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Clinical and Radiographical Evaluation Of Cariostatic Effect Of Silver Diamine Fluoride Individually And In Combination With Chemo-Mechanical Caries Removal Method: An In-Vivo Follow Up Study

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ABSTRACT

Early childhood caries remains a significant problem in pediatric population and to treat this young population with conventional drilling method is sometimes challenging. An In-vitro study by Hamama et al stated that Silver Diamine Fluoride following Chemo mechanical caries removal may have a synergistic antibacterial effect. So, the aim of present In-Vivo study was to evaluate clinically and radiographically cariostatic effect of Silver Diamine Fluoride individually and in combination with Chemo-mechanical Caries Removal (CMCR) method. A total 150 primary mandibular molars with proximal caries without pulpal involvement, in 3 to 6 years age group children were included and randomly and equally divided into 3 groups. In Group 1, caries was excavated with hand instrument and then restored with GIC. In Group 2, After caries removal using hand instrument, SDF was applied prior to restoration with GIC. In Group 3, Caries was removed with CMCR material then SDF was applied prior to restoration with GIC. Clinical and radiographical evaluation was done at 4, 8 and 12 months interval. At 12 months, clinical success of group 1 ,2 and 3 was 85.71%, 93.75% and 95.92% respectively and radiographic success was 85.71 %, 93.75% and 97.96%. There was difference in result between groups but no statistically significant difference found between Group 2 and Group 3 as p value was > 0.05. So, we can conclude that SDF alone and combination of CMCR and SDF has similar cariostatic effect but CMCR has added advantage of patient comfort and less anxiety.

Keywords: *Silver diamine fluoride, Cariostatic, Chemo-mechanical caries removal, Early Childhood Caries.*

1. INTRODUCTION

Early childhood caries, a prevalent dental issue globally and in India, it negatively impacts children's growth, development, nutrition, and oral health, posing significant social and economic challenges for families. Early childhood caries (ECC) has been used to be defined as the presence of one or more decayed, missing, or filled primary teeth in children aged 71 months (5 years) or younger, but has recently been redefined at the Bangkok Declaration by a group of international experts as the presence of a primary tooth with one or more carious (non-cavitated or cavitated lesions), missing (due to caries), or filled surfaces in a child under the age of six years[1]. It can be difficult to treat this young population using traditional drilling techniques. Chemo-mechanical caries removal (CMCR) is a less invasive technique that makes patients who are frightened or impaired feel more at ease.

Secondary caries is the most common cause for the replacement of dental restorations in clinical settings, no matter what kind of material is chosen, secondary caries cannot be completely avoided2. Sevda I. Rimalovska et al (2022)[3] in their study found that there was higher incidence of secondary caries in proximal restorations of primary molars compared to occlusal surface restorations. Silver diamine fluoride (SDF) is a liquid substance which arrest caries by both antibacterial and remineralizing effect. In an In-vitro study by Hamama et al[4], SDF/KI following Carisolv and Papacarie chemomechanical caries removel gels significantly reduced the viability of intra-tubular bacteria in these groups and he stated that SDF following CMCR may have a synergistic antibacterial effect.

So, the aim of present in vivo, follow up study was to evaluate clinically and radiographically cariostatic effect of Silver Diamine Fluoride individually and in combination with Chemo-mechanical caries removal method.

2. MATERIAL AND METHODS

This study was carried out in the Department of Pedodontics and Preventive Dentistry of Government Dental College and Hospital, Ahmedabad. The study protocol was approved by the Institutional Ethical Committee (IEC GDCH/PEDO.6/2022) and Informed consent was obtained from parents/guardians of all children included in this study.

In present study, 150 primary mandibular molars with proximal caries of 3 to 6 years age group children were included. In pre operative radiograph, radiolucency reaching upto outer or middle 1/3 of dentin only were included. Carious teeth with pulpal involvement, sinus tract or fistula formation, acute infection of oral cavity, medically compromised patient and patient with silver allergy were excluded from the study.

The sample size was estimated using G power software version 3.1.9.2. A sample size of 141 was achieved with α value= 0.05, power 1-ß= 0.80, effect size = 0.30 and degree of freedom=2º. It was rounded to 150 with 50 in each group. Selected 150 molars were randomly and equally divided into 3 groups. Each group consists of 50 primary mandibular molars. Randomization was achieved using the lottery method. Group 1: Caries removal by hand instrumentation + Restoration with Glass Ionomer Cement (Control group) (GIC). Group 2: Caries removal by hand instrumentation + Silver diamine fluoride + Restoration with GIC (Experiment group) (SDF+GIC). Group 3: Caries removal with Chemico-mechanical caries removal agent + Silver Diamine Fluoride +Restoration with GIC (Experiment group) (CMCR+SDF+GIC).

In group 1, the soft caries was removed using small and medium size spoon excavators until the remaining dentin had increased resistance to manual instrumentation. Following caries removal, each cavity was rinsed with water and dried with small pellet of cotton. Isolation was done using cotton rolls and mylar strip was placed and restoration with Glass ionomer cement (GC Gold Label 9, GC Corporation, Tokyo, Japan) was done and the restoration was coated with a layer of petroleum jelly (Figure 1a and 1b).

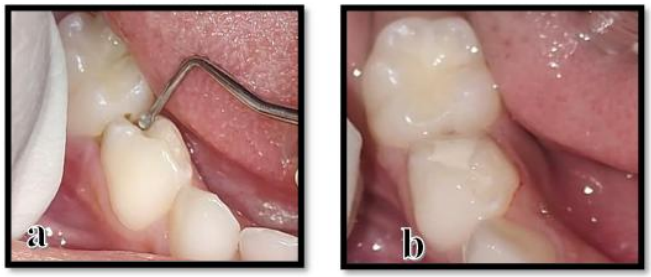

Figure 1a and 1b: Caries excavation with spoon excavator followed by GIC restoration

In group 2, caries was excavated with small and medium size spoon excavators and cavity was cleaned and dried and then isolation was done using cotton rolls. Using a microbrush, SDF (Riva Star) was applied, and capillary action was allowed to absorb it for at least a minute. After allowing the SDF to absorb for at least a minute, extra SDF was gently wiped using cotton pellet. After that, different microbrush was used to continually apply potassium iodide (KI) until the white precipitate totally vanished. Cavity was rinsed with water for 10 seconds anddry, mylar strip was placed and restoration with Type 9 Glass Ionomer cement was done and petroleum jelly was applied over restoration (Figure 2).

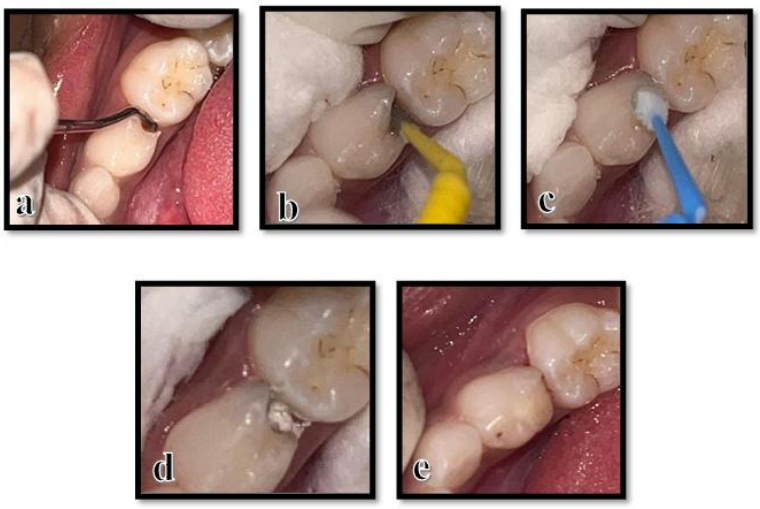

Figure 2: Caries Excavation with hand instrument (a) followed by SDF + KI application (b,c). White precipitate after KI application (d) and GIC restoration (e).

In group 3, Isolation was done using cotton rolls. V CARIE gel (Vishal Dentocare, contains purified enzyme derived from the plant "Caprica Papaya" (Papaya)) was applied in carious lesion and after 30 seconds, carious dentine was softened then excavation was done with small and medium size spoon excavators. More gel was applied and the procedure was repeated until no more carious dentine remains and the gel removed from the tooth was clear. Followed by SDF/KI was applied and then restoration was done using type 9 GIC (Figure 3).

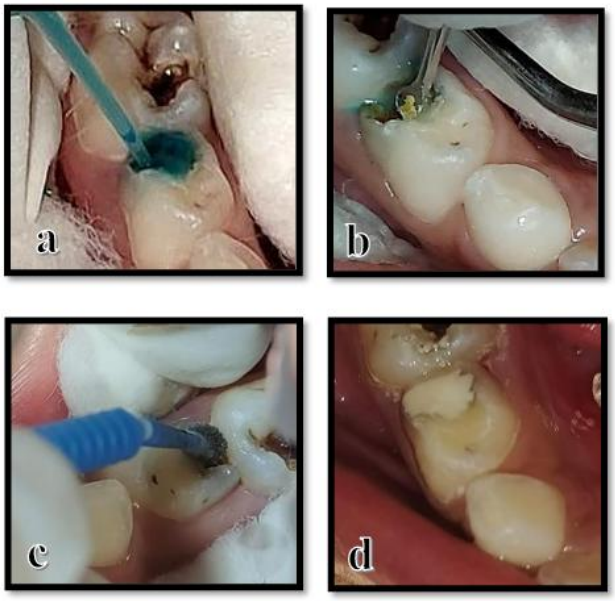

Figure 3: V Carie gel application followed by caries excavation with spoon excavator (a & b), SDF + KI application followed by GIC restoration (c & d).

Personal protective equipment (PPE) (safety glasses, other skin and clothes protection) was used for both patient and operator while doing treatment in group 2 and 3, as SDF can cause staining on skin and clothes. Petroleum jelly was applied on lips and surrounding soft tissue. Care was taken to avoid contamination of prepared surface by petroleum jelly.

All treated teeth were examined clinically and radiographically at 4, 8, and 12 months interval. Clinical evaluation was done by Evaluation criteria for approximal-ART restorations by Frencken, 1999[5]. Treatment was considered to be successful scored by codes: 00,10,11,12 and 13; those considered failed scored by codes: 20, 21, 30 and 40; while those considered to be unrelated to success and failure who were coded: 50, 60, 70 and 90 in Frencken criteria.

The treated teeth were judged as radiographically successful if radiographically previously observed lesion has not progressed further into dentine, normal periodontal ligament space, no external/internal resorption, no periapical/furcation radiolucency and absence of any other signs suggesting pulp involvement.

3. RESULT

After collection of data, the data were coded and entered in Microsoft Excel 2019. The descriptive statistics were presented as proportions. Proportions were compared using Chi square test. Survival analyses were performed by Kaplan-Meier and Log Rank (Mantel-Cox) tests to obtain the overall success rate in relation to observation time. Statistical Package for Social Science (SPSS version 23, IBM). Level of significance was set at $P<0.05$.

In the present study 109 children and total 150 primary mandibular molars were enrolled. The mean age of children in groups were 4.30 years. Table 1 and Table 2 presents a comparison of the clinical and radiographical success rate of restorations at different time intervals. At 12 months, there were 7 clinically and radiographically failed restorations in group 1, with 3 dislodged and lesion progression and 4 having pulp inflammation. In group 2, one dislodged restoration with radiographically lesion progression was found, and 2 had pulp inflammation and signs of irreversible pulpitis. In group 3, one restoration was dislodged but had no lesion progression radiographically, making it considered successful and 1 restoration was failed due to furcation radiolucency and clinically there was a dentoalveolar abscess. So, at 12 months clinical success of group 1 ,2 and 3 was 85.71%, 93.75% and 95.92%. And radiographic success was 85.71 % for Group 1, 93.75% for Group 2 and 97.96% for Group 3. Although there is a difference in success rate of groups but p value is > 0.05, which is statistically insignificant.

Table 1: Comparison of Clinical success rates between groups at a different time interval

Groups	AT 4 MONTHS			AT 8 MONTHS			AT 12 MONTHS		
		Success %	Failure %		Success %	Failure %		Success %	Failure %
Group 1	**n=50**	**50 (100)**	**0**	**n=50**	**45 (90)**	**5 (10)**	**n=49**	**42 (85.73)**	**7 (14.27)**
Group 2	**n=50**	**50 (100)**	**0**	**n=50**	**49 (98)**	**1 (2)**	**n=48**	**45 (93.75)**	**3 (6.25)**
Group 3	**n=50**	**50 (100)**	**0**	**n=50**	**50 (100)**	**0**	**n=49**	**47 (95.92)**	**2 (4.08)**
p value				**0.03***			0.37		

Table 2: Comparison of radiographic success rates between groups at different time interval

Groups	AT 4 MONTHS			AT 8 MONTHS			AT 12 MONTHS		
		Success %	Failure %		Success %	Failure %		Success %	Failure %
Group 1	**n=50**	**50 (100)**	**0**	**n=50**	**45 (90)**	**5 (10)**	**n=49**	**42 (85.73)**	**7 (14.27)**
Group 2	**n=50**	**50 (100)**	**0**	**n=50**	**49 (98)**	**1 (2)**	**n=48**	**45 (93.75)**	**3 (6.25)**
Group 3	**n=50**	**50 (100)**	**0**	**n=50**	**50 (100)**	**0**	**n=49**	**48 (97.96)**	**1 (2.04)**
p value				**0.03***			**0.07**		

Table 3 and Table 4 shows pairwise comparison between groups with Log Rank (Mantel-Cox) tests. According to which, comparing group 1 and group 2 there is statistically significant result as p value is 0.04 for clinical evaluation and 0.01 for radiographical evaluation. There is highly significance result between group 1 and group 3 as p value is 0.004 and 0.001 for clinical and radiographical evaluation. But there is no statistically significant difference between group 2 and group 3.

Table 3: Pairwise comparisons between groups for Clinical evaluation

Groups	Group 1 c^2 (P Value)	Group 2 c^2 (P Value)	Group 3 c^2 (P Value)
Group 1	-		

Group 2	4.15 (0.04*)	-	
Group 3	8.14 (0.004*)	0.81 (0.37)	-

Log Rank (Mantel-Cox) tests, *P<0.05 significant

Table 4: Pairwise comparisons between groups for Radiographic evaluation

Groups	Group 1 c^2 (P Value)	Group 2 c^2 (P Value)	Group 3 c^2 (P Value)
Group 1	-		
Group 2	6.07 (0.01*)	-	
Grou4 3	11.49 (0.001*)	1.66 (0.19)	-

Log Rank (Mantel-Cox) tests, *P<0.05 significant

4. DISCUSSION

The 2018 International Association of Paediatric Dentistry Conference revealed that ECC prevalence in children aged 1-5 years was 17%, 36%, 43%, 55%, and 63% respectively[6]. According to a Systematic Review by Akila Ganesh & M. S. Muthu[7](2019) overall average prevalence of ECC in India is 49.6%.

According to WHO Implementation manual, Ending Childhood Dental Caries[8], Reversing the disease process and preventing or delaying the progression of carious lesions to cavitation and tooth destruction should be the goals of ECC management. Young children may not cooperate completely during dental treatment since they are typically anxious. It is recommended to employ non-invasive or minimally invasive treatment options since they are less resource-demanding, more effective and economical, and less uncomfortable than alternative techniques.

SDF is a topical fluoride solution with 44,800 ppm fluoride and has been used at a concentration of 38%. Of all the fluoride agents available on the market for dental use, its fluoride concentration is the greatest. The SDF acts by its bactericidal "zombie" effect, enzymatic inhibition of biofilm, inhibition of dentinal collagen degradation and loss of mineral content thereby inhibiting demineralization[9]. The new paradigm in caries intervention and management using SDF and ART together is called the "Silver-modified atraumatic restorative technique (SMART)".

In present study, 3 to 6 years age group children with proximal caries in primary mandibular molars were selected and for prevention of secondary caries SDF was used and for patient co-operation CMCR agent was used for caries removal. In group 1 and group 2, proximal caries was excavated with hand instrumentation, so here patient co-operation was good but sometimes pressure of hand excavation caused some apprehension in children. In group 3, caries was softened with CMCR agent and then hand excavation was done so here patients were more comfortable. Also, we had included only mandibular primary molars so while doing excavation in mandibular first primary molars, pulp was exposed in 5 teeth as mesial pulp horns are high in first primary molars. So that tooth was excluded from the study and pulpotomy was performed. In present study SDF was used in Group 2 and Group 3, so parents were informed about black discolouration.

According to multiple comparisons, using SDF increases the micro tensile bond strength during the delayed loading of the restorative material. Since it is not always possible for the patient to return for dental care for numerous SDF treatments and subsequent restorations, we loaded the glass ionomer cement immediately in the current study. Therefore, we chose to employ SDF as a final therapeutic strategy rather than as a interim restorative material. Also, Fröhlich Tatiana Tambara et al[10] (2022) in a systematic review and meta-analysis concluded that SDF dentin pretreatment did not influence the bonding of GIC.

In vitro study by G M Knight et al[11] gives explanation of present study's result as in their study they found that the pre-treatment of SDF and KI gave higher fluoride levels in the deeper layer on dentine than those seen with glass ionomer cement alone is no doubt attributed to the additional fluoride uptake from the topical treatment so it prevents secondary caries and restoration failure. Similar results were found in study by Riaan Mulder et al[12]. Also, May Lei Mei et al[13] experimented different concentrations of SDF and concluded that 38% SDF can be incorporated into restorative therapy to improve the success rate of direct restorations which supports the result of present study.

In present study, in Group 3 we have evaluated combined effect of CMCR and SDF and we found higher success rate

compared to group 1 and group 2, which is explained by in vitro study by Hamama et al[4], in which they evaluated that the application of SDF/KI following NaOCl-based and enzyme-based gel had synergistic effect and significantly reduced the viability of intratubular bacteria. But in present study, we had only included enzyme based gel (V Carie Solve, Vishal Dentocare, contains purified enzyme derived from the plant "Caprica Papaya" (Papaya)) so further studies with both enzyme-based gel and NaOCl based gel is required.

The International Caries Consensus Collaboration (ICCC) 2015[14], guidelines for the removal of carious tissue can be summarised as 1) preserve non demineralised and remineralizable tissue; 2) achieve an adequate seal; 3) avoid discomfort/pain and dental anxiety; 4) maintain pulpal health; and 5) maximise longevity of restoration. Treatment done in this study is in line with all five ICCC principles.

Full coverage restorations with SSC after any pulp treatment increases the success rate and also SSC is the most preferred restoration for cavitated lesions in primary teeth[15]. Comparing to present study we had sealed only with Glass ionomer cement, so present study was lacking in giving proper seal to restoration which can be considered as drawback of the study. And In present study we had recorded only 12 months follow up that is limitation of the study as to evaluate longevity and success of treatment long term follow up is required.

5. CONCLUSION

In present study, maximum treatment success has been achieved in group 3 (CMCR+ SDF+ GIC) as there is a least caries progression compared to group 1 (GIC) and Group 2 (SDF+ GIC), although there is no statistically significant difference between Group 2 and Group 3 as p value is > 0.05. So, we can conclude that SDF alone and combination of CMCR and SDF has similar cariostatic effect.

It can be concluded that by synergizing effect of Chemo-mechanical caries removal method, Silver diamine fluoride and Glass ionomer cement, we can offer efficient, economical and patient friendly treatment approach of caries management to young and anxious children and also, we can give them pain free happy visit and can instil a positive attitude towards a dentistry.

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