

18. Who is organizing the research?

The research is been done in the DEPARTMENT OF PEDIATRIC AND PREVENTIVE DENTISTRY, BBDCODS. The research is self -funded. The participants will have to pay for procedural charges as given by the institution.

19. Will the results of the study be made available after study is over?

Yes

20. Who has reviewed the study?

The HOD and the members of IRC/ IEC of the institution has reviewed and approved the study.

21. Contact for further information

Dr. Needhi Singh

Department of Pediatric and Preventive Dentistry

Babu Banarasi College of Dental Sciences.

Lucknow-227105

Mob- 6388500519

Dr. LaxmiBala

Member Secretary of Ethics Committee of the institution,

Babu Banarasi College of Dental Sciences.

Lucknow

bbdcods.iec@gmail.com

THANK YOU FOR TAKING OUT YOUR PRECIOUS TIME FOR READING THE DOCUMENTS AND PARTICIPATING IN THE STUDY.

Signature of PI……
Name…….
Date……..

ANNEXURE V

बाबू बनारसी दास कॉलेज ऑफ डेंटल साइंसेज

(बाबू बनारसी दास विश्वविद्यालय)

बीबीडी सिटी, फैजाबाद रोड, लखनऊ - 227105 (भारत)

प्रतिभागी सूचना दस्तावेज

अध्ययन शीर्षक

पोटेशियम आयोडाइड के साथ और बिना सिल्वर डायमाइन फ्लोराइड की संभावित और रोगाणुरोधी गतिविधि को धुंधला करने का तुलनात्मक मूल्यांकन।

2. आमंत्रण पैराग्राफ

आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि अध्ययन क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो दोस्तों, रिश्तेदारों और अपने इलाज करने वाले चिकित्सक/पारिवारिक चिकित्सक के साथ इस पर चर्चा करें।

3. अध्ययन का उद्देश्य क्या है?

बच्चों में पोटेशियम आयोडाइड के साथ और बिना सिल्वर डायमाइन फ्लोराइड की क्षरण निवारक प्रभावकारिता और धुंधला क्षमता का निर्धारण और तुलना करना।

4 **. मुझे क्यों चुना गया है?**

आपको इस अध्ययन के लिए चुना गया है क्योंकि आप इस अध्ययन के लिए आवश्यक मानदंडों को पूरा कर रहे हैं।

5. **क्या मुझे भाग लेना है?**

शोध में आपकी भागीदारी पूरी तरह से स्वैच्छिक है। यदि आप ऐसा करते हैं, तो आपको यह सूचना पत्रक रखने के लिए दिया जाएगा और सहमति प्रपत्र पर हस्ताक्षर करने के लिए कहा जाएगा। अध्ययन के दौरान आप किसी भी समय और बिना कोई कारण बताए वापस लेने के लिए स्वतंत्र हैं।

6. **यदि मैं भाग लेता हूँ तो मेरा क्या होगा?**

प्रतिभागी को लाभ होगा क्योंकि स्थानीय संज्ञाहरण प्रभावी होने के बाद आवश्यक दंत चिकित्सा उपचार किया जाएगा। इससे मरीजों को बिना दर्द, डर और चिंता के इलाज कराने में भी मदद मिलेगी।

7 **. मुझे क्या करना होगा?**

इस अध्ययन के लिए माता-पिता की सहमति के बाद ही उपचार किया जाना आवश्यक है, और स्थानीय संज्ञाहरण के प्रशासन के लिए रोगी की सहमति है। अध्ययन में 5-16 वर्ष के आयु वर्ग के लिंग (पुरुष और महिला) दोनों के बच्चों को शामिल किया जाएगा, जिन्हें एएसए I और फ्रैंकल III और IV के रूप में वर्गीकृत दंत चिकित्सा उपचार की आवश्यकता होती है।

8. किस प्रक्रिया का परीक्षण किया जा रहा है?

यह अध्ययन बच्चों में पोटेशियम आयोडाइड के साथ और बिना सिल्वर डायमाइन फ्लोराइड की क्षरण निवारक प्रभावकारिता और धुंधला होने की क्षमता को निर्धारित करने और तुलना करने के लिए किया जा रहा है। अध्ययन के लिए ICDAS II स्कोर 3 या उससे अधिक दोनों लिंगों के प्रारंभिक बचपन के क्षरण वाले बच्चों का चयन किया जाएगा। प्रत्येक नमूने के लिए प्री और पोस्ट ऑपरेटिव कॉलोनी बनाने वाली इकाई की गिनती की जाएगी।

9. अध्ययन के लिए क्या हस्तक्षेप हैं?

प्रारंभिक बाल्यावस्था वाले बच्चों में आईसीडीएएस II का स्कोर 3 और उससे अधिक होता है जिन्हें उपचार की आवश्यकता होती है।

10. भाग लेने के दुष्प्रभाव क्या हैं?

हालांकि प्रक्रिया के गंभीर दुष्प्रभावों की कोई रिपोर्ट नहीं है, लेकिन प्रतिभागी के दांत पर काले धब्बे हो सकते हैं।

11. भाग लेने के संभावित नुकसान और जोखिम क्या हैं?

इस अध्ययन में भाग लेने के कोई नुकसान नहीं हैं।

12. भाग लेने के संभावित लाभ क्या हैं?

प्रतिभागी को लाभ होगा क्योंकि यह एक आक्रामक तकनीक है और कुर्सी की तरफ का समय भी बहुत कम है।

13. क्या होगा यदि नई जानकारी उपलब्ध हो जाती है?

यदि शोध के दौरान अतिरिक्त जानकारी उपलब्ध हो जाती है तो आपको इनके बारे में बताया जाएगा और आप अपने शोधकर्ता के साथ इस पर चर्चा करने के लिए स्वतंत्र हैं, आपका शोधकर्ता आपको बताएगा कि क्या आप अध्ययन जारी रखना चाहते हैं। यदि आप वापस लेने का निर्णय लेते हैं, तो आपका शोधकर्ता आपकी वापसी की व्यवस्था करेगा। यदि आप अध्ययन जारी रखने का निर्णय लेते हैं, तो आपको एक अद्यतन सहमति फॉर्म पर हस्ताक्षर करने के लिए कहा जा सकता है।

14. जब शोध अध्ययन बंद हो जाता है तो क्या होता है?

प्रतिभागियों को कुछ नहीं होगा।

15. अगर कुछ गलत हो जाए तो क्या होगा?

समस्याओं/शिकायतों को एचओडी या आईआरसी द्वारा नियंत्रित किया जाएगा। अगर कुछ गंभीर होता है तो संस्थान समस्याओं का ध्यान रखेगा।

16. क्या इस अध्ययन में मेरे भाग लेने को गोपनीय रखा जाएगा?

हां इसे गोपनीय रखा जाएगा।

17. शोध अध्ययन के परिणामों का क्या होगा?

अध्ययन के परिणामों का उपयोग बच्चों में पोटेशियम आयोडाइड के साथ और बिना सिल्वर डायमाइन फ्लोराइड की क्षरण निवारक प्रभावकारिता और धुंधला होने की क्षमता को निर्धारित करने और तुलना करने के लिए किया जाएगा। किसी भी रिपोर्ट/प्रकाशन के मामले में आपकी पहचान गोपनीय रखी जाएगी।

18. शोध का आयोजन कौन कर रहा है?

यह शोध बाल चिकित्सा और निवारक दंत चिकित्सा विभाग, बीबीडीसीओडीएस में किया गया है। शोध स्व-वित्त पोषित है। प्रतिभागियों को संस्था द्वारा दिए गए प्रक्रियात्मक शुल्क का भुगतान करना होगा।

19. क्या अध्ययन समाप्त होने के बाद अध्ययन के परिणाम उपलब्ध कराए जाएंगे?

हां

20. अध्ययन की समीक्षा किसने की है?

संस्थान के एचओडी और आईआरसी/आईईसी के सदस्यों ने अध्ययन की समीक्षा की और उसे मंजूरी दी।

21. अधिक जानकारी के लिए संपर्क करें

डॉ निधि सिंह

बाल चिकित्सा और निवारक दंत चिकित्सा विभाग

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ-227105

मोब- 6388500519

डॉ. लक्ष्मीबाला

संस्था की आचार समिति के सदस्य सचिव,

बाबू बनारसी कॉलेज ऑफ डेंटल साइंसेज।

लखनऊ

bbdcods.iec@gmail.com

दस्तावेजों को पढ़ने और अध्ययन में भाग लेने के लिए अपना कीमती समय निकालने के लिए धन्यवाद।

पीआई के हस्ताक्षर .....

नाम.....।

तारीख.....

ANNEXURE VI

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105

(INDIA)Child Information

Study title: – COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE.

Document

Introduction

Describe briefly the purpose of this study

We invite you to participate in this study.

What will you have to do?

To participate in this research study, you will be interviewed/ examined by Dr. Needhi Singh and if found to fulfill pre-specified criteria, you will be eligible to be enrolled inthis research study.

Since you are in the age group of 8-18 years we ask your accompanying parent / guardian will also sign a similar form called as the Parent Informed Consent Form.

List all procedures, which will be employed in the study. Point out any that are considered experimental/or otherwise, and explain technical and medical terminology in simple, nontechnical & direct language.

In addition, to record the same parameters daily your parent / guardian will also be provided with a diary where they will enter the same findings accordingly. You will have to tell them about your symptom and they will mark accordingly in the diary

Risks and discomforts

There is no foreseen significant risk / hazard to your health, if you wish to participate in the study. If you follow the directions of the …….. in charge of this study and you are injured due to any procedure given under the study plan, the Sponsor will pay for the medical expenses for the treatment of that injury.

Benefits

If you participate in the study you will receive ……If you appear to have any acute illness ……you will be offered free treatment for those visits in accordance with local standard medical care. You will not be offered free treatment for chronic diseases or conditions not related to study procedures.

Your participation in the study may help others, because this participation will help us determine if the study drug/procedure is safe.

Confidentiality

Your existing medical records may be accessed; personal health information about you may be collected and processed by study investigators for the purpose of performing the study. Information about you will be collected and stored in files with an assigned number,

Your parent / guardian will have the right to access personal information about you at any time with the study doctor and the right to correct this personal information. Your parent / guardian can take away your authorization to collect process and disclose data about you at any time.

Right to refuse or withdraw

You do not have to take part in this research if you do not wish to do so. You may stop participating in the research at any time you wish. The study investigator may decide to withdraw you from the study if he/she considers it is in your best interest

You will be informed of important new findings developed during the course of the studyso you will be able to consider your participation in the study in light of new information **Parents responsibilities**

It is the responsibility of your parent / guardian to come along with you to the centre duringthe study period for all the visits unless you withdraw or are prematurely discontinued from the study. It is also your responsibility and your parent / guardian to report any expected or unexpected reactions (side effects) that you notice during the study period.

We expect your co-operation throughout the study.

ANNEXURE VII

Babu Banarasi Das College of Dental Sciences

(Babu Banarasi Das University)

BBD City, Faizabad Road, Lucknow – 227105 (INDIA)

1. Title of the project: **COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE.**

2. Name of the department/ address of the investigator: **Department Of Pediatric And Preventive Dentistry**

3. Name of Faculty (Guide/Co-Guide) with designation and department: **Dr. Monika Rathore, Head of Department, Department of Pediatric and Preventive Dentistry, Dr Rajiv Gupta, Dean, College of Pharmacy, bbdu**

4. Date of approval by Institutional Research Committee (IRC) (Pl enclose approval letter along with finally approved research proposal): **12th October 2021**

5. Sources of funding: **Self**

6. Study related information:

(i) Place of Study:

(a) BBDU √

(ii) *In-vitro studies on human subjects*: Please specify if it is body fluid blood/tissues/ teeth.

(a) Bile, Saliva etc. [ ]

(b) Teeth, please specify type [ ]

(c) Tissue, please specify type [ ]

(d) Use of stored or left over specimens [ ]

(e) Any other [ ]

(iii) *In-vivo* study on human subjects:

(a) Intervention [√]

(b) Drugs [ ]

(c) Implants [ ]

(d) Any other e.g. X-rays/ultrasound/etc [ ]

(vi) Vulnerable subjects.

(a) Pregnant Woman [ ]
(b) Elderly [ ]
(c) Terminally ill [ ]
(d) Physically/ mentally challenged [ ]
(e) Children under 18 [ ]
(f) Students [ ]
(g) Orphans [ ]

(vii) Survey of human subject:

(a) Verbal questionnaire [ ]
(b) Non- invasive examination [ ]
(c) Invasive procedures [ ]

(viii) SEA (Sereve Adverse Events) reporting:

(a) Is there a plan for reporting of adverse events [ ]
If yes it will be done to Institution (s) [ ] IEC [ ] All [ ]

7. Ethical issues involved in the study:
Less than minimal risk/ minimal risk/ more than minimal risk to the study subjects (for guidance please consult ICMR guidelines 2006)

8. Do you need exemption from obtaining Informed Consent from study subject – if so give justifications

In following cases exemption can be requested:

a. Audits of educational practices.
b. Research on microbes cultured in the laboratory.
c. Research on immortalized cell lines.
d. Computer Simulation and Dental Materials
e. Analysis of data freely available in public domain.
f. Any other.

9. Whether Consent forms and Participant Information Document in English and in Hindi are enclosed?

10. Conflict of interest for any other investigator(s) (if yes, please explain in brief)

11. We the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigator: Date:

Signature of the Guide & Co- Guide of the Department: Date:

Signature of the Head of the Department: Date

(Note: The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

ANNEXURE VIII

BABU BANARASI DAS UNIVERSITY
[Approved by UGC Under Section 2(f) of UGC Act. 1956]
Website : www.bbdu.ac.in / Email ID : info@bbdu.org
Phone Number: +91 - (522) - 6196222 / 6196223

Ref.No.: BBDCODS/BBDU/2023/042 Date: 07th February, 2023

TO WHOM IT MAY CONCERN

This is to certify that **Dr. Needhi Singh** is a bonafide student of the M.D.S program (2020-23) in the department of **Pediatric and Preventive Dentistry**, BBD College of Dental Sciences. She is conducting a study titled **"COMPARATIVE EVALUATION OF STAINING POTENTIAL AND ANTIMICROBIAL ACTIVITY OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE"** in collaboration with College of Pharmacy, BBDU, Lucknow under the guidance of **Dr. Monika Rathore**, Professor and Head, Pediatric and Preventive Dentistry and **Dr. Rajiv Gupta**, Dean, College of Pharmacy, BBD University.

Prof. Dr. Puneet Ahuja
Principal
BBD College of Dental Sciences
BBD University, Lucknow

PRINCIPAL
Babu Banarasi Das College of Dental Science
(Babu Banarasi Das University)
BBD City, Faizabad Road, Lucknow-226028

ANNEXURE IX

CASE HISTORY

DATE:

OPD NO:

PATIENT'S NAME: AGE: SEX: M / F

GUARDIAN NAME:

DATE & PLACE OF BIRTH:

ADDRESS:

PHONE NO.:

I. CHIEF COMPLAINT:

II. HISTORY OF PRESENTING ILLNESS:

RISK FACTORS

III. MEDICAL HISTORY:

Pre term (Before 37 weeks of gestation):

IV. DENTAL HISTORY:

Age of first dental visit:

Dental visit frequency:

V. PARENTAL FACTORS:

Socio economic status:

Parental education:

VI. PERSONAL HISTORY:

Oral hygiene practices:

1. Type of cleaning: Toothbrush/ Finger/ Twig/_____
2. Type of toothbrush: Soft/Medium/Hard
3. Methods of cleaning: Horizontal/ Vertical/ Combination/Circular
4. Material used: Toothpaste/Tooth powder /Sand/Brick Powder/Charcoal/_____
5. Frequency of cleaning per day: Once/ Twice/ Thrice
6. Duration of cleaning: 1-2 mins/ 2-3 mins/ >4mins
7. Time of brushing: Morning / Afternoon / Night

   Before meals/ After meals
8. Frequency of changing toothbrush:
9. Any other oral hygiene aid used:

Dietary habits:

10. Type of diet: Vegetarian/ Mixed
11. Diet restrictions:
12. source of water:
13. Water intake**:**
14. **Snacks consumption frequency: ≤ 1 /day , ≥2/day**

24 hours recall Dietary Chart:

S NO.	Time	Item

S NO.	Form		Frequency	Points
	Liquids		X5	
	Solid & sticky		X10	
	Slowly dissolving		X15	
		Total score		

Sugar Consumption (Per Day):

Type: Frequency:
Time of intake: Form and consistency:

Sweet score:

5 or less : Excellent 10: Good 15 or more: "Watch out" zone

C) **HISTORY OF FEEDING**

Stopped bottle/breast feeding : 12 months/12-18 months/ >18 months

Feeding practice: Bottle use/ Breast feeding on demand

Feeding Frequency: 2-3 times a day/ 3-4 times a day/ >4 times a day

Night time feeding habit: Yes/No

Water consumption followed by bottle/breast feeding: Yes/No

Weaning age:

VII. GENERAL EXAMINATION:

GAIT:

POSTURE:

HEIGHT:

WEIGHT:

BMI:

VIII. LOCAL EXAMINATION:

EXTRA ORAL

Facial symmetry:

T.M.J:

Lymph Node:

Lip Competency:

INTRA ORAL

Tongue:

Floor of mouth:

Palate:

Hard Tissue

Teeth present:

Dental caries:

Incipient caries:

Enamel/Dentinal caries

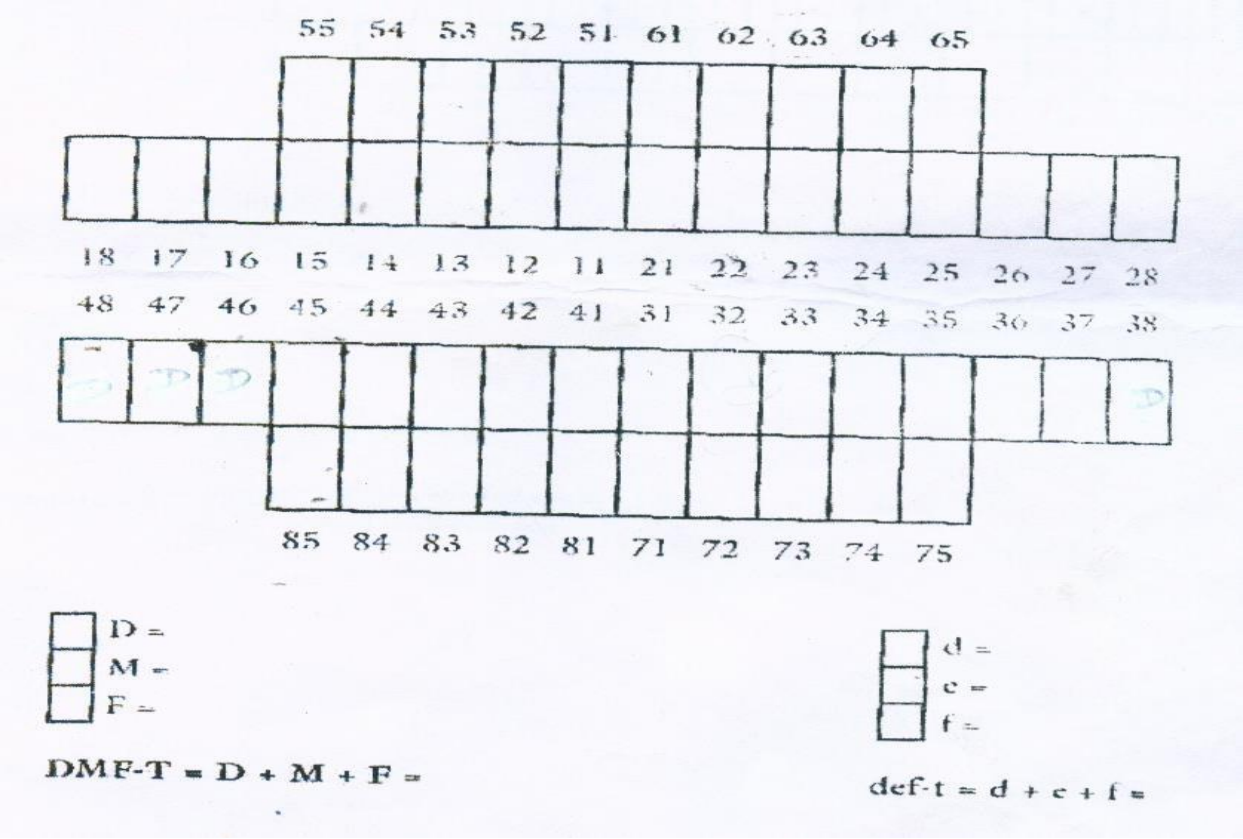
Pulpally involved:

Missing teeth:

Filled teeth:

Root stumps:

Tender on percussion:



DMFT

Enamel hypoplasia:

Dental Fluorosis:

Occlusion: Flush Terminal Plane/ Mesial Step/ Distal Step

Periodontal Status:

Stains: Calculus:

IX. PROVISIONAL DIAGNOSIS:

X. INVESTIGATION:

XI. DIAGNOSIS:

XII. RADIOGRAPHIC INTERPRETATION:

XIII.TREATMENT PLAN:

Emergency phase:

Promotive phase:

Preventive phase:

Curative phase:

Rehabilitative phase:

Maintenance phase – Periodic recall:

ANNEXURE X

ICDAS II

Score 0	Score 1	Score 2	Score 3	Score 4	Score 5	Score 6
No visual signs of carious lesions or any enamel defect	First visible changes in the enamel. Visible only after drying with air. Changes in coloration confined to areas of pits	Change in visible enamel even in the presence of moisture. More extensive and not restricted to pits.	Destruction located in enamel without visible dentin, discontinuities of enamel surface	Dark shadow on the underlying dentin, with or without localized destruction of enamel	Clear cavity with visible dentin; cavity that involves less than half the dental surface	Extensive cavity evident in dentin; cavity deep and wide, involves more than half of the tooth
						

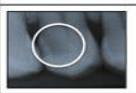
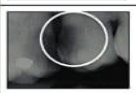
ICCMS™ Caries Categories		ICDAS Radiographic scoring system		
	0	**No radiolucency**		No radiolucency
	RA: Initial stages	**RA 1**		Radiolucency in the outer ½ of the enamel
		RA 2		Radiolucency in the inner ½ of the enamel ± EDJ (enamel-dentine junction)
		RA 3		Radiolucency limited to the outer 1/3 of dentine
	RB: Moderate stages	**RB 4**		Radiolucency reaching the middle 1/3 of dentine
	RC: Extensive stages	**RC 5**		Radiolucency reaching the inner 1/3 of dentin, clinically cavitated
		RC 6		Radiolucency into the pulp, clinically cavitated

Table 3. ICDAS/ICCMS™ radiographic scoring system.

ANNEXURE XI

COLOR ASSESSMENT CRITERIA

SCORE	COLOR
0	WHITE

1	**YELLOW**
2	**LIGHT BROWN**
3	**DARK BROWN**
4	**BLACK**

ANNEXURE XII

STATISTICAL ANALYSIS TOOLS

The data for the present study was entered in the Microsoft Excel 2007 and analyzed using the SPSS statistical software 23.0 Version. The descriptive statistics included mean, standard deviation . The level of the significance for the present study was fixed at 5%.

The intergroup comparison for the difference of mean scores between independent groups was done using the unpaired/independent t test and frequencies wer compared using Chi Square test

Mean

$$\overline{X} = \frac{\Sigma X}{N}$$

Where:

$\overline{X}$ = the data set mean

$\sum$ = the sum of

X = the scores in the distribution

N = the number of scores in the distribution

Range

$$range = X_{highest} - X_{lowest}$$

Where:

$X_{highest}$ = largest score

X_{lowest} = smallest score

Variance

$$SD^2 = \frac{\Sigma(X - \overline{X})^2}{N}$$

The simplified variance formula

$$SD^2 = \frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}$$

Where:

SD^2 = the variance

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Standard Deviation (N)

$$SD = \sqrt{\frac{\Sigma(X - \overline{X})^2}{N}}$$

The simplified standard deviation formula

$$SD = \sqrt{\frac{\Sigma X^2 - \frac{(\Sigma X)^2}{N}}{N}}$$

Where:

SD = the standard deviation

$\sum$ = the sum of

X = the obtained score

$\overline{X}$ = the mean score of the data

N = the number of scores

Independent t-test

Independent t Test can be used to determine if two sets of data are significantly different from each other, and is most commonly applied when the test statistic would follow a normal distribution. The independent samples *t*-test is used when two separate sets of independent and identically distributed samples are obtained, one from each of the two populations being compared

$$t = \frac{\overline{X}_1 - \overline{X}_2}{\sqrt{\left(\frac{(N_1 - 1)s_1^2 + (N_2 - 1)s_2^2}{N_1 + N_2 - 2}\right)\left(\frac{1}{N_1} + \frac{1}{N_2}\right)}}$$

Where X1 =Mean of the first Group, X2 =Mean of the Second Group

Chi Square Test

Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis. When an analyst attempts to fit a statistical model to observed data, he or she may wonder how well the model actually reflects the data. How "close" are the observed values to those which would be expected under the fitted model? One statistical test that addresses this issue is the chi-square goodness of fit test. This test

is commonly used to test association of variables in two-way tables, where the assumed model of independence is evaluated against the observed data. In general, the ***chi-square test statistic*** is of the form

$$X^2 = \sum \frac{(\text{observed - expected})^2}{\text{expected}}$$

.

If the computed test statistic is large, then the observed and expected values are not close and the model is a poor fit to the data

ANNEXURE XIII

PLAGARISM REPORT

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