Journal Homepage: -www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/19175
DOI URL: http://dx.doi.org/10.21474/IJAR01/19175

RESEARCH ARTICLE

"EVALUATING THE EFFICACY OF 38% SDF VS 5% NAF VS APF GEL IN ARRESTING DENTAL CARIES AND REDUCING BACTERIAL ACTIVITY: AN IN-VIVO STUDY"

Dr. Mhaski Parul[1], Dr. Mangla Ritu[2], Dr. Dua Parminder[3], Dr. Vyas Divya[4] and Dr. Neha[5]

1. PG Student, Department of Pediatric and Preventive Dentistry, Himachal Institute of Dental Sciences, Paonta Sahib, Himachal Pradesh.
2. Professor, Department of Pediatric and Preventive Dentistry, Himachal Institute of Dental Sciences, Paonta Sahib, Himachal Pradesh.
3. Professor and HOD Department of Pediatric and Preventive Dentistry, Himachal Institute of Dental Sciences, Paonta Sahib, Himachal Pradesh.
4. Reader, Department of Pediatric and Preventive Dentistry, Himachal Institute of Dental Sciences, Paonta Sahib, Himachal Pradesh.
5. Senior Lecturer, Department of Pediatric and Preventive Dentistry, Himachal Institute of Dental Sciences, Paonta Sahib, Himachal Pradesh.

Manuscript Info

Manuscript History
Received: 31 May 2024
Final Accepted: 30 June 2024
Published: July 2024

Key words:-
Silver Diamine Fluoride (SDF), Caries Arrest, Plaque Index, Streptococcus Mutans

Abstract

Background: The study was formulated to compare the efficacy of 38% SDF as a caries arresting agent as well as antibacterial and antiplaque agent in vivo with 5% sodium fluoride varnish (NaF) and 1.23% acidulated phosphate fluoride (APF) gel.

Study Design: Total of 74 children aged 6-9 years (boys = 34, girls = 40) who had active caries with dmfs/DMFS score equal to or more than 1 were included in the study for a period of 12 months. Children were divided into three different groups-Group 1: 38%SDF; Group 2: 5% fluoride varnish; and Group 3: 1.23% APF gel. Fluoride application was done at baseline, 6th month and 12th month. Saliva collection was done at baseline, after 72 hrs, 6th month and12thmonth.Tryptone-yeastcysteine-sucrose-bacitracin agar (TYCSB) was used inoculate salivary Streptococcus mutans and incubated at 37°C for 72 hrs.The colony characteristics were studied and number of colony forming units of Streptococcus mutans (CFU/ml) of saliva were counted using digital colony counter.All subjects were evaluated for caries arrest status and plaque score (Silness&Loe index)at 6th and 12thmonthas well as Streptococcus mutans counts in saliva at 72 h, 6th and 12thmonth.

Results: Significant reduction was found in caries arrest status; plaque score as well as S. mutans counts in Group 1 as compared with Groups 2 and 3.

Conclusion: In vivo application of SDF is effective in controlling progression of caries, decreases plaque score and S. mutans counts in saliva as compared to fluoride varnish and APF gel.

Corresponding Author:-Dr. Mhaski Parul
Address:- PG Student, Department of Pediatric and Preventive Dentistry, Himachal Institute of Dental Sciences, Paonta Sahib, Himachal Pradesh.

Introduction:-

Evolving research in the field of cariology has brought about a paradigm shift in understanding of the caries process and its management. For caries management and preservation of natural tooth appropriate preventive measures, risk assessment, exact diagnosis and timely treatment procedures that do not compromise sound tooth structure is essential.[1] Dental decay if left untreated can lead to poor oral health and can have longstanding effects on children through adolescent and as adults.

Conventionally, the management of the carious lesions follows removal of carious tissue and replacement with a suitable restorative material. Subsequently, minimal invasive dentistry (MID), which aims at maintenance of sound tooth structure using non-invasive techniques, has replaced the conventional procedures.[2] Based on preventive dentistry, use of topical fluoride may be a useful measure to arrest lesions because fluoride used in various forms have been proven to be effective in dental caries prevention. Due to characteristics of deciduous teeth enamel (half as thick as that of permanent teeth, lower mineral content and higher organic content, and more susceptibility to caries) it is important to use fluoride in primary dentition to control the development and progression of carious lesions. Topical application of fluoride has been proven to be most important method in combating carious lesions.[3]

Though not new, silver diamine fluoride (SDF) most recently has demonstrated amplified attention by clinicians globally due to its effectiveness in arresting the progression of caries. SDF was introduced in Japan in 1970's. It was approved by Food and Drug Administration of United States in 2014.The first SDF material introduced by the Food and Drug Administration was Advantage Arrest (Elevate Oral Care), 38% solution of SDF for desensitizing coldsensitive teeth. Since then, use of SDF has spread rapidly around the world and underserved populations due to its ease of application, its low cost per application and its few side effects.[4] The mechanism of action of SDF is hypothesized to be its anticariogenic properties, ability to increase enamel surface microhardness (SMH), and reduce enamel surface mineral loss. It has an intense antibacterial effect on cariogenic biofilm and hinders caries progression.[3]

Caries prevalence in young children is very high, and most of the decayed teeth are left untreated. Novel approaches are needed to improve this scenario. In case of children who are uncooperative during conventional caries treatment, SDF is safe to use. It proves to be excellent in community setting due to its easy practical implementation and requires less set of equipment's and instruments. This property of SDF improves the access to dental care in remote areas. Thus, aim of this study is to evaluate the effectiveness of topical application of 38% Silver Diamine Fluoride in arresting caries and as antibacterial agent in primary teeth and permanent 1st molars of children.

Objectives of the study were to evaluate the changes in plaque score, caries status and S. mutans counts in saliva after application of SDF, NaF and APF gel.

Material and Method:-

Thepresent study was conducted in the Department of Pediatric and Preventive Dentistry in Himachal Institute of

Dental Sciences, Paonta Sahib, Himachal Pradesh to compare the effectiveness of 38% SDF, 5% NaF, and 1.23% APF gel in inhibiting dentin caries and bacterial activity on primary teeth. The study was conducted on schoolchildren who were bought to outpatient department of Pediatric Dentistry as a part of school dental health programme. The study was approved by Institutional Review Board and Ethical Committee of Himachal Institute of Dental Sciences. Before starting the study permission from school authorities was obtained after explaining its procedure and protocol. A written consent letter was given to parents of all the children explaining the purpose and procedures of this study. Screening of patients was done and children with decayedteeth were included in this study. Preoperative baseline examination was done using a CPITN probe and flat mirror according to DMFS/dmfs index.

Total of 277 children were diagnosed out of which 90 children from 6-9 years age group were selected for the study.A written consent letter was given to parents of all the children explaining the purpose and procedures of this study.

The patients were selected according to the following inclusion and exclusion criteria:

Inclusion Criteria:
1. All permanent first molars fully erupted.
2. Subjects with all deciduous molars present.
3. Children with presence of cavitated caries lesion.
4. Subjects with decayed missing filled surface - dmfs (decayed, missing, filled surface - Primary teeth) and DMFS (Decayed, Missing, Filled Surface) - Permanent teeth score equal to or more than 1.

Exclusion Criteria:
1. Children with ulcerative gingivitis or stomatitis.
2. Cavitated teeth that are nearing natural exfoliation time.
3. Children with more than 1/3rd of the crown missing, or pulpal involvement.
4. Developmentaldental abnormalities such as enamel defects.
5. Serious chronic medical conditions such as congenital heart disease.
6. Known silver allergy.
7. Uncooperative children.
8. Children with special health care needs.

Group Of Samples:
1. GROUP I: 38% SDF
2. GROUP II: 5% NaF varnish
3. GROUP III: 1.23% APF gel

Method for Saliva Collection:-
1. Collection of saliva samples was done in all three groups at baseline and after 72 hours (3rd day).
2. A cotton swab stick was used to take the saliva sample. The swab was wiped from buccal and lingual surfaces of all teeth. The swab was placed in sterile vile containing phosphate buffered saline (pH=7.3) and was transported to microbiology laboratory in an icebox to help maintain the viability of test organism and processed within 4 hours.

Group I: 38% SDF
1. Mucosal surface was covered with Vaseline, to protect from mild burning sensation and staining due to SDF.
2. Isolation of teeth was carried out with help of cotton rolls and high-volume suction.
3. A very small drop of solution was squeezed on the cotton pellet.
4. Application was done for 3-4 minutes on affected surfaces of teeth in single quadrant at 1 time.
5. Patient was asked to clean his mouth by gargling with distilled water or normal saline.
6. Patient was instructed not to drink or eat for 30 minutes.
7. Same procedure was repeated in all quadrants in similar manner.

For Group II (5% NaF Varnish) and Group III (1.23%) APF gel application was done according to manufacturer's instructions. Patients were instructed not to drink or eat for 1 hour.

Figure 1:- SDF application

Figure 2:- NaF varnish application

Figure 3:- APF gel application.

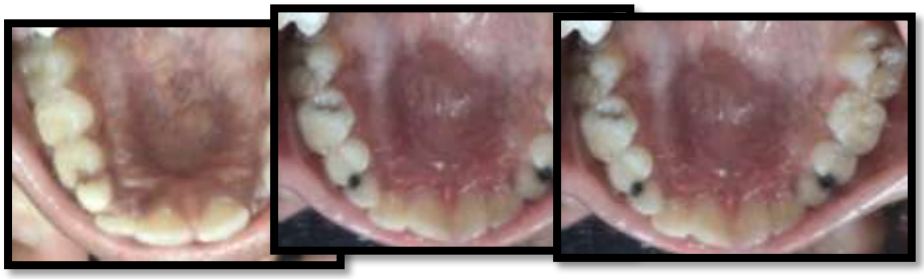
Follow-Up Visits
All the subjects in the groups were followed up and evaluated after 6th, and 12th month for caries status, plaque index and S. mutans count.

Method for microbiological analysis of salivary samples
Collected saliva samples was taken to microbiology lab and vortexed for 30 s to disperse the bacteria. Tryptoneyeast-cysteine-sucrose-bacitracin agar (TYCSB) was used inoculate salivary Streptococcus mutans and incubated at 37°C for 72 hrs. The number of colony forming units of Streptococcus mutans (CFU/ml) of saliva were counted using digital colony counter.

Statistical analysis
The statistical analysis was done using Statistical Package for Social Sciences (SPSS for Windows, Version 19.0). Prior to analysis, normality testing of the data was done using Shapiro-Wilk test which showed that the data were normally distributed (P<0.05).

Results:-

Comparison of Caries Status
Table 1, Graph 1 shows that at 6 months, the arrested caries was significantly higher in SDF (P=0.036*) than that in APF and NaF varnish. At 12 months, it was observed that, the arrested caries was higher in SDF group (P=0.015*) compared to APF group as well as fluoride varnish group.



(a) (b) (c)

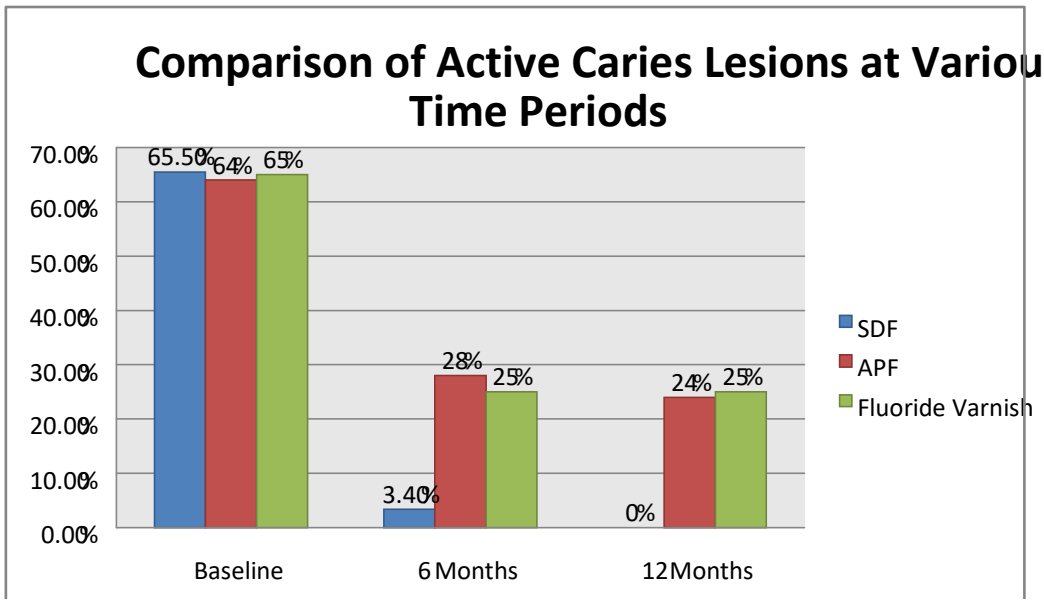
Figure 4:- Shows caries arrest in SDF group at: (a) Baseline, (b) 6 months, (c) 12 months.

Table 1:- Comparison of active caries lesions at various time periods.

		SDF	APF	Fluoride Varnish	P value
Caries Status at Baseline	Active	19 (65.5%)	16 (64%)	13 (65%)	0.993
	Arrested	10 (34.5%)	9 (36%)	7 (35%)	
Caries Status at 6 Months	Active	1 (3.4%)	7 (28%)	5 (25%)	0.036*
	Arrested	28 (96.6%)	18 (72%)	15 (75%)	
Caries Status at 12 Months	Active	0 (0%)	6 (24%)	5 (25%)	0.015*
	Arrested	29 (100%)	19 (76%)	15 (75%)	

*Statistically significant (P<0.05, Chi-square test)

Graph 1:- Comparison of active caries lesions at various time periods.



Comparison of Plaque Index

Table 2 Graph 2 shows that at 12 months, there was a statistically significant difference in mean plaque index scores among the study groups (P=0.001).

The mean plaque index score in APF andNaF varnish group was significantly higher than that in SDF group at 12 months.

Table 2:- Comparison of plaque index among study group.

		N	Mean	Std. Deviation	P value
Plaque Index at Baseline	SDF	29	.7931	.67503	0.257
	APF	25	.8800	.60000	
	Fluoride Varnish	20	1.1000	.64072	
	Total	74	.9054	.64466	
Plaque Index at 6 Months	SDF	29	.3448	.48373	0.126
	APF	25	.2400	.43589	
	Fluoride Varnish	20	.5500	.60481	
	Total	74	.3649	.51216	
Plaque Index at 12 Months	SDF	29	.0690	.25788	0.001*
	APF	25	.2000	.40825	
	Fluoride Varnish	20	.5000	.51299	
	Total	74	.2297	.42353	

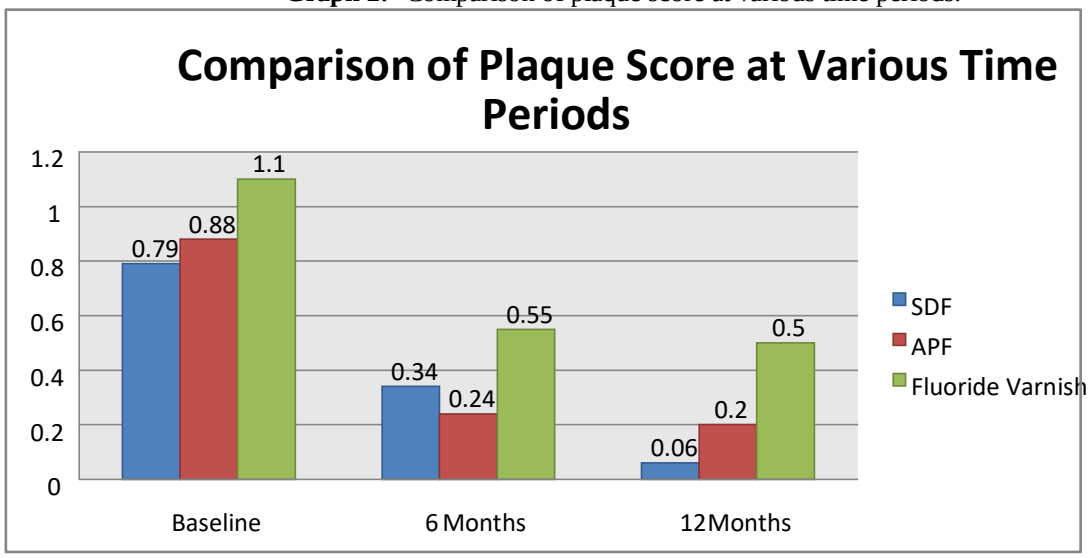
*Statistically significant (P<0.05, Analysis of Variance)

Table 4:- Multiple comparisons among study groups at various time period.

Dependent Variable	Group		Group	Mean Difference	P value
Plaque Index at Baseline	SDF		APF	-.08690	.873
	SDF		Fluoride Varnish	-.30690	.233
	APF		Fluoride Varnish	-.22000	.491
Plaque Index at 6 Months	SDF		APF	.10483	.728
	SDF		Fluoride Varnish	-.20517	.347
	APF		Fluoride Varnish	-.31000	.108
Plaque Index at 12 Months	SDF		APF	-.13103	.441
	SDF		Fluoride Varnish	-.43103*	.001*
	APF		Fluoride Varnish	-.30000*	.034*

*Statistically significant (P<0.05, Tukey's post-hoc test)

Graph 2:- Comparison of plaque score at various time periods.



Comparison of S. mutans Count

Table 3 Graph 3 shows the comparison of S. mutans count among the study groups at various time periods. There was a statistically significant difference in mean S. mutans count among the study groups at baseline (P=0.004).

Table 5 shows that there was a statistically significant difference in S. mutans count between SDF and APF(P=0.006) and NaF varnish (P=0.037).

The mean S. mutans countat 3rddayin APF group(P=0.026) and NaF varnish group (P<0.001) was significantly higher than that in SDF group.

At 6months, the mean S. mutans count in APF group(P=0.002) and NaF varnish group (P<0.001) was significantly higher than that in SDF group.

At 12 months, the mean S. mutans count in APF group(P<0.001) and NaF varnish group (P<0.001) was significantly higher than that in SDF group.

(a) (b) (c)

Figure 5:-Shows S.mutans count in SDF group at: (a) Baseline, (b) 6 months, (c) 12 months.

Table 3:-Comparison of S. mutans count among study group.

		N	Mean	Std. Deviation	P value
S. mutans Count at Baseline	SDF	29	299.6552	99.26454	0.004*
	APF	25	376.0000	73.82412	
	Fluoride Varnish	20	363.5000	83.80899	

	Total	74	342.7027	92.91766	
S. mutans Count at Third Day	SDF	29	264.5172	101.68601	<0.001*
	APF	25	334.4000	96.95704	
	Fluoride Varnish	20	380.0000	86.75434	
	Total	74	319.3378	106.27958	
S. mutans Count at 6 Months	SDF	29	210.0690	73.22272	<0.001*
	APF	25	285.6000	81.14185	
	Fluoride Varnish	20	332.5000	81.55560	
	Total	74	268.6757	92.36276	
S. mutans Count at 12 Months SDF		29	171.4828	51.37858	<0.001*
APF		25	241.0000	60.77623	
Fluoride Varnish		20	257.7000	78.61170	
Total		74	218.2703	72.85495	

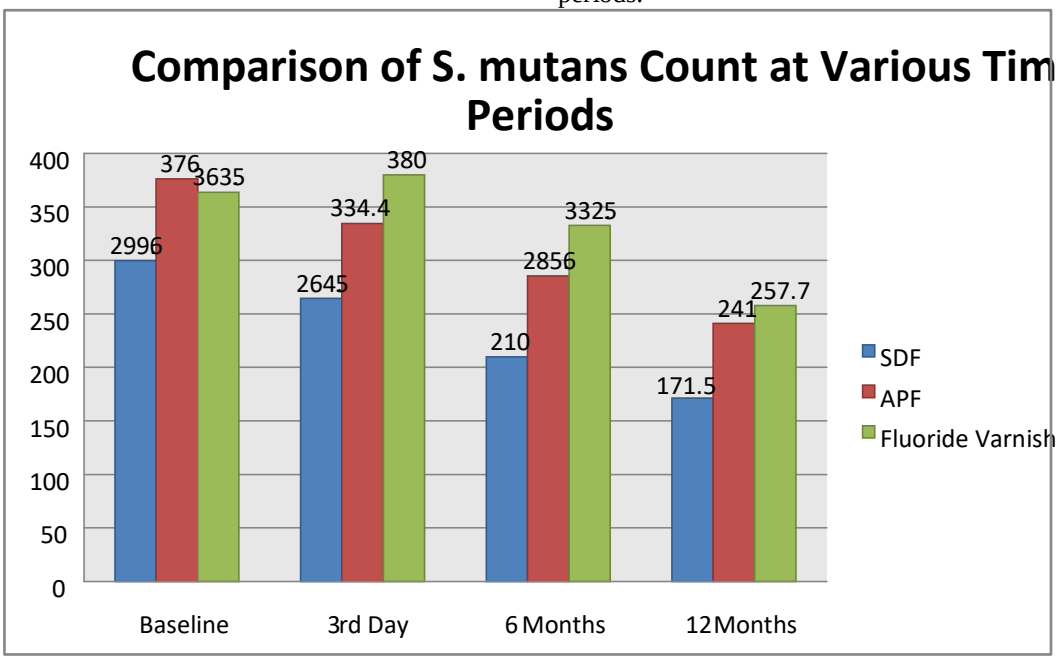
*Statistically significant (P<0.05, Analysis of Variance)

Table 5:- Multiple comparisons of S.mutans count at various time period.

Dependent Variable	Group		Group	Mean Difference	P value
S. mutans Count at Baseline	SDF		APF	-76.34483*	.006*
	SDF		Fluoride Varnish	-63.84483*	.037*
	APF		Fluoride Varnish	12.50000	.882
S. mutans Count at Third Day	SDF		APF	-69.88276*	.026*
	SDF		Fluoride Varnish	-115.48276*	<.001*
	APF		Fluoride Varnish	-45.60000	.261
S. mutans Count at 6 Months	SDF		APF	-75.53103*	.002*
	SDF		Fluoride Varnish	-122.43103*	<.001*
	APF		Fluoride Varnish	-46.90000	.120
S. mutans Count at 12 Months	SDF		APF	-69.51724*	<.001*
	SDF		Fluoride Varnish	-86.21724*	<.001*
	APF		Fluoride Varnish	-16.70000	.651

*Statistically significant (P<0.05, Tukey's post-hoc test)

Graph 3:- Comparison of S.mutans count at various time periods.



Discussion:-

It is proposed that the active carious lesions canbe managed by restorative cavity control and nonrestorative cavity control (NRCC).[5] Nonrestorative cavity control in primary dentition intents to improve their functionality until exfoliation without the need to use an airotor or anaesthesia therefore, it is said to be kids-friendly procedure. It is a favorable approach overconventional treatment because it eliminates the stress and fear. Nowadays, SDF has been the center of attraction for both researchers and dentists. SDF's ability to control the caries process makes it different from other caries preventing agents. As the proposed protocol for caries prevention is non-invasive, cost-effective and practical to carry out, if proven to be effective, it can be used at school or community level health programs to prevent ECC in children from disadvantaged communities.

The present study included children with age group of 6-9 years where the mean age calculated was 7.4 years. It is learned from literature that there is high prevalence of nontreated carious lesions in this group. Also, the second window of infectivity opens at this age, first permanent molars were at highest risk to be affected by dental caries. The present study supported by the proposal given by Johnston and Lewis that professionally applied topical fluorides may be practical preventive treatments that allow more high-risk children to be intervened at early age. It is uncertain if SDF treatment in younger children would be as effective as that in older children, because of their inability to cooperate during the SDF intervention.[6]

In the present study, biannual application protocol for SDF, NaF and fluoride varnish was considered to arrest dentinal caries. Biannual applications of APF gels were used by **Hawkins and Locker**[8] and **Agrawal and Pushpanjali**[9] and found significant reduction.The American Dental Association Council on scientific affairs concluded that applying fluoride varnish every 6 months effectively reduces caries prevalence in high-risk populations.[10] Therefore, considering the frequency of application of Fluoride varnish and APF gel, in this study 6 monthly application of SDF, Fluoride varnish and APF gel was used to maintain the uniformity of application.

In the present study one drop of 38% SDF per child was used this was due to high concentrations of fluoride and silver, the toxicity of 38% SDF remains a concern when applying in young children. A concentration of 38% SDF was selected for the study as it is known to be effective in preventing and arresting caries. Various studies have mentioned that topical application of a 38% SDF solution can inhibit the growth of cariogenic bacteria. The study by **Fung et al. [7]** showed that 38% SDF application had let to an increase of 18%-20% in caries arrest rate as compared to 12% SDF.The studies using 38% SDF reported a statistically significant arrest in carious lesions in children.

In the current study, it was observed that SDF displayed significant caries arresting potential at 6^{th} month (96.6%) and at 12^{th} month (100%) than NaF varnish and APF gel. On intergroup comparison caries arrest rate was significantly higher in SDF group (P=0.036*) than in NaF varnish and APF gel group at 6 months. Similarly, when evaluated at 12^{th} month the arrested caries rate was higher in SDF (0.015*) than in NaF varnish and APF gel group. This could be due to 38% SDF containing a high concentration of both silver (253,870 ppm) and fluoride (48,800 ppm) and having an alkaline property. SDF inhibits bacterial growth initially and eventually increases dentin remineralization. Whereas, 5% NaF varnish has lower concentration of fluoride (22,600 ppm) and APF gel has (12,300 ppm).

According to a randomized controlled trial conducted by **Mabangkhruet al.** [6] on young children who were followed up for 12 months concluded that caries arresting potential of 38% SDF was higher than 5% NaF varnish when applied semi-annually. In a review given by **Osadolor O et al [11]** they concluded that SDF can be used as an intervention to stop the progression of active carious lesion and restore untreated carious teeth using silver modified atraumatic restorative treatment technique.

In the present study, plaque scoring was done using Silness and Loe index. The scoring was done at baseline, at 6^{th} month and at 12^{th} month which showed that there was significant reduction in plaque score in case of SDF group at 12 months (P=0.009) compared to baseline. However, when compared at 12^{th} month there was significant reduction in SDF group (P=0.001) than NaF varnish group and APF gel group. This could be due to follow-up application done at 6^{th} month and 12^{th} month leading to cumulative effect seen at 12^{th} month. According to**Mellberg et al**.,**[12]** topically applied fluoride may result in less plaque accumulation and ultimately decrease in dental caries.

Plaque accumulation on lesion was found to be an important factor affecting the progression of carious lesions. The findings of a study done by **Duangthip et al [13]** support the concept that alteration of biofilm alters lesions

formation and progression. Altogether, these results imply that plaque control at the lesion site is crucial factor affecting the success of caries arrest treatment.

In the present study, in vivo effect on S. mutans counts in saliva was checked and compared. No attempt was made to excavate the carious tissue, which made the application process easier and faster. Some studies have found that removal of caries is not necessary before application of SDF. This suggests that dentists do not need to remove caries from patient's teeth during treatment with SDF.[14] The criteria for saliva sampling were to include children who brushed their teeth regularly, so that normal bacterial count can be established. The technique of saliva sample collection was in accordance with**Wan et al**. [15] The TYCSB media was used for detection of S. mutans.[24] **Surendranath P et al.,**[16] in their review, mentioned the zombie effect of silver wheremain characteristic of biocidal metals like silver is its prolonged activity which slowly releases cations that is toxic to microbes. Therefore, it was decided to evaluate the S. mutans count after 3 days of application in present study and follow-up was set at 6th month and 12th month.

S. mutans count was evaluated and compared at baseline and at all follow-up visits where it was found that there was decrease in S. mutans count in all the three groups. Considering the intergroup significance, significant reduction was found in SDF group (P=0.026) compared to APF group at 3rd day. At 6 months there was significant reduction in S. mutans count in SDF group (P=0.002) compared to NaF varnish and APF gel group. Similarly at 12th month there was significant reduction in S. mutans count in SDF group (P<0.001) than NaF varnish and APF gel group. The results obtained is supported by study done by **Shalin et al**.,[17] in which in vivo application of SDF on enamel significantly decreases S. mutans count as compared to NaF varnish and APF gel.

According to review given by **Zhao IS et al** [14] it was found that SDF possessed antimicrobial action against cariogenic monospecies strains of S. mutans or A.naeslundii, dual species cariogenic biofilms of S.mutans and Lacidophilus and multispecies cariogenic biofilms formed on dentin surfaces. SDF seems to have higher potential in reducing S. mutans count compared to other two agents due to high fluoride content and also antibacterial potential of silver providing an additive effect on reduction of S. mutans count.[8]

SDF can be used in disadvantaged communities where untreated dental caries and early loss of primary teeth are persistent. Due to large number of caries-affected school children and limited resources, topical fluorides, particularly SDF, may be a better alternative for caries control due to its cost-effectiveness, safe and practicability to implement. Its use as a community measure in form of school health programme is worth implementing. Till date, there are not enough studies that compared effect of SDF on reduction of carious lesions, plaque score and S. mutans. Therefore, the present study implicates that 38% SDF effectively arrests carious lesions, reduces plaque score and S. mutans count in saliva.

Conclusion:-

It can be derived that SDF might be used effectively as a topical fluoride agent for caries prevention, plaque control and reduction in S. mutans count in saliva due to its greater antibacterial efficacy as compared to other professionally applied fluoride agents, varnish and APF gel when applied biannually.

Therefore, this study suggests that 38% Silver diamine fluoride is an effective, inexpensive and sustainable option for high-risk children in arresting caries. It is an excellent antimicrobial agent in prevention of biofilm formation and dental caries. It issafe for toddlers who do not cooperate with conventional treatment procedures. SDF treatment is manageable, painless and easy to accomplish in a community setting as it requires less time and fewer resources. No special equipment and no dental specialist are needed. It is likely that SDF treatment can be delivered by trained primary dental care providers or allied health care professionals to improve access to dental care in remote areas or impoverished communities where dental problems like untreated ECC and early loss of primary teeth are dominant. Further the findings of this study can be helpful to guide the decision making among dental practitioners and health policy makers for inclusion of SDF in school-based caries prevention programs.

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