“EVALUATION OF PATIENT SATISFACTION LEVEL AND STREPTOCOCCUS MUTANS COLONY COUNT FOLLOWING A SINGLE APPLICATION OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE AMONG COMMUNITY DWELLING GERIATRIC POPULATION IN CHENNAI CITY- AN INTERVENTIONAL STUDY.”

Dissertation Submitted to

THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

In Partial Fulfillment for the Degree of

MASTER OF DENTAL SURGERY

BRANCH VII

PUBLIC HEALTH DENTISTRY

MAY 2022

THE TAMIL NADU Dr. MGR MEDICAL UNIVERSITY
CHENNAI

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And

DR. P. D. MADAN KUMAR, MDS, aged 44 years, working as Professor and Head of the Department of Public Health Dentistry at the college, having address at Department of Public health dentistry, Ragas Dental college and hospital, (herein after referred to as the 'Researcher and Principal investigator')

And

DR. P.IYAPPARAJA, MDS, aged 33 years, working as Reader of the Department of Public Health Dentistry at the college, having address at Department of Public health dentistry, Ragas Dental college and hospital, (herein after referred to as the 'Guide')

And

DR. C. RAJKUMAR, aged 27 years, currently studying as Post Graduate student in the Department of Public Health Dentistry (herein after referred to as the 'PG/Research student and Co- investigator').

Whereas the 'PG/Research student as part of his curriculum undertakes to research on the study titled **"EVALUATION OF PATIENT SATISFACTION LEVEL AND STREPTOCOCCUS MUTANS COLONY COUNT FOLLOWING A SINGLE APPLICATION OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE AMONG COMMUNITY DWELLING GERIATRIC POPULATION IN CHENNAI CITY- AN INTERVENTIONAL STUDY."** for which purpose the Researcher and Principal investigator shall act as Principal investigator and the College shall provide the requisite infrastructure based on availability and also provide facility to the PG/Research student as to the extent possible as a Co-investigator

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Truly,

Dr. C. Rajkumar.,

ABSTRACT

AIM:

To assess the patient satisfaction level, and *Streptococcus mutans* colony count following a single application of Silver Diamine Fluoride (SDF) with and without Potassium Iodide (KI) among community dwelling geriatric population in Chennai.

OBJECTIVES:

1. To assess subjectively the colour changes of root caries lesions on a single application of SDF with and without KI using standard digital photograph taken by digital single lens reflex camera-canon EOS 70D. **2.** After 7 days, to evaluate the patient's satisfaction level with the appearance of their carious teeth following a single application of SDF with and without KI application (Visual Analogue Scale-VAS), **3.** To evaluate the colony count of *Streptococcus mutans* following a single application of SDF with and without KI solution (digital colony counter).

METHODOLOGY:

An interventional study consisting of 40 geriatric participants with age group of 65 or over the 65 years or more and those who met the eligibility criteria were included. The participants were divided into two groups of 20 participants each (group-1) 38% of Silver Diamine Fluoride varnish

(FAgamin) was applied onto the dental caries lesions, (group-2) 38% of SDF followed by Potassium iodide solution (Riva Star) was applied onto the dental caries lesion. The patient's satisfaction level was measured by using Visual Analog Scale (1921) and *Streptococcus mutans* were cultured using Potassium Tellurite Hydrate 90% & Mitis Salivarius Agar Base and *Streptococcus mutans* colony counts of two different groups were measured using digital colony counter.

RESULTS

The results of this study revealed that, the mean colony count of *Streptococcus mutans* in SDF group at baseline and after 7 days was 1040.50 CFU/ml and 700.90 CFU/ml respectively with a statistical significant difference in their mean CFU/ml values. The mean CFU/ml count of *Streptococcus mutans* in SDF with KI group at baseline and 7 days after intervention was 1202.20 CFU/ml and 857.30 CFU/ml respectively with a statistical significant difference in their mean CFU/ml values. The tooth colour satisfaction level of subjects between both groups showed that most of the participants in the SDF with KI group expressed better satisfaction compared to those in the SDF group.

CONCLUSION

This study concluded that the applications of 38% SDF solution and SDF/KI solution effectively reduced the *Streptococcus mutans* colony count at

7 days follow-up, and the application of KI did not affect the antimicrobial effect of SDF on *Streptococcus mutans*. Further SDF with KI group participants had higher satisfaction level compared to SDF group participants.

KEYWORDS:

Geriatric population, Potassium Iodide, Silver Diamine Fluoride, *Streptococcus mutans,* Satisfaction level.

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INTRODUCTION

Ageing is an unavoidable process, and it is generally measured by chronological age. As a convention, a person aged 60 years or more is often referred to as 'elderly'[1]. Worldwide peoples are living longer because of the increased life expectancy and constant decline in fertility rates. This demographic change has resulted in increasing numbers and proportions of people who are over sixty [1, 2]. However, changes to this conventional way of addressing the ageing population are being continually suggested to incorporate a comprehensive outlook of their social, cultural and medical needs.

According to World Health Organization (2019), the number of people aged 60 years and older was 1 billion. This number is predicted to be 1.4 billion by 2030 and by 2050; it is expected to cross 2.1 billion. This demographic shift is occurring at an unprecedented pace and it will speed up in the upcoming decades, mainly in the developing countries [1].

In India, this trend is likely to be continued in the upcoming decades. The age of sixty and above which shared 8% of population in 2015 might be over 19% in 2050. By the end of this century, the elderly will be nearly 34% of the total population of our country (Caring for Our Elders: Early Responses India Ageing Report – 2017) [3, 4].

World Health Organization addressed the common health conditions in elderly people include hearing loss, cataracts and refractive errors, back, neck pain and osteoarthritis and chronic obstructive pulmonary disease. Ageing gives both challenges and opportunities. It increases the need for primary health care and long-term care, require a larger and better trained workforce and intensify the need for physical and social environments to be made more age-friendly[5,6].

The Global strategy and action plan on ageing and health 2016–2020 and the related Decade of Healthy Ageing, 2020–2030 have suggested response in the following four action areas: change how we think, feel and act towards age and ageing, ensure that communities foster the abilities of older people, deliver person-centred integrated care and primary health services responsive to older people, and provide access to long-term care for older people who need it [3, 7].

In line with these, the oral health burden among the elderly group includes untreated dental caries, severe periodontitis, and toothlessness [7, 8]. This untreated dental caries and poor oral hygiene negatively impacts on the elderly's quality of life, especially because of the pain experience, loss of teeth which can lead to psychological and physical discomfort, social disability and even handicap [7].

In a survey by Raja et al., (2004) in Bengaluru city, India, around half of community-dwelling elders had root caries experience with a prevalence ranging from 36% to 67% [9]. In India, Hariyani et al., (2011) demonstrated that

the annual incidence of root caries in this population was 18.25%, it was also observed that there was an increase of root caries lesions over time even among healthier older adults [10]. The WHO also considered root caries as one of the common oral diseases among the elderly people and recommended that countries adopt strategies for improving the oral health of elderly populations as soon as possible [10, 11, 12].

Root caries is defined as a soft, progressive lesion that is found anywhere on the root surface that has lost its connective tissue attachment and is exposed to oral environment[13]. Root caries is a multifactorial disease that can cause major clinical problem such as pain, discomfort, or tooth loss in the geriatric population and might have negative impacts on oral health-related quality of life [14].

This root caries occurs as a sequel of gingival recession which in turn exposes the root surfaces to the oral environment, making them vulnerable to root caries formation. The primary risk factors for root caries are the exposure of the root surface by gingival recession, reduction of salivary flow, inadequate oral hygiene, sucrose rich diet, and the inappropriate use of removable partial dentures [13, 14, 15]. Also the diagnosis of root caries is a problematic issue as it is not easy to distinguish the clinically accessible sound area and the carious lesion. Lesions often extend to proximal surfaces and sometimes sub-gingival area. Management of such lesion is quite difficult in removing the carious lesion and also to control the moisture during the restorative placement.

Therefore, prevention of root caries is one of the crucial factors to promote oral health for the geriatric population [13, 14, 15].

According to Yasuko Momoi et al., (2016), root caries should be managed differently with a shift from conventional strategy of "early-detection and early-treatment" to "early-detection and long-term management"[16]. Once the restorative treatment is chosen, it is often more advantageous to use Glass-ionomer than resin composite. It is critical to prevent root caries among geriatric people, particularly those who are institutionalized. Therefore non-surgical intervention has been advocated for treat the shallow root caries lesions. In addition, now days as we face an aged and older society, the use of silver diamine fluoride (SDF) with high demineralization inhibitory and antimicrobial effect is being re-evaluated as the "rescue material" for root caries [16].

The topical application of fluoride agents is a conservative treatment and a potentially good alternative to the surgical approach. Fluorides have been proved to be the single most effective weapon in the still limited arsenal of anti-caries agents in the last 60 years. Studies also conclude that the preventive effects of fluoride are almost exclusively topical [16].

Since 1969, Silver Diamine Fluoride (SDF), Ag (NH3) 2F, has been used to prevent caries. Topical SDF is a clear liquid that is painted on the active caries surface in milligram amounts and arrests the caries. The use of SDF for arresting dental caries in deciduous, and permanent teeth is not a novelty in

Dentistry. Since the 1970s, when it was developed, it has been widely used in Japan, as well as in other countries such as Brazil, Argentina, China, and Australia. Notwithstanding, it was not commonly used in the United States of America until 2014, when the use of SDF was cleared by the Food and Drug Administration (FDA-2015) as an agent to treat tooth hypersensitivity and, in an off- label indication, for caries arresting management for both deciduous and permanent dentition [16, 17].

SDF's caries arresting activity is achieved through a variety of mechanisms. Shimizu and Kawagoe et al., (1976) described three possible mechanisms of action of SDF on dental caries. This includes obturation of dentinal tubules, decreased in dye permeability, and increased in electric resistance, limiting the acid invasion of microorganisms thereby preventing collagen from degradation. Silver Diamine Fluoride ($Ag(NH3)_2 F$) reacts with the tooth mineral hydroxyapatite (HA) ($Ca10 (PO4)6 (OH)_2$) and in turn hardens the tooth. Anti-enzymatic actions of the reaction products between Ag(NH3)2F and organic components include silver ions (Ag+) which exert a great antimicrobial effect, killing or interfering in the microorganisms' metabolic processes. Silver ions can bind to the cell-wall structure and inhibit the mobility of the bacteria or promote the rupture of the membranes. They also can form organometallic complexes inside the bacterial cell, liberating silver ions that will interact with the DNA of the microorganisms, resulting in inactivation of bacterial DNA/RNA or mutation of the DNA, leading to the

death of the bacteria. *Streptococcus mutans*, a primary pathogen in dental caries, are less able to form a biofilm on teeth treated with SDF in ex vivo [18, 19, 20].

The most commonly used SDF concentration is 38%, which represents 44,800 ppm of fluoride and 255,000 ppm of silver. These two elements, in such a high concentration have a synergistic activity, with a bactericidal action on cariogenic microorganisms, promotion of mineralization, inhibition of demineralization of tooth hard tissues, and decrease of the destruction of the organic portion of the dentin. Yvonne S. Lin et al., (2018), conducted a study of pharmacokinetics of 38% topical SDF in healthy adult volunteers. He concluded that topical application of 38% SDF, in growing use in the United States, is safe and well-tolerated in healthy adults [21].

Bathsheba Turton et al., (2020) stated that the major draw-back of arrest of caries treatment with silver fluoride solutions is carious lesions become darker in color. This can result in poor aesthetics which could potentially be stigmatizing or unacceptable. For that reason, it was important to explore ways in which clinicians can achieve the most aesthetically favourable outcome [22]. Knight et al., (2005), introduced a new approach to overcome this problem by applying a saturated solution of potassium iodide (KI) immediately after SDF application. Silver phosphate is the sub product of the SDF reaction with hydroxyapatite that is responsible for tooth staining. While applying saturated solution of KI (1 g KI/mL) after SDF treatment, the subsequent reaction will

result in silver iodide (AgI) and tri-potassium phosphate (K3PO4). The last one is the chemical substance responsible for the reduction of tooth staining [23].

The application of SDF is simple, painless, non-invasive, and inexpensive. It may be regarded as a very appealing approach for the prevention and treatment of root caries in the elderly, particularly in those with limited locomotion and impaired self-care ability. However, limited literature evidences were available for application of SDF on individuals with root caries [23, 24].

Preza D et al., (2008), conducted a study on bacterial profiles of root caries in elderly patients. They stated that, putative etiological agents of root caries include *Streptococcus mutans, lactobacilli,* and *Actinomyces* [25]. According to Lei Mei et al., (2013), 38% SDF inhibits multi-species (*Streptococcus mutans, Streptococcus sobrinus, Lactobacillus acidophilus, and Actinomyces naeslundii*) cariogenic biofilm formation on dentin carious lesions and reduces the demineralization process [26]. Zhang et al (2013) & R. LI et al., (2016) investigate subjective effects of SDF application preventing and arresting dental root caries in community dwelling elders. However there are no studies to evaluate the antimicrobial effect of 38% SDF on the *S.mutans* colony count on root caries lesions, especially any geriatric population [15, 27].

Based on this, the present study was designed to evaluating patient's satisfaction level and *Streptococcus mutans* colony count following a single

application of SDF with and without KI among the community-dwelling geriatric population in Chennai city.

HYPOTHESIS

RESEARCH QUESTION:

Is there any significant change in patient satisfaction level, and *Streptococcus mutans* colony count following a single application of silver diamine fluoride with and without potassium iodide among community dwelling geriatric population in Chennai city.

NULL HYPOTHESIS:

There is no significant difference in patient satisfaction, and *Streptococcus mutans* colony count following a single application of silver diamine fluoride with and without potassium iodide among community dwelling geriatric population.

ALTERNATE HYPOTHESIS:

There is a significant difference in the patient satisfaction, and *Streptococcus mutans* colony count following a single application of silver diamine fluoride with and without potassium iodide among community dwelling geriatric population.

AIM AND OBJECTIVES

AIM:

To assess the patient satisfaction level, and *Streptococcus mutans* colony count following a single application of silver diamine fluoride with and without potassium iodide among community dwelling geriatric population in Chennai.

OBJECTIVES:

1. To assess subjectively the color changes of root caries lesions on a single application of SDF with and without KI using standard digital photograph taken by digital single lens reflex camera-canon EOS 70D.
2. To evaluate the patient satisfaction level with the appearance of their carious teeth following a single application of SDF with and without KI application after 7 days. Using visual analog scale (1921).
3. To evaluate the colony count of *Streptococcus mutans* following a single application of SDF with and without KI solution after 7 days.

REVIEW OF LITRATURE

W. Zhang et al., (2013)[15], this controlled clinical trial investigated the effectiveness of silver diamine fluoride and oral health education in preventing and arresting root caries. Two hundred sixty-six elderly subjects who had at least 5 teeth with exposed root surfaces and did not have serious life-threatening medical diseases were allocated to 3 groups according to a computer-generated random list: group 1 (the control group) received oral hygiene instructions (OHI) annually; group 2 received OHI and silver diamine fluoride (SDF) application annually, and group 3 was given OHI and SDF application annually, plus an oral health education (OHE) program every 6 months. Two hundred twenty-seven elderly subjects were followed for 24 months. The mean numbers of new root caries surfaces in groups 1, 2 and 3 were 1.33, 1.00 and 0.70, respectively. Group 3 had fewer root surfaces with new caries than group 1. The mean numbers of arrested root caries surfaces in groups 1, 2 and 3 were 0.04, 0.28 and 0.33, respectively. Group 3 and group 2 had a greater number of active root caries surfaces which became arrested than group 1. Annual application of SDF together with biannual OHE was effective in preventing new root caries and arresting root caries among community-dwelling elderly subjects.

R. Li et al., (2016)[27], this study investigate the effectiveness of silver diammine fluoride (SDF) solution application in arresting dental root caries and to assess the color of arrested caries lesions. This study was conducted in

elderly centres in Hong Kong. A total of 83 elders with 157 root surfaces with active caries lesion were randomly allocated into 3 groups: Gp1 (placebo control)—annual application of soda water; Gp2–annual application of SDF solution; Gp3–annual application of SDF solution immediately followed by potassium iodide (KI) solution. Colour of the arrested root caries lesion was assessed with reference to PANTONE colour plates and classified into one of the followings: yellow (7401U); light brown (1245U); dark brown (4635U); and black (Black U). Status of root surfaces was assessed every 6 months by the same independent examiner. After 30 months, 100 (64%) of the included root caries lesions were reviewed. The arrest rates of root caries were 45%, 90%, and 93% in Gp1 (control), Gp2 (SDF) and Gp3 (SDF/KI), respectively. Application of SDF solution, with or without application of KI afterwards, is effective in arresting root caries among elders in a water fluoridated area. In the long term, blackening of arrested root caries is not reduced by immediate application of KI after the application of SDF.

H.P. Tan et al., (2010)[28] Root caries is common in institutionalized elders, and effective prevention methods are needed. This clinical trial compared the effectiveness of four methods in preventing new root caries. From 21 residential homes, 306 generally healthy elders having at least 5 teeth with exposed sound root surfaces were randomly allocated into one of four groups: (1) individualized oral hygiene instruction (OHI); (2) OHI and applications of 1% chlorhexidine varnish every 3 months; (3) OHI and applications of 5%

sodium fluoride varnish every 3 months; and (4) OHI and annual applications of 38% silver diamine fluoride (SDF) solution. Twothirds (203/306) of the elders were followed for 3 years. Mean numbers of new root caries surfaces in the four groups were 2.5, 1.1, 0.9, and 0.7, respectively. SDF solution, sodium fluoride varnish, and chlorhexidine varnish were more effective in preventing new root caries than giving OHI alone.

J.C. Llodra et al., (2005)[29] We hypothesized that the six-monthly application of silver diamine fluoride (SDF) can arrest the development of caries in the deciduous dentition of six-year-old schoolchildren and prevent caries in their first permanent molars. A prospective controlled clinical trial was conducted on the efficacy of a 38% SDF solution for caries reduction. Four hundred and twenty-five six-yearold children were divided into two groups: One group received SDF solution in primary canines and molars and first permanent molars every 6 months for 36 months. The second group served as controls. The 36-month follow-up was completed by 373 children. The mean number of new decayed surfaces appearing in primary teeth during the study was 0.29 in the SDF group vs. 1.43 in controls. The mean of new decayed surfaces in first permanent molars was 0.37 in the SDF group vs. 1.06 in controls. The SDF solution was found to be effective for caries reduction in primary teeth and first permanent molars in schoolchildren.

R. Yee et al., (2009)[30] Arresting Caries Treatment (ACT) has been proposed to manage untreated dental caries in children. This prospective randomized

clinical trial investigated the caries-arresting effectiveness of a single spot application of: (1) 38% silver diamine fluoride (SDF) with tannic acid as a reducing agent; (2) 38% SDF alone; (3) 12% SDF alone; and (4) no SDF application in primary teeth of 976 Nepalese schoolchildren. The a priori null hypothesis was that the different treatments have no effect in arresting active cavitated caries. Only the single application of 38% SDF with or without tannic acid was effective in arresting caries after 6 months (4.5 and 4.2 mean number of arrested surfaces), after 1 year (4.1 and 3.4), and after 2 years (2.2 and 2.1). Tannic acid conferred no additional benefit. ACT with 38% SDF provides an alternative when restorative treatment for primary teeth is not an option.

Bella Monse et al., (2012)[31]. The objective of the study was to assess and compare the effect of a single application of 38% SDF with ART sealants and no treatment in preventing dentinal (D3) caries lesions on occlusal surfaces of permanent first molars of school children who participated in a daily school-based toothbrushing program with fluoride toothpaste. The prospective community clinical trial in the Philippines was conducted over a period of 18 months and included 704 six- to eight-year-old school children in eight public elementary schools with a daily school-based fluoride toothpaste brushing program. Children were randomly assigned for SDF application or ART sealant treatment. Children from two of the eight schools did not receive SDF or ART sealant treatment and served as controls. SDF or ART sealant

treatment was applied on sound occlusal surfaces of permanent first molars. A one-time application of 38% SDF on the occlusal surfaces of permanent first molars of six- to eight-year-old children is not an effective method to prevent dentinal (D3) caries lesions. ART sealants significantly reduced the onset of caries over a period of 18 months.

Peter Milgrom et al., (2018)[32] The Stopping Cavities Trial investigated effectiveness and safety of 38% silver diamine fluoride in arresting caries lesions. The study was a double-blind randomized placebo-controlled superiority trial with 2 parallel groups. Sixty-six preschool children with ≥1 lesion were enrolled. Silver diamine fluoride (38%) or placebo (blue-tinted water), applied topically to the lesion. The primary endpoint was caries arrest (lesion inactivity, Nyvad criteria) 14–21 days post intervention. Average proportion of arrested caries lesions in the silver diamine fluoride group was higher (0.72; 95% CI; 0.55, 0.84) than in the placebo group (0.05; 95% CI; 0.00, 0.16). No harms were observed. Topical 38% silver diamine fluoride is effective and safe in arresting cavities in preschool children.

C.H. Chu et al., (2002)[33] untreated dental caries in Chinese pre-school children is common. This prospective controlled clinical trial investigated the effectiveness of topical fluoride applications in arresting dentin caries. Three hundred seventy-five children, aged 3-5 years, with carious upper anterior teeth were divided into five groups. Children in the first and second groups received annual applications of silver diamine fluoride solution (44,800 ppm

F). Sodium fluoride varnish (22,600 ppm F) was applied every three months to the lesions of children in the third and fourth groups. For children in the first and third groups, soft carious tissues were removed prior to fluoride application. The fifth group was the control. Three hundred eight children were followed for 30 months. The respective mean numbers of arrested carious tooth surfaces in the five groups were 2.5, 2.8, 1.5, 1.5, and 1.3 ($p < 0.001$). Silver diamine fluoride was found to be effective in arresting dentin caries in primary anterior teeth in pre-school children.

Juliana Mattos-Silveira et al., (2014)[34], Aim is to evaluate the efficacy and cost-efficacy of SDF in arresting initial lesions compared to resin infiltration and exclusively flossing (control group). Our second aim is to assess discomfort and satisfaction regarding interventions. This is a randomized clinical trial, double-blinded, placebo-controlled study. A minimum sample size of 504 surfaces will be required for each subgroup. Individuals will be randomly allocated in three groups of interventions: SDF, resin infiltration, and control group. Individuals will be assessed at 1 and 3 months after treatment to evaluate dental biofilm and at 6, 12, and 24 months to assess caries progression by visual examination and/or radiography. Our hypothesis is that SDF is the most cost-efficacious option from all tested interventions. If our hypothesis is confirmed, the use of SDF in private and public contexts could represent an easier and effective option in the treatment of enamel approximal caries in children/adolescents.

Alan Deutsch, BDS et al., (2016)[35] An alternate technique of care to prevent, arrest and manage root caries using aqueous silver fluoride followed by stannous fluoride (AgF+SnF2) in aged care is demonstrated by three case studies. With increasing age, the inability to maintain own oral care from dementia, illness or frailty and polypharmacy induced salivary gland hypofunction will result in dental caries becoming a progressively greater burden for the elderly. Future generations of elders will live longer and need to maintain many more teeth longer than earlier generations. Both silver diamine fluoride (SDF) and AgF+SnF2 arrest and prevent caries and are easy to use in residential aged care facilities. However, in aged care, AgF+SnF2 may offer advantages over SDF. AgF+SnF2 used to arrest and prevent caries in children can be modified to provide effective but minimally invasive care for an ageing and frail population. These techniques are rapid, inexpensive and nonthreatening suited to treat frail elders, dementia patients exhibiting challenging behaviors and patients with multiple rapidly progressing decay. Silver fluoride, applied before placing glass-ionomer cement (GIC) restorations is an important adjunct to the atraumatic restorative technique and may retard caries reactivation more than GIC used alone.

Mei ML et al., (2013)[24], this study aimed to investigate its mechanism of action. the effect of 38% SDF on cariogenic biofilms and dentin carious lesions. We used five common cariogenic bacteria (Streptococcus mutans, Streptococcus sobrinus, Lactobacillus acidophilus, Lactobacillus rhamnosus and Actinomyces naeslundii) to form a cariogenic biofilm that generated

carious lesions with a depth of approximately 70 um on human dentin blocks. We applied 38% SDF to the lesions in the test group and water to those in the control group. The blocks were incubated in the artificial mouth for 21 days before evaluation. Microbial kinetics, architecture, viability and distribution were evaluated every 7 days using colony forming unit (CFU), scanning electron microscopy and confocal laser scanning microscopy. The CFU results revealed fewer colony forming units in the test group compared with the control group. Scanning electron microscopy and confocal microscopy showed less bacterial growth in the test group, and confluent cariogenic biofilm in the control group. The microhardness and weight percentages of calcium and phosphorus in the test group from the outermost 50mum were higher than in the control group. EDS showed that calcium and phosphous were higher in outer 50 mum in test groups than in the control FTIR revealed less exposed collagen I in the test lesions compared with the control group 38% SDF inhibits multi-species cariogenic biofilm formation on dentin carious lesions and reduces the demineralization process.

Chelsea Mitchell et al., (2021)[36], The authors conducted a case series to determine arrest of root surface caries lesions in older adults when teeth were treated topically with 38 % silver diamine fluoride (SDF).The study was a prospective, single center case series. The patients were 62 older adults (age ≥55 years) who sought treatment at a dental school clinic. 38 % SDF was applied for two minutes with a micro brush. Treated lesions were re-evaluated

at 2–3 weeks. Treatment was repeated every six months. Survival analysis methods for clustered data were used to estimate the caries lesion arrest probability over time separately for root surfaces and at crown margins. Fifty-five participants returned for follow-up (44 % female, mean age (SD) 79.8 (7.4)). The probability of a lesion arresting with treatment ranged from 82.9 to 91.6%. Arrest rates at 18 months were slightly higher in root surfaces than around crown margins, 91.6 % (95 % CI 69.1–97.1) versus 89.8 % (95 % CI 71.6–96.3). All furcal lesions (n = 7) were arrested by 6 months, 100 % (95 % CI 59–100). Repeated application of 38 % SDF at 6-month intervals was effective in arresting decay of root surface lesions and lesions around crowns in older adults. Study outcomes support SDF treatment for older adult patients who are frail and residing in nursing homes or dependent living facilities.

Marta Diogo Garrastazua et al., (2019)[37], the aim of this exploratory trial was to compare the 3-month effect of two antimicrobials on the salivary levels of *Streptococcus mutans* (SM) in children. Ninety school children aged 6–10 years participated. They were divided into two groups according to treatment used: 1% chlorhexidine gel (CHX) or 30% silver diamine fluoride (SDF). Saliva for SM colony forming unit (CFU)/ml counting was harvested in four periods: baseline (prior to antimicrobials); P1 (24 h after antimicrobial therapy); P30 (30 days after antimicrobial therapy); and P90 (90 days after antimicrobial therapy). CFU/ ml data was submitted to repeated measures by analysis of variance (ANOVA). Only the time factor influenced the results, with a reduction of SM for all evaluated periods in comparison to the baseline.

No influence of antimicrobials or interactions of factors were detected. P30 presented the lowest levels of SM and at P90, SM levels were similar to P1 but still lower than the baseline observations. SDF and CHX presented a similar effect on SM within each period of evaluation. It was concluded that 30% SDF presents similar antimicrobial effects as 1% CHX over time. SDF might be used as an adjunctive therapy for controlling dental caries in children.

MATERIALS AND METHODS

Study Design: Interventional study

Study Setting: Institutional based-Field setting

Study Duration: 6 months (November 2020 to April 2021)

Study Group: Geriatric population- more than 60 years of old.

BACKGROUND OF THE STUDY AREA:

The current study was carried out among geriatric population (more than 60 years old) in Chennai city, who had root caries.

The study was conducted from November 2020 to April 2021**.** The participants for this study were recruited from St. John Britto home for aged women, Kovalam and Vishranthi Old age home for women, Palavakam.

ETHICAL CLEARANCE: (ANNEXURE-1)

A detailed study protocol explaining the objectives and methodology of the study was approved by the Institution Review Board, Ragas Dental College and Hospital. The study was initiated after obtaining ethical clearance.

PERMISSION FROM AUTHORITIES:

Permission to conduct the study was obtained from:

- Principal, Ragas Dental College and Hospital, Chennai.
- The Secretary of Vishranthi Old age Home, Palavakam.**(ANNEXURE-2)**

- The Secretary of St. John Britto Old age home, Kovalam.**(ANNEXURE-3)**

REGISTRATION IN CLINICAL TRIAL REGISTRY: (ANNEXURE-4)

The protocol of the study was registered in the Clinical Trial Registry of India. This registry is maintained by Indian Council of Medical Research. The protocol of the study was accepted after review. The Register number of the protocol was CTRI/2021/10/037210.

INFORMED CONSENT: ANNEXURE-5,6 (ENGLISH & TAMIL)

Written consent (bilingual) was obtained from the participants after they duly read the information sheet. They were explained about the purpose and procedure of the study and assured that their participation in the study was purely voluntary and that they can withdraw from the study at any stage. They were also informed that the data collected will be kept confidential and will be used only for research purpose.

STUDY DESIGN:

This interventional study was designed to assess the patient satisfaction's level, and *Streptococcus mutans* colony count following a single application of silver diamine fluoride with and without potassium iodide, which was carried out among community dwelling geriatric population (more than 60 years old) from Vishranthi Old age Home, Palavakam, and St. John Britto Old Age home, Kovalam, Chennai city.

SAMPLE SIZE DETERMINATION: (ANNEXURE-7)

The sample size for the present study was calculated based on the data from a study conducted by Hung chu et al., (2011)[38] on effectiveness of Silver Diamine Fluoride (SDF) solution application in arresting dental root caries and to assess the color of arrested caries lesions was used to calculate the sample size using G*Power software (version 3.0.10).

The following inputs were given in the software: the alpha error was set at 5% (0.05) with 80% (0.80) as the power of the study, the effect size d = 0.96300 mean (1.10, 0.57) and standard deviation of *S.mutans* colony count (0.28, 0.12) from the study conducted by Hung chu et al., (2011)[38] were used. The sample size estimated was 19 in each group.

Hence, anticipating a drop out of the study subjects in the follow up period, the sample size was increased by 10%

This was approximated to 20 in each group. Hence, for the present study we included 40 geriatric individuals in each group. Thus, a total of 40 geriatric participants were included in the study.

ELIGIBILITY CRITERIA:

INCLUSION CRITERIA:

- Geriatric age group population were included (above 60 years of age)
- Subjects with a minimum of 20 teeth present in their oral cavity.

- Subject having one or more root/root surface with caries which were not indicated for extraction. (Billings root surface caries index(1986)- Grade-I, II, III) **(ANNEXURE-7)**
- Subjects who given written informed consent before the commencement of the study.

EXCLUSION CRITERIA:

- Subjects with cognitive problems in communication and not able to do their normal self-care activity were excluded.
- Subjects with a known history of allergy against silver or any other metallic allergies.
- Subjects having one or more root/root surface with caries which were indicated for pulpal therapy or extraction. (Billings root surface caries index(1986)- grade-IV) **(ANNEXURE-8)**
- Subjects reporting with any acute conditions of the oral cavity requiring immediate attention.
- Subjects whose salivary gland functions had been significantly affected by any disease, medication, or treatment such as radiotherapy in the head and neck region.

INSTRUMENTS AND MATERIALS USED: (PHOTOGRAPH -1)

- Disposable head caps, gloves and mouth masks
- Plane Mouth mirrors (Number 5)
- Explorer

- Kidney trays
- Applicator tips
- Glass Dappen dish
- 38% Silver Diamine Fluoride varnish (FAgamin)
- 38% Silver Diamine Fluoride with Potassium Iodide varnish (Riva Star)
- Vaseline
- Cheek retractor
- Digital single lens reflex camera (Canon EOS 70D, Tokyo, Japan)
- Portable compressor unit
- Hand scaler instruments
- Sterilizing solution (Korsolex®)
- Rectangular Trays
- Cotton rolls & Cotton holder
- Saliva container (Plastic) & Ice packs
- Potassium Tellurite Hydrate 90% & Mitis Salivarius Agar Base

Autoclaved instruments were used and adequate number of each instrument was carried to the field. During data collection, chemical method of disinfection using Korsolex (Glutaraldehyde- 7gms; Polymethyl urea derivatives- 11.6 gms; 1, 6 dihydroxy 2, 5 droxyhexane - 8.2gm) diluted by adding water was used. Used instruments were washed and placed in the disinfectant solution for 30 minutes, then re-washed and drained well.

RECRUITMENT OF STUDY SUBJECTS:

From Thiruvanmiyur to Kovalam totally 19 old age homes are registered. Among them that 12 old age homes were approached for conduct this study, each and every steps, nature and purpose of the study was explained to them. Finally the following two old age homes gave consent to conduct the study among geriatric people from their old age homes:

- Vishranthi Old-age Home, Palavakam.
- St. John Britto Old Age home, Kovalam.

Both the old-age had a total of 140 geriatric people.

The clinical examination was done in Vishranthi old age home and St. John Britto Old Age home in a period of November 2020 to January 2020 by examining 3-5 geriatric people for each day. Overall 40 patients who met the eligibility criteria were recruited for the study.

CALIBRATION OF THE EXAMINER:

The investigator was adequately trained and calibrated to administer the questionnaire, collect the saliva samples and visual analogue scale and application procedure of Silver Diamine Fluoride and Potassium Iodide at the Department of Public Health Dentistry, Ragas Dental College and Hospital, Chennai, under the supervision of the Head of the department. A single calibrated investigator recorded *Streptococcus mutans* colony count, and took the standardized

photograph of root caries lesions to assess the patient's satisfaction on visual analogue scale recording proforma.

The study was conducted in two phases,

1. Screening for eligibility (November 2020 to January 2021)
2. The main study (February 2021 to April 2021)

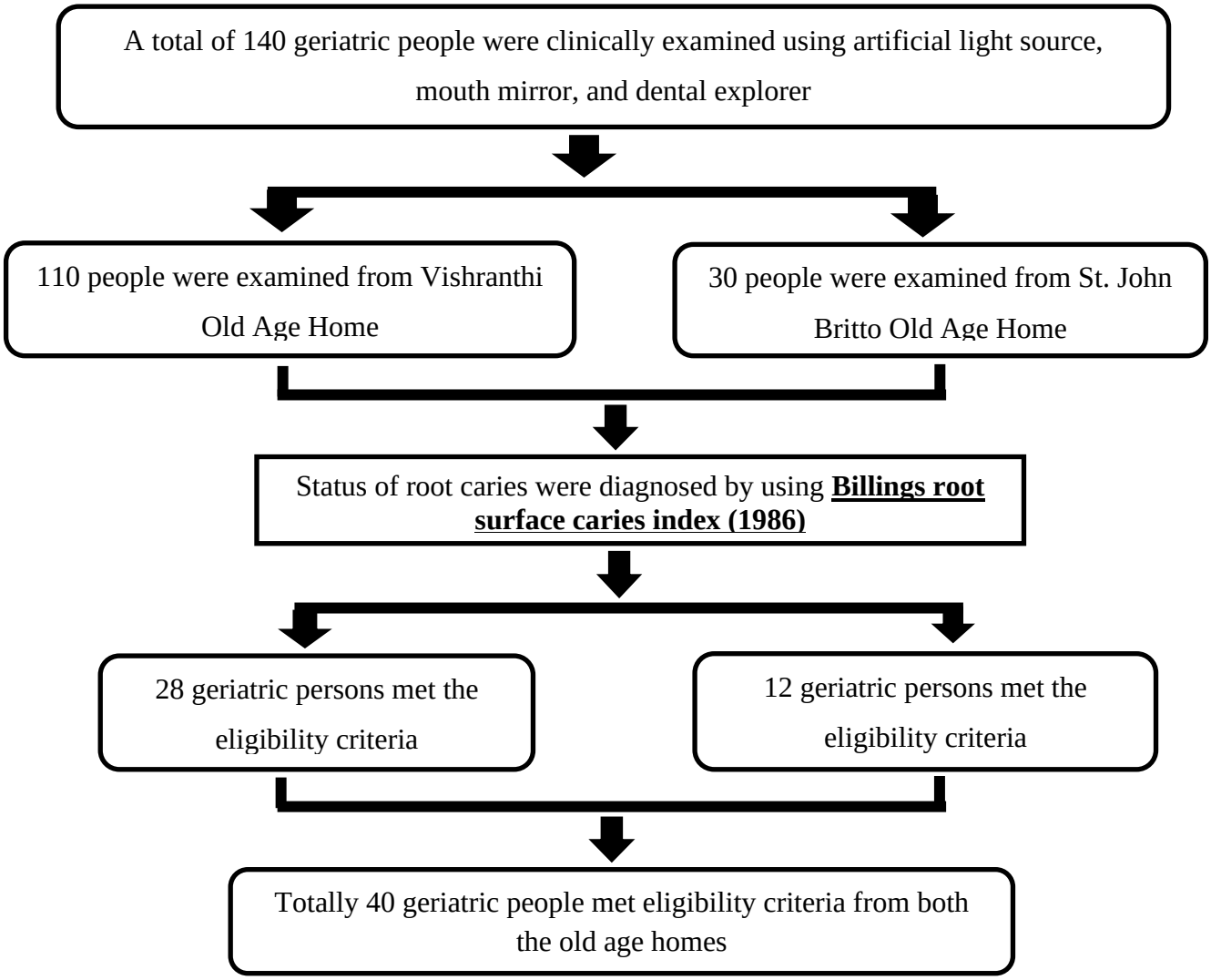
MAIN STUDY

PHASE-1: SCREENING FOR ELIGIBILITY: (November 2020 to January 2021) (PHOTOGRAPH -2)

- By Proper COVID-19 precautionary protocols such as wearing of face mask, face shield, using of hand sanitizers and maintaining of social distancing were followed during the screening phase.
- Intra-oral examination was carried out with the help of artificial light source with subjects in a supine position. Probing of root caries lesions were performed using a dental explorer and mouth mirror. Plaque and calculus obscuring visual inspection of the tooth surfaces were removed using cotton buds and ultra-sonic scaling.
- The screening was done once in a week in both the old age home by a single calibrated investigator with help of one assistant. On the day of screening three to five geriatric persons were examined, and it took approximately five to ten minutes for each person.

- All the 40 subjects who met the Billings root caries index (1986) grade less than three or equal to three were included **(ANNEXURE-7).**

PHASE-1: SCREENING FOR ELIGIBILITY:



PHASE-II: GROUPING, INTERVENTION, AND ASSESSMENT

(January 2021 to April 2021).

DEMOGRAPHIC DATA: (PHOTOGRAPH-3)

Questionnaires were provided to all the participants. The following data were collected: name, age in years, educational status, occupation, and medical history, frequency of snaking and frequency of brushing per day. In addition present photograph of root caries lesions were obtained by using Digital single lens reflex camera (Canon EOS 70D, Tokyo, Japan).

GROUPING:

After the clinical examinations were done subjects who fulfilled the eligibility criteria were randomly allocated into two groups by lottery method; (GROUP-1 and GROUP-2)

PHOTOGRAPH OF ROOT CARIES LESION BEFORE INTERVENTION: (PHOTOGRAPH-4)

Standard photograph of root caries lesion was taken by using digital single lens reflex camera (Canon EOS 70D, Tokyo, Japan).

SALIVA SAMPLE COLLECTION: (PHOTOGRAPH -5a)

The un-stimulated saliva samples were collected by spitting method as per the protocol described by Yamuna et al. (2017) to assess the *Streptococcus*

mutans. Briefly, the participants were informed not to consume solid food or liquids at least two hours prior to saliva sample collection and were also advised to avoid performing any oral hygiene procedures immediately before sample collection. The participants were then instructed to rinse their mouth with water to remove any food debris, and sit upright with the head slightly tilted forward and the eyes open. Saliva was allowed to accumulate in the floor of the mouth. After five minutes un-stimulated whole saliva was collected by asking the participants to spit the whole saliva into sterile container for 5-10 minutes. At least 3 ml of un-stimulated saliva samples were collected in a sterile wide-mouthed plastic container with screw capped lid.

STORAGE & TRASPORT OF SALIVA SAMPLE: (PHOTOGRAPH 5b)

The samples thus obtained were then stored in a sample collection box containing frozen ice packs and were transported immediately in cold chain maintained at ~4°C to the laboratory for further processing. The samples were maintained at 2- 8°C until processing, no longer than 6 hours.

Then these salivary samples were taken to the lab for colony count of *Streptococcus mutans* by using Potassium Tellurite Hydrate 90% & Mitis Salivarius Agar Base.

LABORATORY PROCEDURE: The automated laboratory procedure was carried out by the principal investigator under the guidance of trained

laboratory technicians at, Avigen Biotech Private limited, Pallavaram, and Chennai using the following.

- Vortex mixer**(PHOTOGRAPH-6a)**
- Potassium Tellurite Hydrate 90%
- Mitis Salivarius Agar Bass (HiMedia, Mumbai)
- Digital colony counter**(PHOTOGRAPH-6b)**

MICROBIAL PROCEDURE:

Determination of total CFU/ml in saliva sample: (PHOTOGRAPH- 7a, 7b, and 7c)

All saliva samples were processed to isolate and determine the total colony forming unit following the protocol described earlier by Zhou et al. (2017). Briefly, for each sample the inoculum was prepared as gradient dilutions (1:1, 1:10, 1:100) in sterile distilled water and mixed thoroughly using a vortex mixer. After serial dilution of the saliva sample, each 100µl of the standard dilution were inoculated by using sterile swab spread over (lawn culture technique) the surface of Vortex mixer Potassium Tellurite Hydrate 90% Mitis Salivarius Agar Bass (HiMedia, Mumbai), and the plates were incubated at 37°C for 48hrs. The species wise isolated colonies were enumerated using digital colony counter. The total colony forming units per millilitre (CFU/ml) of saliva were determined by the formula:

$$\frac{\text{Total number of colony counted}}{\text{Volume of sample inoculum}} \text{ X dilution factor (CFU/ml)}$$

All the isolates were spectated by conventional phenotyping methods which included Blue Mitis Salivarius Agar test. **(PHOTOGRAPH-8)**

INTERVENTION:

GROUP 1: 38% of Silver Diamine Fluoride varnish (FAgamin) **(PHOTOGRAPH -9a)**

GROUP 2: 38% of SDF followed by Potassium Iodide (KI) solution (Riva Star) **(PHOTOGRAPH – 9b)**

PROCEDURAL STEPS FOR APPLICATION OF SDF IN GROUP-1:

- Gross debris was removed from the root caries lesion to allow better SDF contact with the carious root surface. **(PHOTOGRAPH -9c)**
- Before application of SDF onto the root caries lesion a protective coating (Vaseline) was applied to the lips and buccal mucosa to prevent a temporary henna-appearing tattoo. **(PHOTOGRAPH -9d)**
- Cotton rolls were used for isolation followed by air drying of the teeth before applying SDF.
- A micro brush was used for the application of SDF on the carious root surface. A single drop of SDF was found sufficient for the entire appointment. The use of micro-brush prevented unwanted soft/hard tissue exposure.
- The brush was bent and dipped in SDF. It was dapped on the side of dappen dish to remove excess liquid.

- It was then applied on to the root surface where the excess liquid was again removed using cotton pellets.
- The total application time 3 to 4 minutes/tooth after which compressed air was blown on the surface till the medicament dried.

PROCUDURAL STEPS FOR APPLICATION OF SDF & KI IN GROUP-2: (PHOTOGRAPH – 10a)

- Similar precautions were carried out for group-2 (SDF with KI group) as like group-1(SDF). In addition, application of SDF was followed by KI solution application.
- Application of SDF with KI was done for 3 to 4 minutes with a separate applicator tips. **(PHOTOGRAPH – 10b)**

SPECIFIC INSTRUCTIONS TO THE STUDY PARTICIPANTS:

- The participants in both groups were asked not to rinse and eat anything at least for 45 minutes following application.

ASSESSMENT AND FOLLOW-UP AFTER 7 DAYS:

After 7 days a standardized photograph of the present root caries lesion **(PHOTOGRAPH-11)** was taken and showed to the study subjects in laptop screen to compare it with the previous photograph of root caries lesion and then patient's satisfaction level **(PHOTOGRAPH-12)** was measured using Visual Analogue Scale (1921).

VISUAL ANALOGUE SCALE: (ANNEXURE-9)

The Visual Analogue Scale was used to score the patients' satisfaction level regarding the intervention provided. This scale scores were ranges from 0-10. The scores were classified into 3 categories (0 to 4 – not satisfied, 5 – neutral, 6 to 10 – satisfied).

- After 7 days un-stimulated saliva samples of both groups were collected and **(PHOTOGRAPH-13a, 13b, & 13c)** the *Streptococcus mutans* colonies were cultured using the same medium of Potassium Tellurite Hydrate 90% & Mitis Salivarius Agar Bass, and colony counts values were assessed by digital colony counter then the pre and post Streptococcus mutans colony counts values were compared.
- Finally the teeth where the intervention applied was restored with type-2 glass ionomer cement restoration **(PHOTOGRAPH-14).** (GC Gold label)

PHASE-II: GROUPING, INTERVENTION, AND ASSESSMENT

DEMOGRAPHIC DATA COLLECTION

(Name, age in years, educational status, occupation, and medical history, frequency of snaking and frequency of brushing per day)

↓

GROUPING (LOT METHOD)

GROUP-1(SDF) & GROUP-2(SDF with KI)

↓

Standardized Picture of the root caries lesion taken by digital single lens reflex camera (Canon EOS 70D)

↓

SAMPLE COLLECTION:

Un-stimulated saliva samples were collected (spit mouth method) & colony of *Streptococcus mutans* were cultured using Potassium Tellurite Hydrate 90% & Mitis Salivarius Agar Base.

INTERVENTION: **Applicator tip**

Group 1: 38% SDF varnish (FAgamin) 3-4 minutes

After 7 davs

Group 2: SDI solution followed by KI solution (Riva Star) 3-4 minutes

A standardized photograph of the root caries lesion by digital single lens reflex camera & Un-stimulated saliva samples were collected

EVALUATION:

Patient satisfactory level on color of root caries lesion (Visual Analogue Scale-1921)

Streptococcus mutans colony counts of two different groups by digital colony counter

Restoration with type-2 glass ionomer cement (GC Gold label) After 7 days.

HANDLING OF BIOMEDICAL WASTE:(PHOTOGRAPH 15)

Following the CDC Guidelines for Environmental *Infection* Control in Health-Care Facilities (2003), the waste generated was segregated as per the disposal option in "Bio-hazard" labeled specific-coloured bags which was then handed over to the disposable management team associated with the respective hospitals for disposing the bio-medical waste. At the end of each day of examination the entire set of instruments were autoclaved (121^0, 15 lbs pressure 15 minutes).

LABORATORY WASTE DISPOSAL:

The testing of the samples was carried out in the Avigen Biotech Private limited, Chennai under the supervision of laboratory technician. Standard precautionary measures like PPE kit and face shield were worn while testing the samples and once the testing was completed all the waste and the specimen containers were discarded into their respective color coded hazardous waste bags present in the laboratory. **(PHOTOGRAPH-15)**

STATISTICAL PROCEDURES:

The following statistical procedures were carried out:-

1. Data compilation and presentation
2. Statistical analyses

DATA COMPILATION AND PRESENTATION:

Data obtained were compiled systematically in Microsoft Excel 2010 spread sheet. The dataset was subdivided and distributed meaningfully and presented as graphs and tables.

STATISTICAL ANALYSIS:

Statistical analyses were performed using a personal computer in IBM corp. Statistical Package for Social Sciences software for windows; version 20.0 (Armonk, NY). Data comparison was done by applying specific statistical tests to find out the statistical significance of the obtained results. Depending upon the nature of the data, the statistical tests were chosen. P-value of < 0.05 was considered to be significant.

Kolmogrov-Smirnov and Shapiro-Wilks normality tests were used to check whether the variables follow normal distribution or not. The variables followed not normal distribution. Wilcoxon signed-rank test was applied to compare the *Streptococcus mutans* value within groups; Mann-Whitney Test was applied to compare the *Streptococcus mutans* values between the groups. To find the satisfaction level between the groups Chi-square test was used and when expected cell frequency was less than 5, Fishers Exact test was applied.

PHOTOGRAPH-1: INSTRUMENTS AND MATERIALS USED:

PHOTOGRAPH-2: SCREENING FOR ELIGIBILITY

PHOTOGRAPH-3 DEMOGRAPHIC DATA COLLECTION

PHOTOGRAPH-4: PHOTOGRAPH OF ROOT CARIES LESION BEFORE INTERVENTION

PHOTOGRAPH -5a & 5b : UNSTIMULATED SALIVA SAMPLE COLLECTION, STORAGE AND TRASPORT

5a

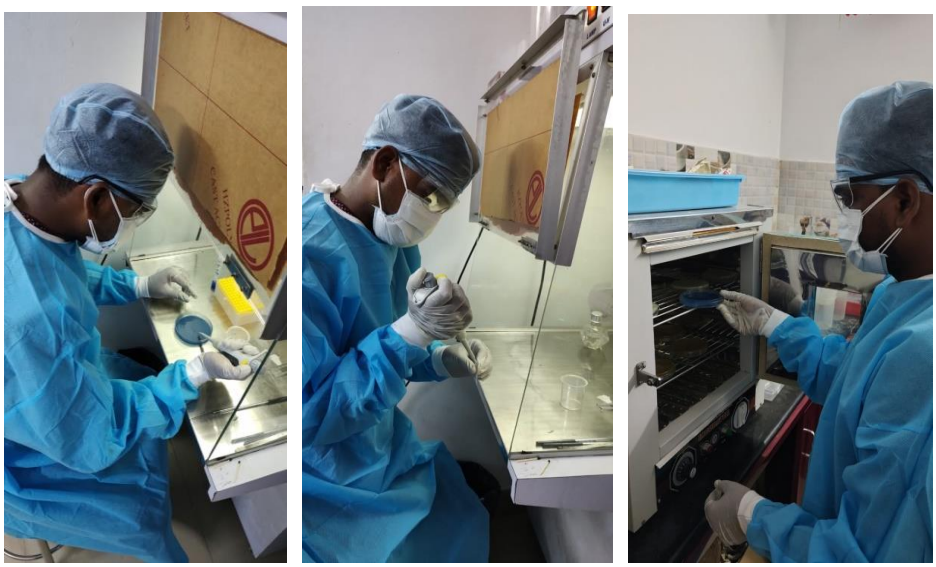
5b

PHOTOGRAPH -6a & 6b: VORTEX MIXTURE & DIGITAL COLONY COUNTER

6a

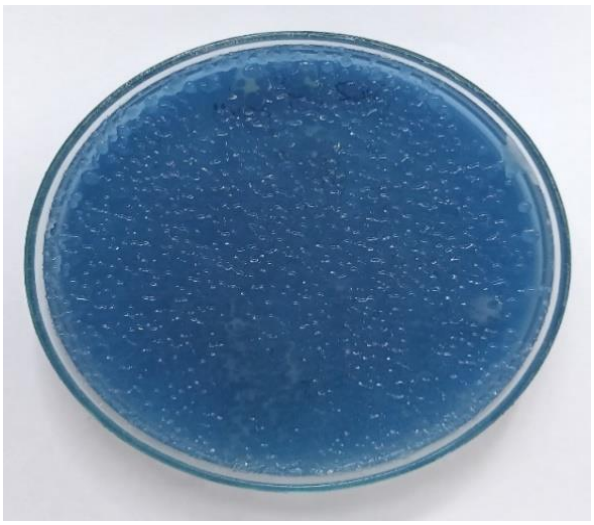
6b

PHOTOGRAPH-7a, 7b & 7c: INVESTIGATOR INOCULATING SALIVA SAMPLE ON MITIS SALIVARIUS AGAR BASE WITH POTASSIUM TELLURITE HYDRATE 90%.



7a **7b** **7c**

PHOTOGRAPH-8: PRE-OP *STREPTOCOCCUS MUTANS COLONIES*



BEFORE INTERVENTION
S.Mutans Colonies

PHOTOGRAPH -9a & 9b: 38% OF SILVER DIAMINE FLUORIDE VARNISH (FAgamin) & 38% OF SDF FOLLOWED BY POTASSIUM IODIDE SOLUTION (Riva Star)

9a

9b

PHOTOGRAPH -10a: REMOVAL OF GROSS DEBRIS FROM ROOT CARIES LESION

PHOTOGRAPH –10b: APPLICATION OF PROTECTIVE COATING (VASELINE) TO THE LIPS AND BUCCAL MUCOSA

10b

PHOTOGRAPH-10c & 10d: APPLICATION OF 38% SILVER DIAMINE FLUORIDE VARNISH BY USING MICRO SPONGE BRUSH & APPLICATION OF 38% SILVER DIAMINE FLUORIDE VARNISH FOLLOWED BY KI SOLUTION APPLICATION

10c

10d

PHOTOGRAPH -11:AFTER 7 DAYS PHOTOGRAPH OF ROOT CARIES LESION

PHOTOGRAPH -12: ASSESSMENT OF PATIENT'S SATISFACTION LEVEL USING VISUAL ANALOG SCALE.

PHOTOGRAPH – 13a & 13b : UNSTIMULATED SALIVA SAMPLES COLLECTION, STORAGE & TRASPORT AFTER 7 DAYS

13a

13b

PHOTOGRAPH- 13c: AFTER 7 DAYS FOLLOW-UP *STREPTOCOCCUS MUTANS COLONIES*

AFTER INTERVENTION
S.Mutans Colonies

APH-14: RESTORATION WITH TYPE-2 GLASS IONOMER CEMENT AFTER 7 DAYS

PHOTOGRAPH-15: LABORATORY WASTE DISPOSAL

RESULTS

The present study was done to evaluate the patient's satisfaction level and *Streptococcus mutans* colony count following a single application of Silver Diamine Fluoride (SDF) with and without Potassium Iodide among community dwelling geriatric population in Chennai city. This study was done among 40 geriatric participants for a period of 6 months who fulfilled the eligibility criteria. Among them, 20 participants were assigned to SDF and 20 participants to SDF with Potassium Iodide (KI) group (Figure-2). All the 40 participants were female and they were present for the entire duration of the study.

FIGURE 1: DISTRIBUTION OF STUDY PARTICIPANTS AT BASELINE BETWEEN TWO GROUPS

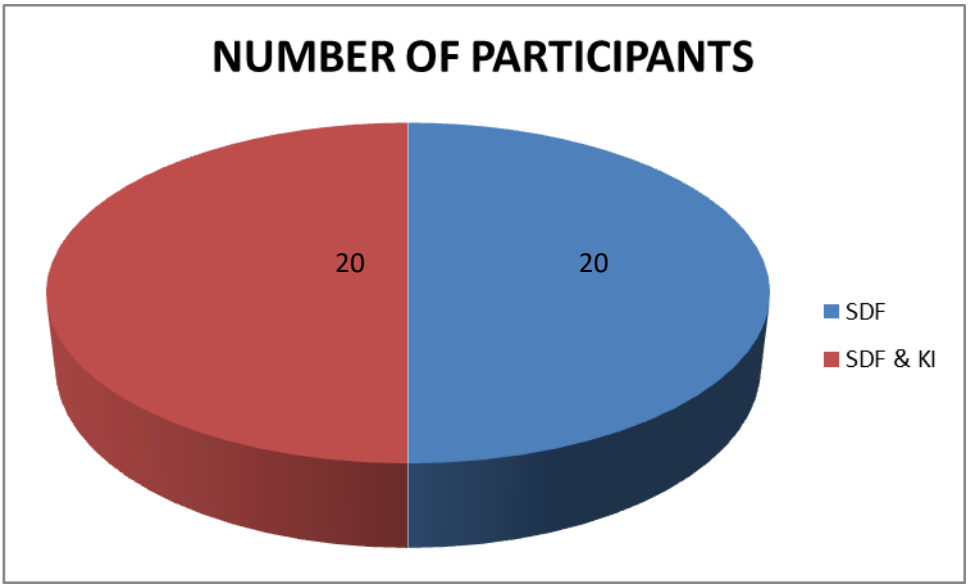


TABLE 1: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON THEIR AGE

AGE	GROUPS		TOTAL	STATISTICAL VALUE	P-VALUE*
	SDF	SDF & KI			
60- 70	8	12	20	**3.305**	**0.243**
71-80	7	7	14		
81-90	5	1	6		
TOTAL	**20**	**20**	**40**		

*Fisher exact test p value≤ 0.05 implies statistical significance.

Table-1 & Figure-3 shows that, in the SDF group 8 participants were between 60-70 years, 7 participants were between 71-80 years, 5 participants were between 81-90 years. In the SDF with KI group 12, 7, and 1 participant respectively were in the age group of 60-70, 71-80, and 81-90 years respectively. No statistically significant difference was observed between the groups based on their age (p value=0.243).

FIGURE: 2 DISTRIBUTIONS OF STUDY PARTICIPANTS BASED ON THEIR AGE

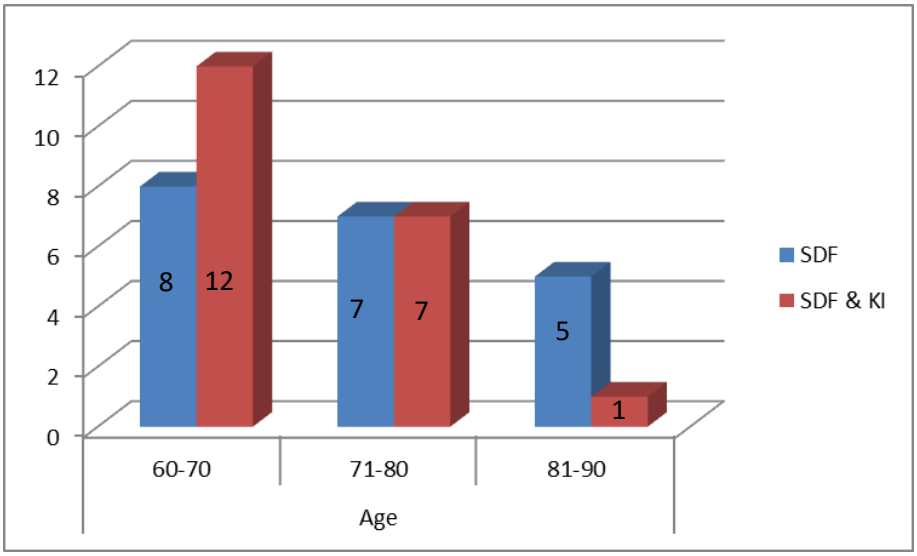


TABLE 2: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON THEIR EDUCATIONAL LEVEL

EDUCATIONAL LEVEL	GROUPS		TOTAL	STATISTICAL VALUE	P-VALUE*
	SDF	SDF & KI			
PRIMARY	13	13	20	**0.000**	**1.000**
SECONDARY	7	7	20		
TOTAL	20	20	40		

*Chi Square test, p value ≤0.05 implies statistical significance

Table-2 & Figure-4 shows that, the distribution of participants based on their level of education, the education levels were classified into four

categories- i) Primary and ii) Secondary, iii) Post-secondary, iv) Tertiary, There were 13 participants who completed primary educational level and 7 who had completed secondary educational level in the SDF group. In the SDF with KI based group, 13 participants had completed primary level of education and 7 participants had completed secondary level of education. There was no statistically significant difference in the level of education of the participants between the groups (p= 1.000).

FIGURE 3: DISTRIBUTIONS OF STUDY PARTICIPANTS BASED ON THEIR EDUCATIONAL LEVEL

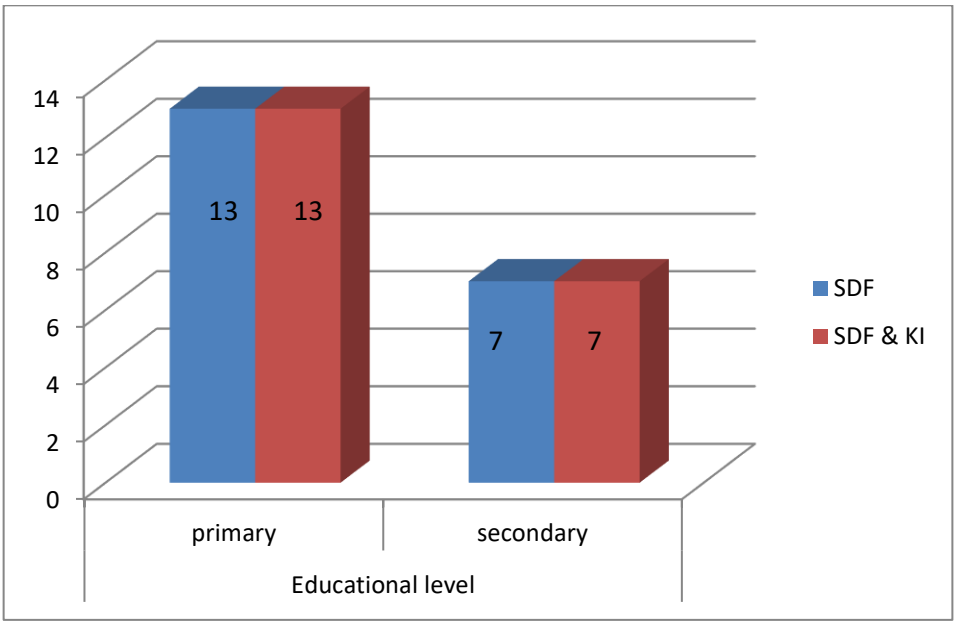


TABLE 3: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON THEIR BRUSHING FREQUENCY

BRUSHING FREQUENCY PER DAY	GROUPS		TOTAL	P-VALUE*
	SDF	SDF & KI		
ONCE	15	16	31	**1.000**
TWICE	5	4	9	
TOTAL	20	20	40	

***Fisher exact test p value≤ 0.05 implies statistical significance**

Table-3 & Figure-5 represents, the distribution of participants based on their brushing frequencies. The brushing frequencies were classified into two categories- i) Once/day, and ii) Twice/day, There were 15 participants who brushed once a day and 5 participants who brushed twice a day in the SDF group. In the SDF with KI group, 16 participants brushed once a day and 4 participants brushed twice a day. There was no statistically significant difference in the frequency of brushing of the participants between the groups (p= 1.000).

FIGURE 4: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON THEIR BRUSHING FREQUENCY

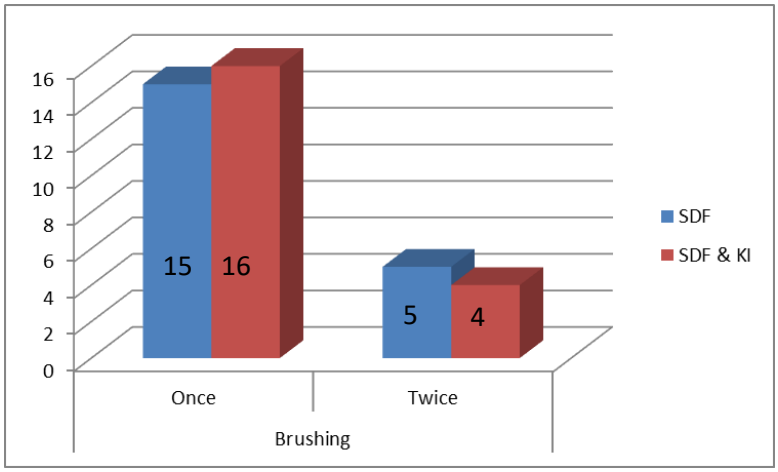


TABLE 4: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON THEIR SNACKING FREQUENCY

SNACKING FREQUENCY PER DAY	GROUPS		TOTAL	STATISTICAL VALUE	P-VALUE*
	SDF	SDF & KI			
NIL	2	0	2	2.801	0.231
ONCE	17	20	37		
TWICE	1	0	1		
TOTAL	20	20	40		

Fisher exact test p value≤ 0.05 implies statistical significance

Table-4 & Figure-6 shows, the distribution of participants based on their snacking frequencies. The snacking frequencies were classified into three categories- i) Nil, ii) Once/day, and iii) Twice/day, There were 2 participants not taking any snack and 17 participants who snacked once a day and 1 participant who snacked twice a day in the SDF based group. In the SDF with KI based group, all the 20 participants took snack once a day. There was no statistically significant difference in the frequency of snacking of the participants between the groups (p= 0.231).

FIGURE 5: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON THEIR SNACKING FREQUENCY

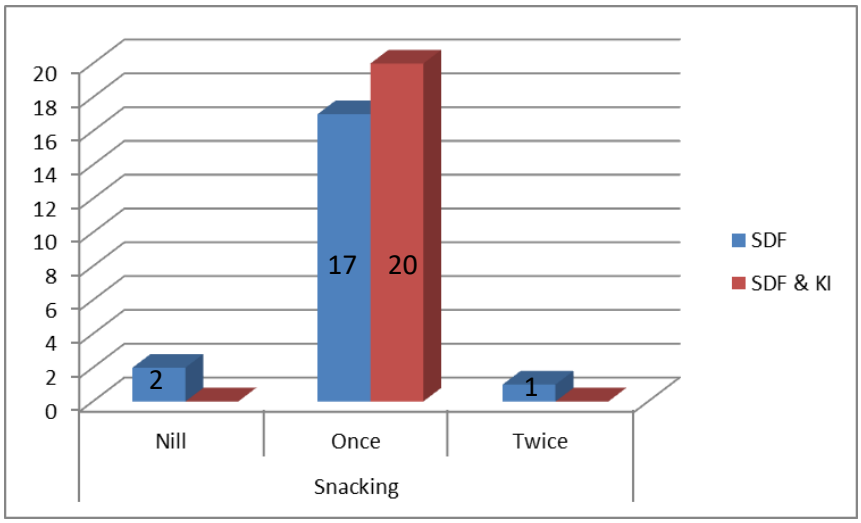


TABLE 5: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON USAGE OF ADDITIONAL ORAL HYGIENE AIDS

ORAL HYGIENE AIDS PER DAY	GROUPS		TOTAL	P-VALUE*
	SDF	SDF & KI		
YES	2	3	5	**1.000**
NO	18	17	35	
TOTAL	20	20	40	

Fisher exact test p value≤ 0.05 implies statistical significance

Table-5 & Figure-7 shows, the distribution of participants based on usage of additional oral hygiene aids. It was classified into two categories- i) Yes, ii) No, There were 2 participants who used oral hygiene aids and 18 participants who were not using oral hygiene aids in the SDF group. In the SDF with KI group, 3 participants were using oral hygiene aids, and 17 participants were not using oral hygiene aids. There was no statistically significant difference in the usage of additional oral hygiene aids of the participants between the groups (p= 1.000).

FIGURE 6: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON USAGE OF ORAL HYGIENE AIDS

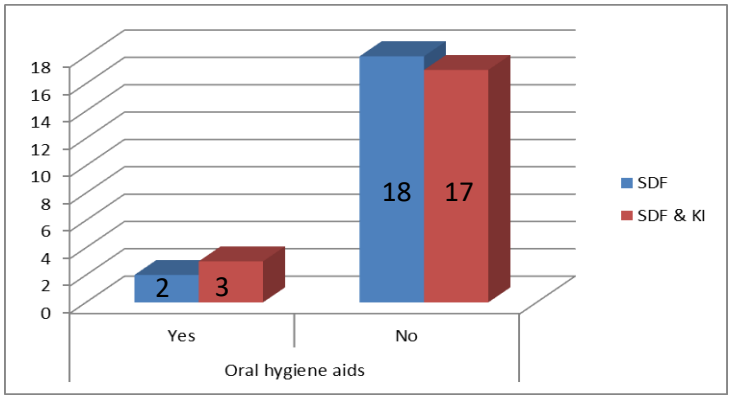


TABLE 6: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON BILLINGS ROOT CARIES INDEX

GROUPS	CATEGORIES (GRADE)							TOTAL	STATISTICAL VALUE	P-VALUE
	I	II	III	I & II	I & III	II &III	I, II &III			
SDF	1	0	5	6	2	3	3	**20**	9.446	**0.112**
SDF & KI	1	5	5	2	0	5	2	**20**		
TOTAL	**2**	**5**	**10**	**8**	**2**	**8**	**5**	**40**		

Fisher exact test p value≤ 0.05 implies statistical significance

Table-6 & Figure-8 shows that distribution of study participants based on billings root caries index. It was classified into 7 categories: grade-I, grade-II, grade-III, grade-(I & II), grade-(I & III), grade-(II & III), and grade-(I, II &III) for convenience of analysis. In SDF group only one study participant was

diagnosed with grade-I root caries, 5 participants were diagnosed with grade-iii root caries, 6 participants were diagnosed with grade-(I & II) root caries, 2 participants were diagnosed with grade-(I & III) root caries, 3 participants were diagnosed with grade-(II & III) root caries, and 3 study participants were diagnosed with grade-(I, II, & III).

In SDF with KI group, 1, 5, 5, 2, 5, and 2 participants respectively were in the categories of grade-I, grade-II, grade-III, grade-(I & II), grade-(II & III), and grade-(I, II & III) of root caries respectively. No statistical significant difference was observed between the groups based on the billings root caries index (p value=0.112).

FIGURE 7: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON BILLINGS ROOT CARIES INDEX

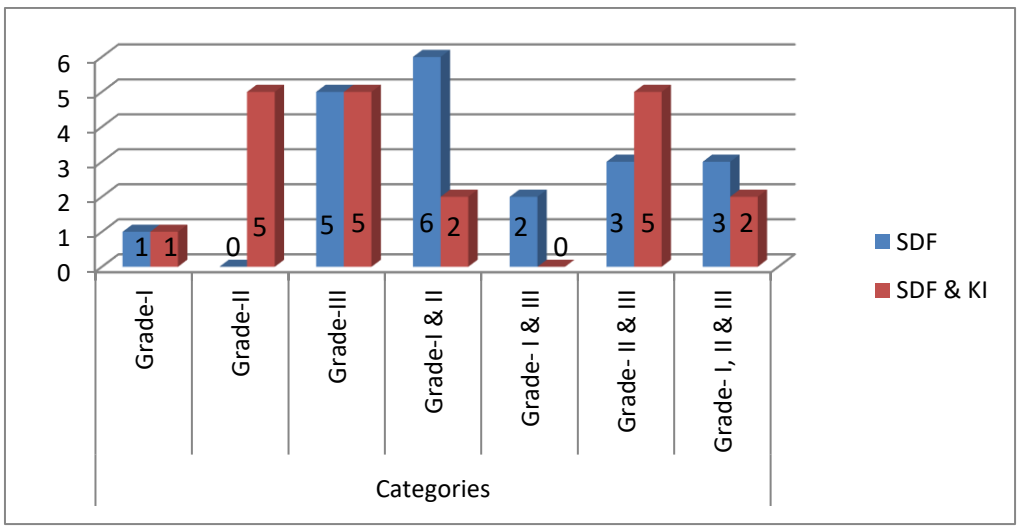


TABLE 7: DISTRIBUTION BASED ON MEAN STREPTOCOCCUS MUTANS COLONY COUNT *CFU/ml* AT BASELINE AND AFTER 7 DAYS AMONG STUDY POPULATION.

VARIABLES	**SDF GROUP**		**SDF & KI GROUP**			
S. Mutans	**N**	**Mean CFU/ml (±SD)**	**N**	**Mean CFU/ml (±SD)**	**Z-value**	**P-value**
At Baseline	**20**	1040.50 ± 194.085	**20**	1202.20 ± 292.432	-1.569	**0.117**
After 7 days	**20**	700.90 ± 178.196	**20**	857.30 ± 265.728	-2.029	**0.042**[#]
Z-value		-3.920		-3.920		
P-value		**0.000***		**0.000***		

*Wilcoxon signed-rank test p value <0.05 = statistically significant.

[#] Mann-Whitney Test p value <0.05 = statistically significant.

Table-7 shows that, the mean colony count of *Streptococcus mutans* of the study participants in SDF and SDF with KI group. The mean colony count of *Streptococcus mutans* in SDF group at baseline and after 7 days was 1040.50 CFU/ml and 700.90 CFU/ml respectively with a statistical significant difference in their mean CFU/ml values (p=0.000). The mean CFU/ml count of *Streptococcus mutans* in SDF with KI group at baseline and 7 days after

intervention was 1202.20 CFU/ml and 857.30 CFU/ml respectively with a statistical significant difference in their mean CFU/ml values (p=0.000). While comparing the baseline mean CFU/ml of *streptococcus* mutans between SDF and SDF with KI groups, there was no statistical significant difference between SD and SDF with KI group (p=0.117). After 7 days follow-up the mean CFU/ml value of *streptococcus* mutans between SDF and SDF with KI groups, was statistically difference (p=0.042).

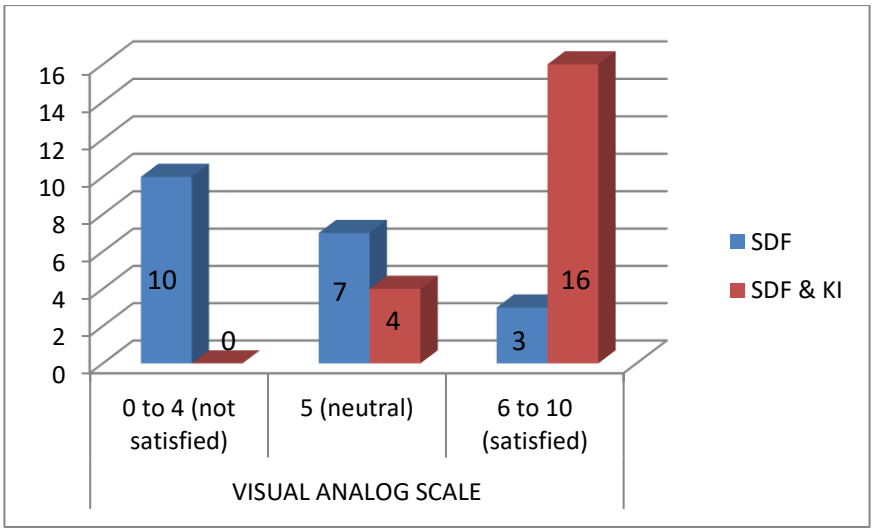
TABLE 8: DISTRIBUTION BASED ON POST APPLICATION OF SDF AND SDF WITH KI SATISFACTION LEVEL OF STUDY PARTICIPANTS (VISUAL ANALOG SCALE)

VISUAL ANALOG SCALE	GROUPS		TOTAL	STATISTICAL VALUE	P-VALUE
	SDF	SDF & KI			
NOT SATISFIED	10	0	10	**21.089**	**0.000**
NEUTRAL	7	4	11		
SATISFIED	3	16	19		
TOTAL	20	20	40		

Fisher exact test p value≤ 0.05 implies statistical significance

Table-8 & Figure-9 shows that, the distribution of participants based on satisfaction level of their tooth color by using visual analog scale. Visual analog scale was classified into three categories: not satisfied, neutral, satisfied. In SDF group 10 study participants were not satisfied, 7 participants were neutrally satisfied, and 3 participants were satisfied with their tooth color. In SDF with KI group none of the participants were said not satisfied with their tooth color, 4 participants were neutrally satisfied with their tooth color, 16 participants were satisfied with their tooth color. There was statistically significant difference in the tooth color satisfactory level of the participants between the groups (p=0.000). SDF with KI group participants had high satisfaction level compared to SDF group participants

FIGURE 8: DISTRIBUTION OF STUDY PARTICIPANTS BASED ON VISUAL ANALOG SCALE (POST-APPLICATION OF SDF & SDF WITH KI)



DISCUSSION

The present study was conducted to assess the patient's satisfaction level and to evaluate the *Streptococcus mutans* colony count following a single application of SDF with and without KI among a community-dwelling geriatric population in Chennai city. An interventional study design was considered to be an appropriate design to assess the effectiveness of the SDF and the benefit offered by KI to alter its staining properties.

The majority of tooth loss in the elderly population is attributed to periodontal diseases followed by dental root caries, which are considered the most prevalent disease entities among these populations. Many elderly populations still hold the opinion that tooth loss is a part of the ageing process, which cannot be prevented. Further, they have hardly been introduced to the concept of preventive dentistry at their younger age. In addition to their age and abilities, they may be reliant on caregivers to make medical and dental appointments. Hence, there is a pressing need to maintain their oral hygiene and incorporate preventive measures to reduce their risk of dental diseases, especially dental root caries among these geriatric populations.

In a survey conducted by Raja et al., (2004) in Bengaluru city, India, around half of the community-dwelling elders had root caries prevalence ranging from 36% to 67% [9]. Hariyani et al., (2018) said the annualized root caries incidence and increment were 18.25% and 0.45 respectively, which further increased to

9.4% and 0.43 root surfaces respectively in 5 years [10]. Root caries can be measured by using Katz root caries index (1979), Billings (1986) root surface caries severity index, root surface caries index, root caries criteria as given by Banting DE (1980), Root caries as assessed by ICDAS- International Caries Detection and Assessment System, Root caries as assessed by National Institute of Dental and Craniofacial Research, Bauer et al (1988), Diagnosis of root caries, Rosen et al (1996), Diagnosis of root caries. Among these four root caries indices could be used for measuring root caries in a community setting. Though root caries index by Ralph V Katzin (1979) assessed the simple prevalence measures for root caries that was more specific by including the concept of teeth at risk for root caries, its drawback was the inability to detect the cement-enamel junction, either because of the obliteration by restoration or calculus [39]. Banting DE et al., (1980) had classified carious root lesions as a discrete well–defined and discolored soft area, an explorer enters easily and displays some resistance, the lesion was located either in the cement–enamel junction or wholly on the root surface. This root caries index was possible to determine with 83% accuracy in those persons who were likely to experience root caries in the population, but did not mention the treatment modalities for each state of root caries lesion [39].

In ICDAS criteria for root caries, root caries are frequently observed near the cement-enamel junction, although lesions can appear anywhere on the root surface, However limitations of this index was that root caries assessment criteria had not been tested in any epidemiological or clinical studies and thus

may lead to over estimation of the seriousness of dental caries [39]. Billings Root Caries Index (1985) provided a complete epidemiologic description of root caries and further aided in monitoring the progression or arrestment of root caries lesions. In Billings root caries index, root caries lesions were classified into incipient, shallow, cavitated or pulpal. Using this index, the root caries lesions could be assigned more objectively to various treatment categories. This index was simple, easy to calculate in community setting and can also used for preventive purpose of root caries lesions [40]. Hence, in our study, root caries lesions were assessed based on the Billings Root Caries Index (1985). The subjects in our study had a minimum of one root caries lesion and a maximum of six root caries lesions in their mouth.

SDF's caries arresting activity was achieved through a variety of mechanisms. Shimizu and Kawagoe et al., (1976) described three possible mechanisms of action of SDF on dental caries. This includes (i) obturation of dentinal tubules leading to decrease in dye permeability, (ii) inhibits demineralization and promotes the demineralization of demineralized enamel and dentine, and (iii) antimicrobial effect of silver ions, killing or interfering in the microorganisms' metabolic processes[18, 19]. In the present study, SDF with and without KI had the advantage, particularly during the COVID-19 pandemic situation, because of its anti-cariogenic property, low cost, and simple procedure (non-invasive) for application to the geriatric population in a community setting with minimal infrastructure to prevent dental root caries formation. Similarly, Tan et al.,

(2010), stated that the SDF solution had advantages when used in clinical and community programs, including their effectiveness in preventing root caries. Its low cost and non-invasive application procedures makes it a good preventive agent which could be used even by allied health workers if they are sufficiently trained [28].

In this interventional study, subjective evaluation of patient's satisfaction level on application of SDF with and without KI was assessed. In our study, the subject's satisfaction level was assessed using a visual analog scale. While comparing satisfaction levels of subjects between SDF group and SDF followed by KI group, most of the subjects were satisfied with the application of SDF with KI than SDF group. LI. R et al., (2016) assessed the color of the arrested root caries lesion subjectively using PANTONE color plates and he found that the application of SDF with and without KI was equally effective in arresting root caries among elders in water fluoridated area, though on long term, the blackening of arrested root caries was not reduced by the immediate application of KI after SDF application [27].

Chun Hun et al., (2012) reported *Streptococcus mutans* as the primary pathogen in both dental and root caries. SDF possessed an anti-microbial activity against the cariogenic biofilm of *S. mutans* formed on dentine surfaces[38]. Lei Mei et al., (2013), stated that the application of 38% of SDF inhibits multi-species cariogenic biofilm formation on dentin carious lesions and reduces the demineralization process, the results showed that at the end of

the 7th day, the CFU in the test group dropped to low values (log CFU < 1) for all of the species. Also, scanning electron microscopy and confocal microscopy showed less bacterial growth in the SDF group [26]. Furthermore, 38% of SDF solution contains high concentrations of silver and fluoride ions, which could inhibit the growth of multi-species cariogenic biofilms. Also, Karched et al., (2019), stated that, because of the potent in vivo antibacterial activity of SDF and SDF + KI, *Streptococci mutans* growth was completely inhibited in most of the dentin samples in 7 to 14 days [41]. Similarly, in our study, after the application of SDF and SDF with KI solution, the salivary *Streptococcus mutans* colony count was significantly reduced in 7 days of follow-up.

Zhang W et al., (2013) conducted a study among two hundred twenty-seven elderly subjects, and stated that the annual application of SDF together with biannual Oral Health Education (OHE) was effective in preventing new root caries and arresting root caries among community-dwelling elderly subjects[15]. Tan et al. (2010), on the other hand, investigated the effect of 38% SDF on the prevention of root caries in community-dwelling elderly people across 21 community centres. In their study, SDF solution, sodium fluoride varnish, and chlorhexidine varnish were applied to the participants. The participants who were followed up for 3 years showed that applications of SDF solution, sodium fluoride varnish, and chlorhexidine were more effective in preventing new root caries than giving oral hygiene instructions alone. However, the SDF

was more effective in preventing new caries than the other two groups [28]. Mitchell et al., (2021) stated that repeated application of 38 % SDF at 6-month intervals was effective in arresting decay of root surface lesions and lesions around crowns in older adults [36]. Deutsch et al., (2016) conducted a study on 243 residents (mean age of 83) from 19 Melbourne residential and found that the application of 38% SDF before placing glass-ionomer cement (GIC) restorations was an important adjunct to the atraumatic restorative technique which may retard caries reactivation more than GIC when used alone [35]. In our study, root caries status was assessed by using the Billings Root Index, and there was no change in the status of root caries lesions from the baseline to after 7 days of application of SDF with and without KI. Therefore, the treated root lesions were restored with type-2 glass ionomer cement and then protected with Vaseline.

However, in contrast to our study, Li R et al., (2016) stated that the long term, blackening of arrested root caries was not reduced by immediate application of KI after SDF application [27]. This could not be evaluated in our present study as the follow-up was limited to 7 days for each participant. However, within the limited scope of the study, the participants in the SDF + KI group expressed better satisfaction with the treatment compared to those in the SDF group. This may be explained by differences in large sample size and the age of participants.

STRENGTH OF THE PRESENT STUDY:

1. In this study, root caries lesions were treated by the application of SDF with and without KI. It was an inexpensive and easy technique to apply compared to other conventional restorative treatments during the COVID-19 pandemic period in a community setting.

2. Ethical clearance was obtained from the Institutional Review Board. The study was registered with the Clinical Trial Registry of India (CTRI).

LIMITATIONS:

1. This study was conducted only on female participants using a limited sample size.

2. The short duration of the study prevented us from assessing the long-term effects of both interventions.

3. Though the study was done in an institutional setup, other fluoride sources could have affected the study's results.
4. In this study, only subjective assessment of patient's satisfaction level was done after application of SDF with and without KI.
5. In this study, only *Streptococcus mutans* colony count was evaluated.

SUMMARY

The present interventional study was to determine the patient satisfaction level and *Streptococcus mutans* colony count following a single application of silver diamine fluoride with and without potassium iodide among the community-dwelling geriatric population in Chennai city for a period of 6 months. The participants of the study were recruited from Vishranthi Old Age Home, Palavakam, and St. John Britto Old Age Home, Kovalam.

The study was conducted in two phases, in phase-I: Screening for eligibility and phase-II: The main study. In the screening phase, clinical examinations were done once a week in old age homes. The subjects who met the Billings root caries index (1986) grade less than three or equal to three were included in this study. A total of 40 subjects participated in this study.

In the main study, grouping, intervention, and assessment were done. A total of 40 subjects were divided into 20 each into two groups by lottery method, as group-A (SDF) and group-B (SDF with KI). Then a standard photograph of the root caries lesion was taken using a digital single-lens reflex camera (Canon EOS 70D, Tokyo, Japan). Un-stimulated saliva samples were collected (spit mouth method) & colonies of *Streptococcus mutans* were cultured using Potassium Tellurite Hydrate 90% and Mitis Salivarius Agar Base. In the intervention phase, group-A subjects were applied with SDF, and group B subjects were applied with SDF followed by KI solution for 3-4 minutes. After

the intervention, both groups were followed up for 7 days. Then a standardized photograph of the root caries lesion was then taken similarly as before and un-stimulated saliva samples were collected.

The patient's satisfaction level regarding the treatment was assessed on a Visual Analogue Scale and *S.mutans* colony counts of the two groups were assessed using a digital colony counter. Finally, the teeth where the intervention was given were restored with type-2 glass ionomer cement at the end of 7 days.

This study concluded that salivary *Streptococcus mutans* colony count was reduced in both the groups after application of SDF and SDF with KI groups. The tooth color satisfaction level of subjects between both groups showed that most of the participants in the SDF with KI group expressing better satisfaction compared to those in the SDF group.

CONCLUSION

Based on this interventional study, 38% of SDF had anti-cariogenic property, low cost, and simple procedure (non-invasive) for application to the geriatric population in a community setting with minimal infrastructure to prevent dental root caries formation.

The application of 38% SDF solution or SDF/KI solution effectively reduced the salivary *Streptococcus mutans* colony count at 7 days follow-up, and application of KI did not affect the antimicrobial effect of SDF on *Streptococcus mutans,* and it reduced the black staining of root caries lesion at 7 days follow-up. While comparing satisfaction level of subjects between SDF group and SDF followed by KI group, most of the subjects were satisfied with the application of SDF with KI than SDF group. However, the cost implication of the wider use of SDF with KI needs to be understood.

RECOMMENDATIONS

- SDF is a minimally invasive non-aerosolizing option that prevented non-cavitated lesions and arrested early decay among community dwelling geriatric population when applied independently or concurrently with restorative procedures.
- Professional organizations, policy makers, and providers should broaden optional SDF use by informing clinical guidelines, reimbursement policies, and treatment decisions.
- Future research should address clinical, social, service delivery, workforce, and economic outcomes using diverse population-based samples, and the mechanisms underlying single application success and caries prevention potential.

BIBLIOGRAPHY

1. United Nations Department of Economic and Social Affairs Population Division World Population Ageing 2017, 1– 124.
2. Malik C, Khanna S, Jain Y, Jain R. Geriatric population in India: Demography, vulnerabilities, and healthcare challenges. J Family Med Prim Care. 2021; (10): 72-6.
3. Panchali Batraa, Pratap Sainib, Vijay Yadavc, Oral health concerns in India Journal of Oral Biology and Craniofacial Research. 2020; 10(1); 171–174.
4. Anusavice KJ. Dental caries: risk assessment and treatment solutions for an elderly population. Compend Contin Educ Dent. 2019; 23(3); 12–20.
5. Griffin SO, Griffin PM, Swann JL, Zlobin N. Estimating rates of new root caries in older adults. J Dent Res. 2004; 83: 634-638.
6. López R, Smith PC, Göstemeyer G, Schwendicke F. Ageing, dental caries and periodontal diseases. J Clin Periodontol. 2017; 44(18): S145-S152.
7. Kassebaum NJ, Bernabe E, Dahiya M. Global Burden of Untreated Caries: A Systematic Review and Metaregression. J Dent Res. 2015; 94(5): 650–658.
8. Masood M, Newton T, Bakri NN, Khalid T, Masood Y. The relationship between oral health and oral health related quality of life among elderly people in United Kingdom. J Dent. 2017; 56(1): 78– 83.

9. Balasubramanian Kumara-Raja, Gubbihal Radha. Prevalence of root caries among elders living in residential homes of Bengaluru city, India. J Clin Exp Dent. 2016; 8(3): 260-267.
10. Hariyani N, Setyowati D, Spencer AJ, Luzzi L, Do LG. Root caries incidence and increment in the population - A systematic review, meta-analysis and meta-regression of longitudinal studies. J Dent. 2018; 77: 1-7.
11. Du M, Jiang H, Tai B, Zhou Y, Wu B, Bian Z. Root caries patterns and risk factors of middle-aged and elderly people in China. Community Dent Oral Epidemiol. 2009; 37: 260-266.
12. Simunkovic SK, Boras VV, Panduric J, Zilic IA. Oral health among institutionalised elderly in Zagreb, Croatia. Gerodontology. 2005; 22: 238-241.
13. Agarwal A, Reddy L V, Saha S, Grover S, Sinha P. Risk indicators for root caries in geriatric population of Lucknow City: A cross-sectional study. J Indian Assoc Public Health Dent. 2018; 16: 18-21.
14. R.J. Marino, C.S. Fu, R.A. Giacaman, Prevalence of root caries among ambulant older adults living in central Chile, Gerodontology. 2015; 32; 107–114.
15. W. Zhang, C. McGrath, E.C.M. Lo, J.Y. Li. Silver Diamine Fluoride and Education to Prevent and Arrest Root Caries among Community-Dwelling Elders, Caries Res. 2013; 47: 284–290.
16. Momoi Y, Hayashi M, Fujitani M, Fukushima M, Imazato S, Kubo S, Nikaido T, Shimizu A, Unemori M, Yamaki C. Clinical guidelines for

treating caries in adults following a minimal intervention policy--evidence and consensus based report. J Dent. 2012; 40(2): 95-105.

17. Horst JA, Ellenikiotis H, Milgrom PL. UCSF Protocol for Caries Arrest Using Silver Diamine Fluoride: Rationale, Indications and Consent. *J Calif Dent Assoc*. 2016; 44(1): 16-28.
18. Shah S, Bhaskar V, Venkatraghavan K, Choudhary P, M. G, Trivedi K. Silver Diamine Fluoride: A Review and Current Applications. *Journal of Advanced Oral Research*. 2014; 5(1): 25-35.
19. E. Schwarz, E.C.M. Lo. Dental health knowledge and attitudes among the middle-aged and the elderly in Hong Kong. Commun. Dent. Oral Epidemiol. 1994; 22; 358–363.
20. Fakhruddin KS, Egusa H, Ngo HC, Panduwawala C, Pesee S, Samaranayake LP. Clinical efficacy and the antimicrobial potential of silver formulations in arresting dental caries: a systematic review. *BMC Oral Health*. 2020; 20(1): 160.
21. Lin YS, Rothen ML, Milgrom P. Pharmacokinetics of 38% topical silver diamine fluoride in healthy adult volunteers. J Am Dent Assoc. 2019; 150(3):186-192.
22. Turton B, Horn R, Durward C. Caries arrest and lesion appearance using two different silver fluoride therapies on primary teeth with and without potassium iodide: 12-month results. Clin Exp Dent Res. 2021; 7(4): 609-619.

23. Knight GM, McIntyre JM, Mulyani. The effect of silver fluoride and potassium iodide on the bond strength of auto cures glass ionomer cement to dentine. Aust Dent J. 2006; 51(1): 42-5.
24. Mei ML, Chin-Man Lo E, Chu CH. Clinical Use of Silver Diamine Fluoride in Dental Treatment. Compend Contin Educ Dent. 2016; 37(2): 93.
25. Preza D, Olsen I, Aas JA, Willumsen T, Grinde B, Paster BJ. Bacterial profiles of root caries in elderly patients. J Clin Microbiol. 2008; 46(6): 2015-21.
26. Mei ML, Li QL, Chu CH, Lo EC, Samaranayake LP. Antibacterial effects of silver diamine fluoride on multi-species cariogenic biofilm on caries. *Ann Clin Microbiol Antimicrob*. 2013; 12: 4-9.
27. Li R, Lo EC, Liu BY, Wong MC, Chu CH. Randomized clinical trial on arresting dental root caries through silver diammine fluoride applications in community-dwelling elders. J Dent. 2016; 51: 15-20.
28. Tan HP, Lo EC, Dyson JE, Luo Y, Corbet EF. A randomized trial on root caries prevention in elders. J Dent Res. 2010; 89(10): 1086-90.
29. J.C. Llodra, A. Rodriguez, B. Ferrer, V. Menardia, T. Ramos, M. Morato. Efficacy of silver diamine fluoride for caries reduction in primary teeth and first permanent molars of schoolchildren: 36-month clinical trial. J Dent Res. 2005; 84; 721–724.

30. R. Yee, C. Holmgren, J. Mulder, D. Lama, D. Walker, and W. van Palenstein Helderman. Efficacy of Silver Diamine Fluoride for Arresting Caries Treatment. Dent Res. 2009; 88(7): 644-647.
31. Monse B, Heinrich-Weltzien R, Mulder J, Holmgren C, van Palenstein Helderman WH. Caries preventive efficacy of silver diammine fluoride (SDF) and ART sealants in a school-based daily fluoride toothbrushing program in the Philippines. *BMC Oral Health*. 2012; 12: 52-58.
32. Milgrom P, Horst JA, Ludwig S, Rothen M, Chaffee BW, Lyalina S, Pollard KS, DeRisi JL, Mancl L. Topical silver diamine fluoride for dental caries arrest in preschool children: A randomized controlled trial and microbiological analysis of caries associated microbes and resistance gene expression. J Dent. 2018; 68: 72-78.
33. Chu CH, Lo EC, Lin HC. Effectiveness of silver diamine fluoride and sodium fluoride varnish in arresting dentin caries in Chinese pre-school children. J Dent Res. 2002; 81(11): 767-70
34. Mattos-Silveira J, Floriano I, Ferreira FR, Viganó ME, Frizzo MA, Reyes A, Novaes TF, Moriyama CM, Raggio DP, Imparato JC, Mendes FM, Braga MM. New proposal of silver diamine fluoride use in arresting approximal caries: study protocol for a randomized controlled trial. Trials. 2014; 15: 448-455.
35. Deutsch A. An alternate technique of care using silver fluoride followed by stannous fluoride in the management of root caries in aged care. Spec Care Dentist. 2016; 36(2): 85-92.

36. Mitchell C, Gross AJ, Milgrom P, Mancl L, Prince DB. Silver diamine fluoride treatment of active root caries lesions in older adults: A case series. J Dent. 2021; 105: 103-6.
37. Garrastazu MD, Mathias-Santamaria IF, Rocha RS, Diniz MB, Caneppele TMF, Bresciani E. Three-Month Effect of Silver Diamine Fluoride (SDF) in Salivary Levels of Streptococcus Mutans in Children. An Exploratory Trial. Oral Health Prev Dent. 2020; 18(1): 325-330.
38. Chu CH, Mei L, Seneviratne CJ, Lo EC. Effects of silver diamine fluoride on dentine carious lesions induced by Streptococcus mutans and Actinomyces naeslundii biofilms. Int J Paediatr Dent. 2012; 22(1): 2-10.
39. Horst JA, Ellenikiotis H, Milgrom PL. UCSF Protocol for Caries Arrest Using Silver Diamine Fluoride: Rationale, Indications and Consent. J Calif Dent Assoc. 2016; 44(1):16-28.
40. Gugnani N, Pandit IK, Srivastava N, Gupta M, Sharma M. International Caries Detection and Assessment System (ICDAS): A New Concept. Int J Clin Pediatr Dent. 2011; 4(2): 93-100.
41. Haiat A, Ngo HC, Samaranayake LP, Fakhruddin KS. The effect of the combined use of silver diamine fluoride and potassium iodide in disrupting the plaque biofilm microbiome and alleviating tooth discoloration: A systematic review. *PLoS One*. 2021; 16(6): 1-18.

ANNEXURE – 1

RAGAS DENTAL COLLEGE & HOSPITAL
(Unit of Ragas Educational Society)
Recognized by the Dental Council of India, New Delhi
Affiliated to The Tamilnadu Dr. M.G.R. Medical University, Chennai
2/102, East Coast Road, Uthandi, Chennai - 600 119. INDIA.
Tele : (044) 24530002, 24530003 - 06. Principal (Dir) 24530001 Fax : (044) 24530009

TO WHOM SO EVER IT MAY CONCERN

Date: 30-06-2021,
Place: Chennai.

From
The Institutional Ethics Committee
Ragas Dental College and Hospital
Uthandi, Chennai -119

The Project topic titled **"Quantitative and Qualitatively evaluate the patient's satisfaction level *and Streptococcus mutans* colony count following a single application of Silver Diamine Fluoride with and without Potassium Iodide among Community Dwelling Geriatric population in Chennai city- An Interventional Study"** submitted by Dr.Rajkumar.C has been approved by the Institutional Ethics Committee of Ragas Dental College and Hospital.

Dr. N.S.AZHAGARASAN, MDS
Member Secretary,
Institutional Ethics Committee,
Ragas Dental College & Hospital,
Uthandi, Chennai-600119.

ANNEXURE – 2

Home :
No. 4/227, M.G.R. Salai, Palavakkam, Chennai - 600 041
Phone : **2449 0972, 2449 4757,** Mobile : **98412 94757** (7.00 a.m. - 7.00 p.m.)

Admn. Office :
Flat No.1, "Sapthagiri Apartments"
No. 187 (Old No. 83), T.T.K. Road, Alwarpet, Chennai - 600 018
Phone : **2499 6634, 2499 4806** (10.30 a.m. - 5.00 p.m.)
E-mail : vishranthi_trust@yahoo.com
Web : www.vishranthi-trust.in

Vishranthi
CHARITABLE TRUST
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VISHRANTHI HOME FOR AGED DESTITUTE WOMEN

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Treasurer : **Smt. Sundari Jayaraman** 94451 24135
Secretary : **Smt. R. Srilekha** 98400 59143

07.04.2021
Date.....

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr. C. Rajkumar, Post Graduate student, Department of Public Health Dentistry, Ragas Dental College & Hospital, was given permission to screen our inmates and conduct his study titled, **"Evaluation of Patient's satisfaction and Streptococcus mutans colony count following a single application of Silver Diamine Fluoride with and without Potassium Iodide among Community Dwelling Geriatric population in Chennai City – An Interventional Study".**

He has successfully completed his study over a period of 6 months - November 2020 to April 2021.

For VISHRANTHI CHARITABLE TRUST
R. Srilekha
Secretary

DONATIONS ARE EXEMPTED UNDER 80-G OF THE INCOME TAX ACT, 1961

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Smt. Nalini Ramanathan 98840 28717
Smt. Geetha Srivathsan 98849 64464
Smt. Lakshmi Rajagopal 97899 08243
Smt. Lakshmi Narasimhan 94446 28734
Smt. Kamala Venkat Rao 99402 72547
Smt. Sujatha Anand 98419 46711
Smt. Asha Sridharan 94449 61502
Smt. Annapoorani Rangaraju 94451 67526

ANNEXURE – 3

ph: 044-27472025

St. JOHN DE BRITTO HOME
FOR AGED WOMEN

East Coast Road, Kovalam- 603 112,
Kancheepuram District, Tamil Nadu, South India.

Date: 01.07.2021

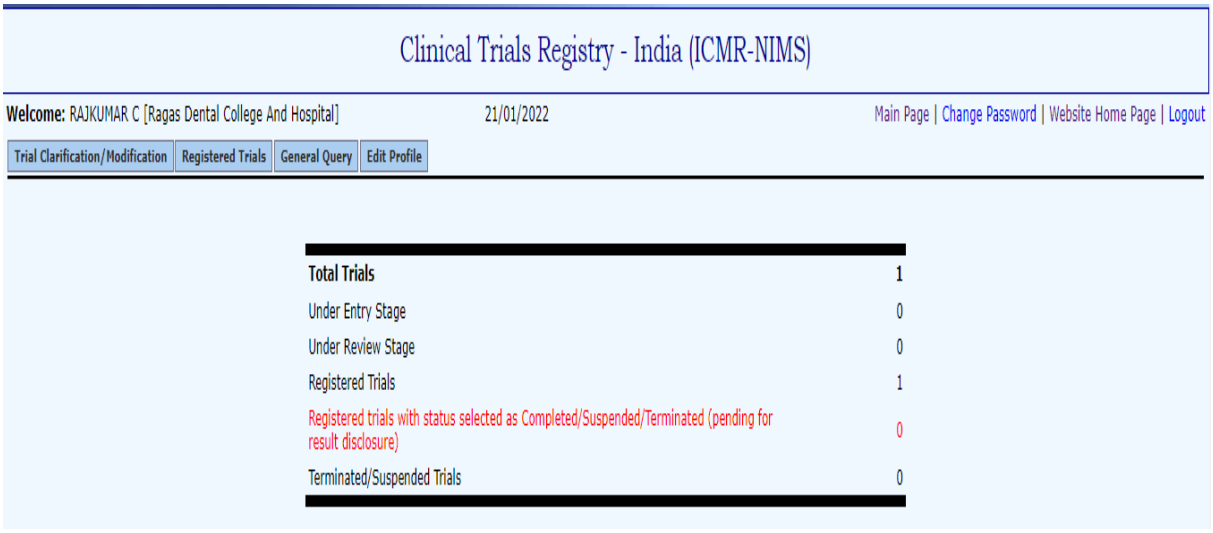
TO WHOMSOEVER IT MAY CONCERN

This is to certify that Dr. C. Rajkumar, Post-graduate student, Department of Public Health Dentistry, Ragas Dental College and Hospital, was given permission to screen our inmates and conduct his study titled, **"Evaluation of patient's satisfaction and *Streptococcus mutans* colony count following a single application of Silver Diamine Fluoride with and without Potassium Iodide among Community Dwelling Geriatric population in Chennai city - An Interventional Study."**

He has successfully completed his study over a period of 6 months (November-2020 to April-2021).

Sr. Sebasty
ST.JOHN DE BRITTO HOME
FOR AGED WOMEN
East coast Road,
Kovalam- 603 112.
Kancheepuram District.

ANNEXURE – 4

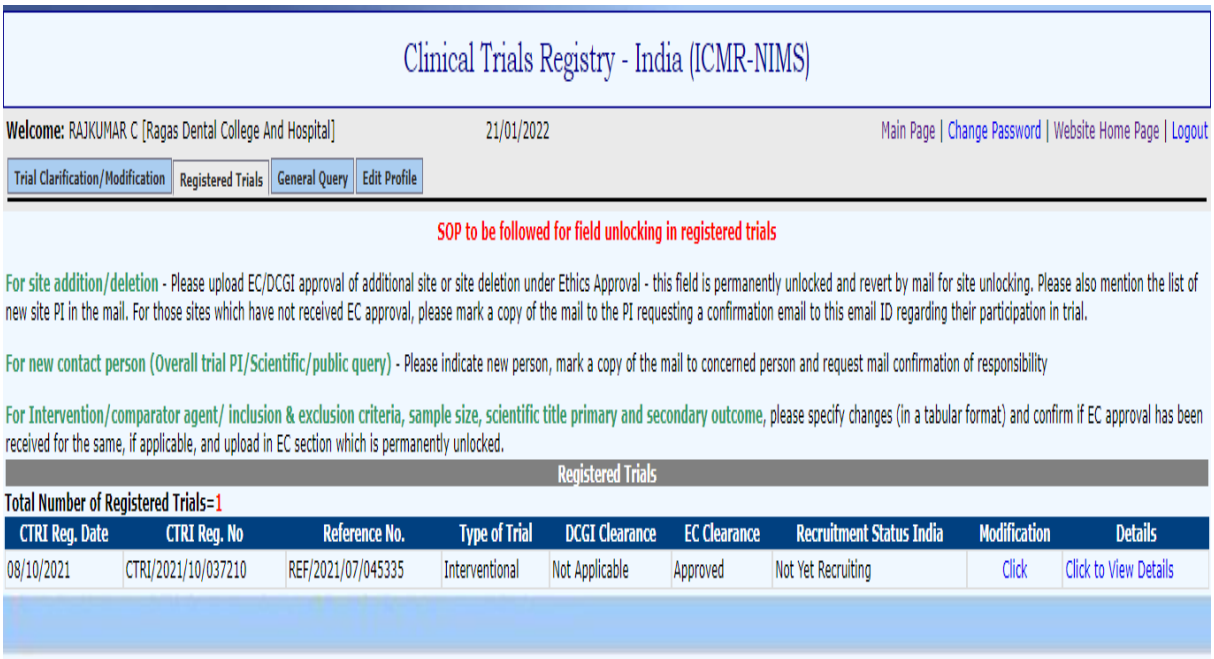


Clinical Trials Registry - India (ICMR-NIMS)

Welcome: RAJKUMAR C [Ragas Dental College And Hospital] 21/01/2022 Main Page | Change Password | Website Home Page | Logout

Trial Clarification/Modification | Registered Trials | General Query | Edit Profile

Total Trials	**1**
Under Entry Stage	0
Under Review Stage	0
Registered Trials	1
Registered trials with status selected as Completed/Suspended/Terminated (pending for result disclosure)	0
Terminated/Suspended Trials	0



Clinical Trials Registry - India (ICMR-NIMS)

Welcome: RAJKUMAR C [Ragas Dental College And Hospital] 21/01/2022 Main Page | Change Password | Website Home Page | Logout

Trial Clarification/Modification | Registered Trials | General Query | Edit Profile

SOP to be followed for field unlocking in registered trials

For site addition/deletion - Please upload EC/DCGI approval of additional site or site deletion under Ethics Approval - this field is permanently unlocked and revert by mail for site unlocking. Please also mention the list of new site PI in the mail. For those sites which have not received EC approval, please mark a copy of the mail to the PI requesting a confirmation email to this email ID regarding their participation in trial.

For new contact person (Overall trial PI/Scientific/public query) - Please indicate new person, mark a copy of the mail to concerned person and request mail confirmation of responsibility

For Intervention/comparator agent/ inclusion & exclusion criteria, sample size, scientific title primary and secondary outcome, please specify changes (in a tabular format) and confirm if EC approval has been received for the same, if applicable, and upload in EC section which is permanently unlocked.

Registered Trials

Total Number of Registered Trials=1

CTRI Reg. Date	CTRI Reg. No	Reference No.	Type of Trial	DCGI Clearance	EC Clearance	Recruitment Status India	Modification	Details
08/10/2021	CTRI/2021/10/037210	REF/2021/07/045335	Interventional	Not Applicable	Approved	Not Yet Recruiting	Click	Click to View Details

ANNEXURE-5

INFORMED CONSENT FORM

TITLE

"Evaluation of patient's satisfaction level and Streptococcus mutans colony count following a single application of Silver Diamine Fluoride with and without Potassium Iodide among Community Dwelling Geriatric population in Chennai city- An Interventional Study."

DETAILS OF THE INVESTIGATOR:

Dr. C. Rajkumar, Mobile Number: 9626712641

Post graduate student,

Department of Public Health Dentistry,

Ragas Dental College and Hospital.

UNDERTAKING BY THE INVESTIGATOR:

Your consent for the above study is sought. We undertake to maintain complete confidentiality regarding the information obtained from you during the study. If you have any doubts regarding the study, please feel free to clarify the same. The investigator and contact number is given below:

PARTICIPANT'S CONSENT

I _____, residing at _____

_____, do hereby solemnly and state as follows.

I am aware of the facts stated here under.

I was informed and explained about the pros and cons of the study in the _____ language known to me.

I give my consent after knowing the full consequences of the study.

I have given voluntary consent for the study without any individual pressure or distress.

I have also been informed about the purpose and procedures of the study that is to be conducted. I understand that if I give my consent for the study, I will have to provide the necessary details required for the study and co-operate.

Signature of the investigator(s). Signature of the Participant

Date:

Place: Signature of witness

ANNEXURE-6

INFORMED CONSENT FORM (TAMIL)

ராகஸ் பல் மருத்துவமனை மற்றும் கல்லூரி

<u>ஆய்வின் தலைப்பு:</u>

"சென்னை நகரத்தில் உள்ள சமூகத்தில் வசிக்கும் வயதான மக்களிடையே சில்வர் டையாமைன் ஃப்ளூரைடுடன் பொட்டாசியம் அயோடைடு மற்றும் இல்லாமல் பயன்படுத்தப்பட்டதைத் தொடர்ந்து நோய்யாளின் திருப்த்தி நிலை மற்றும் ஸ்ட்ரெப்யகாக்கஸ் மியூட்டன்ஸ் காலனி எண்ணிக்கையை மதிப்பீடு செய்தல் - ஒரு தலையீட்டு ஆய்வு"

<u>ஆய்வாளரின் பொறுப்பு</u>

மேற்கூறப்பட்ட ஆய்விற்குத் தங்களின் ஒப்புதலைக் கோருகிறோம். இந்த ஆய்வின் போது தங்களிடமிருந்து பெறப்பட்ட தகவல்களையும் அதன் மீதான முடிவுகளையும் பற்றி முழுமையான ரகசியத்தைக் காப்போம் என்று உறுதி கூறுகிறோம். இந்த ஆய்வு பற்றி தங்களுக்கு ஏதேனும் சந்தேகம் இருந்தால் தயவுசெய்து அது பற்றி சுதந்திரமாகக் கேட்டுத் தெரிந்துகொள்ள விழைகிறோம். ஆய்வாளரின் பெயரும் தொலைபேசி எண்ணும் கீழே தரப்பட்டுள்ளன.

பெயர்: டாக்டர் ச. ராஜ்குமார். **தொலைபேசி எண்: 9626712641**

தகவலாளியின் ஒப்புதல் படிவம்

நான்----------,----------

---------- என்ற முகவரியில் இருந்து கீழ்க்கண்டபடி உறுதியுடன் தெரிவித்துக் கொள்வது:

இங்கு நான் தகவலாளி, கீழ்க்கொடுத்திருக்கும் தகவல்களைப் பற்றித் தெரிந்துவைத்திருக்கிறேன்.

இந்த ஆய்வின் நல்லவை தீயவை பற்றியும் இதன் முடிவுகள் பற்றியும் எனக்கு விளக்கமாகச் சொல்லப்பட்டிருக்கிறது. இந்த ஆய்வின் போது எந்த விதமான துளையிடும் செயல்முறையும் செய்யப்படமாட்டாது என்றும் எந்த ஓர் அசௌகரியமும் எனக்கு நேராது எனவும் எனக்குத் தெரிந்த ----------மொழியில் விளக்கப்பட்டுள்ளது.

இந்த ஆய்வின் முழுமையான விளைவை அறிந்தே நான் என் ஒப்புதலைத் தருகிறேன். வலுக்கட்டாயமாகவோ தனிநபரின் நெருக்கடி காரணமாகவோ அல்லாமல் நான் சுயமாக என்னை இந்த ஆய்வில் சேர்ப்பதற்கு ஒப்புதலைத் தருகிறேன்.

என் மீது நடத்தப்படும் இந்த ஆய்வின் நோக்கத்தையும் செயல்முறையையும் பற்றி எனக்குத் தெரிவிக்கப்பட்டிருக்கிறது. இந்த ஆய்விற்கு ஒப்புதலைத் தருவதினால் ஆய்விற்குத் தேவையான முழுமையான தகவல்களை நான் சொல்ல சொல்லவேண்டும் என்பதையும் இந்த ஆய்வின் போது ஏற்படும் முடிவிற்கு நான் ஒத்துழைக்கவேண்டும் என்பதையும் நான் அறிந்திருக்கிறேன்.

நான் ---------- இந்த ஆய்வில் பங்கேற்க ஒப்புதலைத் தருகிறேன்.
(அ)

நான் ---------- என் மகன் / மகள் இந்த ஆய்வில் பங்கேற்க ஒப்புதலைத் தருகிறேன்.

ஆய்வாளரின் கையொப்பம் தகவலாளியின் கையொப்பம்

இடம்: சாட்சியின் கையொப்பம்

ANNEXURE – 7

SAMPLE SIZE CALCULATION

t tests - Means: Difference between two independent means (two groups)

Analysis: A priori: Compute required sample size

Input: Tail(s) = Two

Effect size d = 0.91300

α err prob = 0.05

Power (1-β err prob) = 0.80

Allocation ratio N2/N1 = 1

Output: Noncentrality parameter δ = 2.8890000

Critical t = 2.0322445

Df = 34

Sample size group 1 = 19

Sample size group 2 = 19

Total sample size = 38

Actual power = 0.8013861

ANNEXURE – 8

BILLINGS ROOT CARIES INDEX (1986):

17	16	15	14	13	12	11	21	22	23	24	25	26	27
47	46	45	44	43	42	41	31	32	33	34	35	36	37

Grade I: (Incipient) = 1

- Surface texture; soft, can be penetrated with a
- Dental Explorer
- No surface defect
- Pigmentation; variable, light tan to brown

Grade II: (Shallow) = 2

- Surface texture: soft, irregular, rough, can be penetrated with a dental explorer
- Surface defect (less than 0.50 mm in depth)
- Pigmentation; variable, tan to dark brown

Grade III: (Cavitation) = 3

- Surface texture; soft, can be penetrated with a dental explorer
- Penetrating lesion, cavitation present (greater than 0.50 mm in depth) no pulpal involvement
- Pigmentation; variable, light brown to dark brown

Grade IV: (Pulpal) = 4

- Deeply penetrating lesion with pulpal or root canal involvement
- Pigmentation; variable, brown to dark brown

DEMOGRAPHIC DATA

NAME;- AGE/GENDER;-

EDUCATION LEVEL: □ Primary □ Secondary □ Post-secondary □ Tertiary

ADDRESS;-

Frequency of snaking per day……

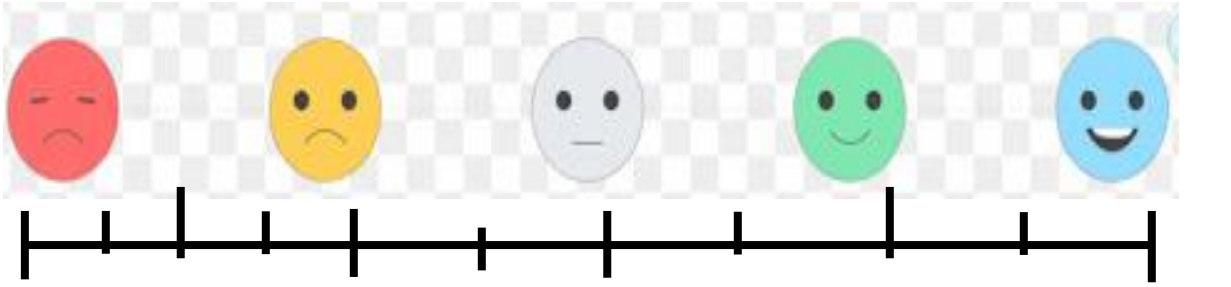
Frequency of brushing per day……..

Using of any other oral hygiene aids?

A) Yes B) No

ANNEXURE-9

VISUAL ANALOGUE SCALE



0 2 4 6 8 10

Not at all satisfied

0-4

Neutral

5

Satisfied

6-10

ANNEXURE-10

PLAGIARISM CERTIFICATE

Curiginal

Document Information

Analyzed document	EVALUATION OF PATIENT SATISFACTION LEVEL AND STREPTOCOCCUS MUTANS COLONY COUNT FOLLOWING A SINGLE APPLICATION OF SILVER DIAMINE FLUORIDE WITH AND WITHOUT POTASSIUM IODIDE AMONG COMMUNITY DWELLING GERIATRIC POPULATION IN.docx (D125504417)
Submitted	2022-01-19T15:36:00.0000000
Submitted by	C.Rajkumar
Submitter email	rajsachin1994@gmail.com
Similarity	4%
Analysis address	rajsachin1994.mgrmu@analysis.urkund.com

ANNEXURE – 11

MASTER SHEET

S.No	Name	Age	ıcationa l	Brushing	Snaking l	hygiene	at all sati	Neutral	Satisfied	y count b	ay count after treatment		
1	Devi.M	63	primary	once	once	no			8	1444	672		
2	Omana.S	72	primary	once	once	no			8	948	556		
3	saraswathi	80	primary	once	once	no			8	1245	890		
4	maniyamr	76	primary	once	once	no			8	1836	1578		
5	nthammal	65	primary	once	once	no			8	1276	988		
6	ıjalakshmi	72	primary	once	once	no			8	906	688		
7	gowri.n	68	secondary	once	once	no			8	956	792		
8	lakshmi.s	71	secondary	once	once	no			8	1588	1098		
9	parvathi	75	secondary	once	once	no			8	1412	985		
10	suntharan	66	primary	once	once	no			8	1431	997		
11	ıla. M(Kov	67	secondary	twice	once	no			8	1211	953		
12	visalam	76	secondary	twice	once	no			8	897	661		
13	kalyani.g	67	secondary	twice	once	no			8	984	669		
14	kalyani.k	62	primary	once	once	no			8	1022	873		
15	rukumani	61	primary	once	once	no			8	1692	1134		
16	uniyamma	63	primary	once	once	no			8	1321	984		
17	elisabeth	65	primary	once	once	no			8	983	864		
18	sebestin..	60	primary	once	once	no			8	724	646		
19	anjalai. S	69	primary	once	once	no			8	624	576		
20	sangeetha	78	primary	once	once	no			8	1144	942		

S.No	Name	Age	ıcationa l	Brushing	Snaking l	hygiene	general ıat all sati	Neutral	Satisfied	y count b	ay count after treatment		
21	ganthamn	82	primary	once	once	no	yes(a)		6	987	659		
22	visalam.n	72	secondary	once	once	no	yes(a)		6	1093	806		
23	bhanumat	81	primary	once	once	no	yes(a)		6	1376	979		
24	chinamma	78	primary	once	once	no	yes(a)		6	983	789		
25	Rokku	62	primary	once	once	no	yes(a)		6	1072	983		
26	lakshmi.v	78	secondary	once	once	no	yes(a)		6	1588	980		
27	raani	64	primary	once	once	no	yes(a)		6	976	702		
28	susila.k.s	65	secondary	twice	once	no	yes(a)		6	897	574		
29	janaki.r	74	primary	once	once	no	yes(a)		6	943	589		
30	Devaki(ko	80	secondary	once	once	no	yes(a)		6	1213	862		
31	jayalakshr	68	primary	nil	twice	no	yes(a)		6	1426	905		
32	sai	68	primary	nil	once	no	no(b)		6	900	548		
33	sagunthal	88	primary	once	once	no	yes(a)		6	988	709		
34	saroja, r	86	primary	once	once	no	yes(a)		6	1321	860		
35	rosy.l(Kov	82	secondary	twice	once	no	yes(a)		6	763	506		
36	saratha. V	67	primary	twice	once	no	yes(a)		6	983	790		
37	sumathi k	76	primary	once	once	no	yes(a)		6	1432	869		
38	alamellu.(	60	secondary	twice	once	no	yes(a)		6	984	765		
39	muthulak:	65	primary	twice	once	no	yes(a)		6	1653	921		
40	kannamm	76	secondary	once	once	no	yes(a)		6	1321	980		