

Original Article

Comparative Evaluation of 'Less Invasive Approach' of caries excavation and 'Only Arrest And No Excavation Approach' in dental caries management in primary molars- A Randomised Controlled Trial

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ABSTRACT:

Background- Painless dentistry, minimising fear, minimal intervention and instilling positive dental attitude are some of the factors justifying the speciality of pediatric dentistry. Caries excavation using Carie-Care, Polymer bur are two such minimally-invasive approaches. Recently, a drill-free approach Silver-Diamine-Fluoride (SDF) has been introduced in the practice of MID for arrest of carious lesion. **Aim-**To compare two contemporary strategies- 'Less Invasive Approach'(polymer bur/Carie-Care) and 'Only Arrest and No Excavation Approach'(SDF). **Method and Materials-** 45-primary molars were randomly divided into 2 groups- Group1 (Less Invasive Approach, LIA) included polymer bur and Carie-Care with 15 samples each, and Group2 (Only Arrest and No Excavation Approach, OAANE) included SDF with 15 samples. **Statistical analysis:** The data obtained was subjected to statistical-analysis using Chi-square test. **Results-** In primary outcome, both the LIA and OAANE groups were found to be-painless with SDF taking the lead. In secondary outcome, on comparison between-Group1A and Group1B, Carie-Care showed-significant reduction in pain ($p < 0.05$) and better-caries removal efficacy though statistically insignificant. **Conclusion-** Both the LIA and OAANE groups were found to be effective for pediatric patients. Carie-Care was found to be more effective than polymer burs in terms of pain experienced during operative procedures and caries removal efficacy. SDF application was reported to be easy and painfree as well as well accepted by the parents. At the end of 3 months all the samples were asymptomatic clinically.

Key words: caries arrest, SmartPrep burs, Chemomechanical caries removal, dental caries, Minimal invasive dentistry, SDF

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INTRODUCTION

Dental caries is a pandemic disease affecting man kind in both developed as well as developing countries.^[1] National Oral Health Survey conducted in India stated that its prevalence in Indian children has increased from 51.9% to 63.1% in 5-15 years of age group, respectively.^[2] In children, the disease is marked by rapid destruction of primary teeth with early cavitation owing to their lesser inorganic content.^[3] In order to preserve the functional integrity of the primary teeth, early childhood caries must be managed by appropriate means.

The conventional ways of treating dental caries were primarily based on the concept of "Extension for

Prevention" proposed by **GV Black in 1893**^[4] which inadvertently lead to removal of considerable amount of healthy tooth structure, thereby compromising its structural strength. Moreover, the pressure and heat generated by high speed rotary instruments, the vibration, noise and pain stimulus associated with it, has, been reported to cause aversion in many patients towards dental treatment more so in children.^[5]

Henceforth, to minimize these shortcomings, a more conservative approach is preferred especially in paediatric dental practice. A conservative or minimally invasive approach involves minimal excavation of caries thus saving the natural tooth

structure while causing less pain and discomfort to the children.

Following this approach various chemical compositions have been introduced for chemomechanical caries removal such as Sodium-hypochlorite, GK 101, and carisolv.^[6] Chemo-mechanical approach to tooth tissue removal serves as an alternative to traditional drilling.^[7] Recently, a new chemomechanical caries removal system, (Carie Care™) (Unitech – Biotech, Pharmaceuticals Pvt Ltd, India) has been introduced to improvise upon the drawbacks associated with the previous products.^[6]

Another self limiting concept in mechanical caries removal has been brought into practice by Boston in 2003 who introduced a new Polymer prototype bur, also known as SmartPrep bur.^[5] Polymer burs are described as “dentin safe,” burs as they remove only infected dentine while saving the sound dentine. A systematic review conducted by **Falk Schwendicke et al. in 2015** concluded that polymer burs were by far the least investigated method for caries removal in vitro as well as in vivo.^[8] It also concluded that there was insufficient data concerning their efficiency in caries removal to formulate definitive recommendations concerning their use.

Lastly, the objective of minimally invasive dentistry is not only to preserve as much as sound tooth structure but also to remineralise the inner layer of the carious lesion thereby arresting the caries. In addition to this, a better understanding of the disease process in the recent years also promotes use of techniques or materials that can arrest caries without any excavation. In this regard, one of the novel materials, Silver diammine fluoride (SDF) has been advocated for the arrest of the carious lesion. **Quock et al. in 2011** in their study stated that silver diammine fluoride (38%) was a modality which challenged the need for mechanical excavation of a cavitated lesion, due to its ability to arrest dental caries and prevent recurrent lesion.^[9]

Also, the use of SDF as a preventive or therapeutic modality can prevent or delay dental treatment until a child reaches a more cooperative age; therefore, it is a non-surgical alternative to managing caries in populations where surgical management of decay is not an option.^[10]

Thus, the primary aim of the present study was to evaluate and compare the two contemporary strategies that is 'Less Invasive Approach' (using polymer bur or Chemomechanical caries removal with Carie Care) and 'Only Arrest and No Excavation Approach' (using Silver Diamine Fluoride). The secondary objective of the study was to compare and assess the efficacy of Carie Care and polymer bur in removal of caries and to assess the clinical acceptability of SDF as an arresting agent.

MATERIALS AND METHODS

ETHICAL APPROVAL

Before the start of the study, ethical approval was sought from the Institutional Ethical Board of J.N Kapoor D.A.V(C) Dental College and Hospital, Yamunanagar for conducting the study.

STUDY DESIGN

Children in the age group of 4-10 years visiting the Out-Patient Clinics in the Department of Paedodontics and Preventive Dentistry at D.A.V. (C) Dental College, Yamuna Nagar were screened for at least one primary molar involved with dentinal caries in their oral cavity. 45 Primary molars were finally selected according to the following inclusion criteria: Fully erupted primary molar with active cavitated carious lesion, extending into dentin (ICDAS 4 or 5), teeth that were restorable and showing lack of clinical evidence of pulpal degeneration (pain on percussion, history of swelling, sinus tract), teeth with no radiographic signs of internal and/or external resorption and/or no furcation radiolucency. And the exclusion criteria included: non consent of the parents to participate in the study, allergy to any restorative material to be used in the study, medically compromised patients, teeth with history of spontaneous pain or pulpal degeneration, submerged teeth and teeth near to physiological exfoliation.

The parents of the children were provided detailed information about the treatment procedure. Written consent was sought from parents prior to treatment. Assent was also sought from the children participating in the study before their inclusion.

RANDOMISATION AND DIVISION OF SAMPLES

All the selected 45 primary teeth were randomly divided into two groups (Group 1 and Group 2) with the allocation ratio of 2:1. Group 1 was further divided into 2 equal subgroups: Group 1A and Group 1B. Randomization codes were generated by using computer software (www.randomizer.org). A block size of 5 was used to allow for equal number of patients in all the three groups- Group 1A, Group 1B and Group 2 and allocation concealment was ensured by using sealed envelope techniques. The details are as below:

Group 1 included 'Less Invasive Approach' (LIA) group and samples were treated by either using SmartPrep burs or CMCR (Carie Care). Group1 was divided into two equal Groups: **Group 1A** which consisted of 15 samples/ subjects treated with SmartPrep burs and **Group 1B** which again consisted of 15 samples/ subjects who were treated with Carie-care.

Group 2: included 'Only Arrest and No Excavation Approach' (OANEA) and consisted of 15 samples/ subjects treated by simply applying SDF intended for arresting caries

CLINICAL PROCEDURE

Preoperative clinical and radiographical examination was done to ensure proper case selection. Following this, pre operative pictures were taken. Samples were isolated using cotton rolls and saliva ejectors in all the three groups.

Group 1A: After isolation, the carious tissue was removed using polymer bur mounted on a low speed handpiece in circular movements starting from the centre of the lesion to the periphery as recommended by the manufacturer. Caries removal was continued until the polymer bur became dull after repeated contact with healthy dentin and became visibly abraded and blunt. There was no limitation to the number of burs needed for each carious lesion, but the aim was to remove all the carious portion of dentin. Cutting was continued until no further chips or flakes of softened dentin were created and the bur ceased to progress into sound dentin.

Group1B: After isolation, Carie Care™ was applied by means of a disposable applicator tip to the cavitated carious lesion and was allowed to work for 60 seconds. When the gel was cloudy, the gel and softened carious dentine was removed gently by

scraping with normal spoon excavator without applying pressure. Second application of the gel was performed in cases where caries was hard. The gel was then removed and the cavity was wiped with a moistened cotton pellet and rinsed with water.

In both Group 1A and Group1B after caries excavation caries detector dye (Kuraray Medical Inc., Tokyo, Japan) was applied for ten seconds followed by rinsing with water for ten seconds to verify caries removal efficacy. This was followed by restoring the cavity with glass ionomer cement (GIC Fuji II cement).

Group 2: After isolation, one drop of SDF was placed in a plastic dappen dish and was applied directly to the active cavitated carious lesion with a small disposable brush for 2-3 minutes until the lesion turned hard and black. Hardness of cavitated surface was checked with probe for the indication that the lesion has been arrested. Soft tissue was carefully protected and the child was asked not to drink or eat for atleast 30 mins. After the arrest of caries was achieved using SDF, the remaining tooth structure was restored with glass ionomer cement (GIC Fuji II cement).

ASSESSMENT PROCEDURES

- 1) In accordance to the primary aim, the carious lesion after excavation using LIA or with OANEA was assessed for 'Need of any further Treatment' as per the descriptor given in table1

Table- 1: Need for further treatment

Score	“Description of need for further treatment”
1.	No need for further treatment (caries is either completely excavated or arrested and the depth of the cavity seems to be adequate)
2.	Need for further treatment

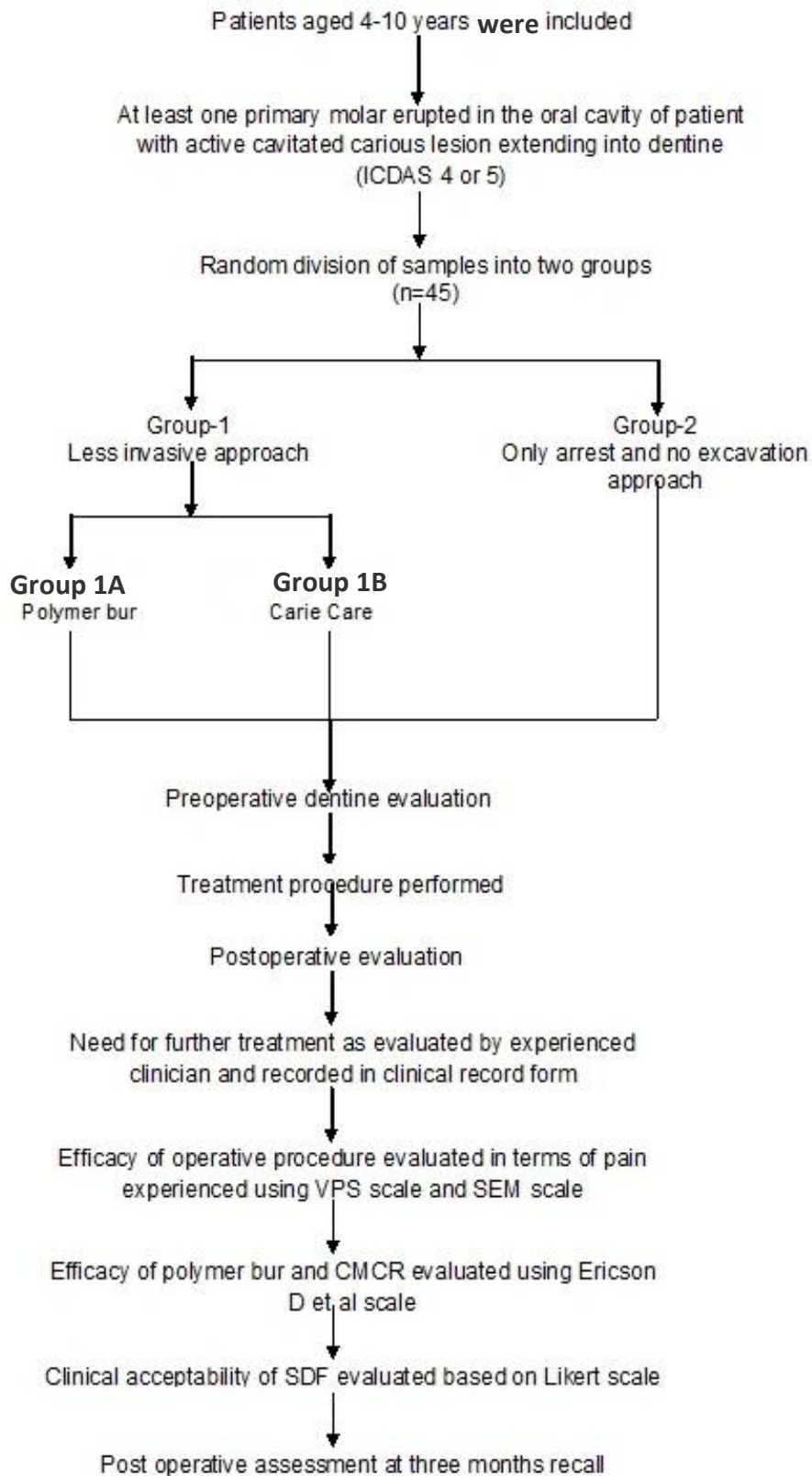
This scoring was done by two independent peer clinicians who scored it. In case of any disagreement an experienced clinician arbitrated over it and his score was considered as final. In addition to this, the efficacy of these approaches was also evaluated in terms of pain experienced during operative procedures. This was assessed both by the patient and the operator using **Verbal pain scale (VPS)**, given by Keele.^[11] and **Sound Eye Motor (SEM) scale**, given by Wright et al in 1999^[12] respectively.

- 2) In accordance to the secondary objective of the study, efficacy of caries removal by polymer bur or Carie Care was evaluated using Ericson D et al scale (1999).^[13]

Lastly, in order to assess the clinical acceptability of SDF, a valued questionnaire was used only for Group 2(SDF group) patients and parents were asked to score the same using Likert’s Scale.^[10]

Patients were then recalled after 3 months. During this visit clinical and radiographical evaluation of teeth were done for presence of pain, tenderness, secondary caries, sinus formation, progress of carious radiolucency and for any pathological changes in the pulp/ periapical region.

Flow chart for Methodology



STATISTICAL ANALYSIS

At the end of the study period, the data was collected and subjected to statistical analysis. Statistical analysis was carried out by Chi-square test using SPSS (Version 21.0)

RESULTS

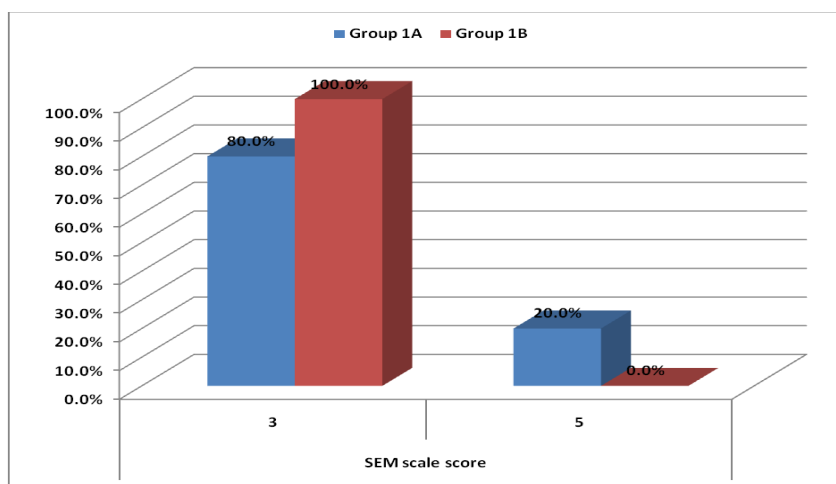
Inter group comparison between Group1 and Group 2 of “Need for further treatment” found that in Group 2, all 100% samples presented ‘No need for further treatment’. In Group 1, 86.67% samples showed ‘No need for further treatment’ whereas 13.33% samples presented ‘Need for further treatment’. The results were found to be statistically non-significant ($p=0.138$).

On Inter group comparison of pain evaluation between Group 1 and Group 2 as per VPS scale score, 15 (100%) samples experienced no pain in Group 2 while in Group 1, one of the sample (3.3%) showed mild pain (pain recognizable but no discomfort). However, the results were statistically non significant. ($p=0.475$).

Inter group comparison of pain evaluation between Group 1 and Group 2 as per SEM scale, found that in Group 2, 100% samples were painfree, while in Group 1 27 (90%) samples were painfree but 10% of the samples showed Discomfort. The results were however non significant ($p=0.25$).

On inter-group comparison of pain evaluation between Group 1A and Group1B, the distribution of SEM scale score comfort was significantly more among Group 1B compared to Group 1A ($p=0.048^*$) (Graph1)

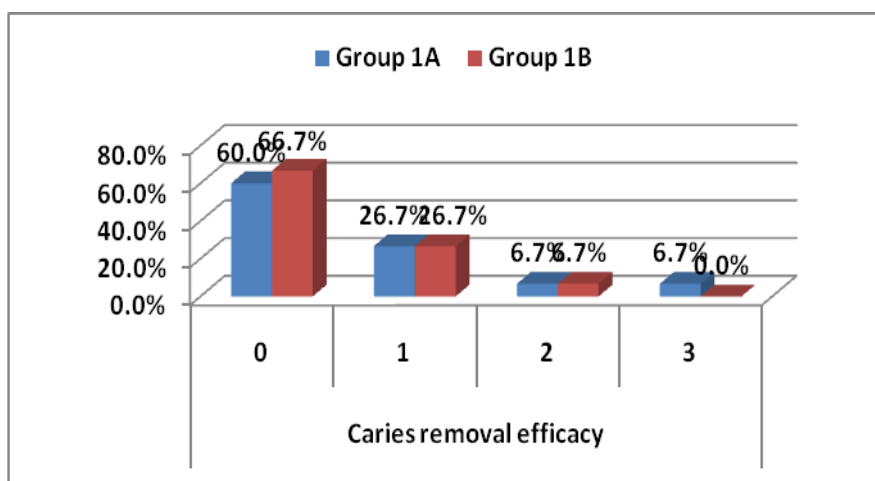
Graph1



SEM is an objective method for pain assessment where measurement of comfort and pain is taken according to three types of observations; Sound, Eye, and Motor. The minimum and maximum scores of pain reaction ranges from 3 -12

Inter group comparison of caries removal efficacy for Group1A (Polymer Bur) and Group1B (Care Care) showed no significant difference in distribution of caries removal efficacy ($p\text{-value}=1.000$) (Graph 2).

Graph2



All the participants “strongly agreed” that SDF application was an easy process and its application was pain free. The results of the clinical acceptability of SDF as an arresting agent are given in table 2.

Table 2

	Strongly agree		Agree		Neutral	
	Frequency	%age	Frequency	%age	Frequency	%age
SDF application seems to be an easy process	15	100.0%	0	0.0%	0	0.0%
I am comfortable with discoloration of cavities after SDF placement	8	53.3%	6	40.0%	1	6.7%
SDF application was pain free for my child	15	100.0%	0	0.0%	0	0.0%
The taste of SDF was acceptable to my child	10	66.7%	5	33.3%	0	0.0%

Clinical and radiographical evaluation at the end of 3 months found all (100%) the samples to be asymptomatic as none of the patient reported with pain, tenderness, secondary caries, sinus formation, progression of carious radiolucency and any pathological changes in the pulp/ periapical region. The results were found to be statistically non-significant between all the three groups ($p=1.000$).

DISCUSSION

Untreated dental caries is a global pandemic **Edelstein BL, 2006**.^[14] Although effective methods for the prevention and interception of the caries are available, still the unmet need for treatment, especially in children doesn't seem to be diminishing with most of the patients still reporting with cavitated lesions in our clinical practice (**Dean JA, Avery DR, Mc Donalds RE, 2011**).^[15]

Traditional management of cavitated lesions involve the use of high speed rotary instruments that leads to pain and discomfort to the patients. Vibration, sound and discomfort associated with it, evokes fear, and anxiety especially in children. Therefore, while treating cavitated lesions in primary teeth a minimally invasive approach that involves minimal excavation and discomfort is always preferable.

Boston in 2003, introduced SmartPrep polymer bur, which is able to distinguish between infected and affected dentin and has the advantage of cutting fewer dentinal tubules, thereby causing less pain sensation (**Hassan AF et al, 2016**).^[16] The hardness of sound dentin ranges from 70 to 90 KHN and carious dentin ranges from 0 to 30 KHN. The hardness of SmartPrep polymer bur is 50 KHN, thus it is made to remove only the carious layers of the dentin, and wear off when contacting healthy dentin (**Maarouf R et al**).^[17]

A systematic review conducted by **Oliveira et al. in 2016**^[18] provided clear recommendations urging clinicians to further investigate the clinical efficiency of polymer burs, the pain encountered and discomfort caused by such treatment modality.

Another product, Carie-Care is a chemomechanical caries removal agent that has been locally produced and its main active ingredient is derived from papaya extract, an endoprotein, chloramines, and dye. In

addition, the preparation contains specific percentages of essential oils from plant sources, which have anti-inflammatory, analgesic, and mild anesthetic effect which reduces the pain perception during the operative procedure (**Nagaveni NB, et al 2017**).^[6] This newly developed chemo-mechanical caries removal agent Carie Care has shown some promising results in in – vitro as well as in-vivo studies.

In recent years, arrest of caries without any excavation has gained increasing acceptance in the practice of minimally invasive dentistry (**Zhi QH, et al. 2012**).^[19] Clinical studies have demonstrated that use of 38% SDF can prevent and arrest caries in cases where conventional restorative treatment for caries is not affordable or available (**Chu- CH, et al. 2015**).^[9] Topical application of silver daimmine fluoride (SDF) solution has been shown to be effective in arresting active caries in primary teeth by forming fluorapatite which is highly resistant to acid and is mainly responsible for remineralisation of carious lesion, while, the silver phosphate has antibacterial properties which act by inhibiting the enzymes activities on dextran- induced agglutination of cariogenic strains of *S.mutans* (**Suzuki T et al, 1976**)^[20], **Knight GM et al, 2006**).^[21] Thus this study was done to evaluate and compare the two contemporary strategies LIA (using polymer bur and Carie care) and OANEA(using SDF).

4-10 yrs age group was selected for this study as this age group falls in one of caries incidence peak ages (4-8 yrs, 11-19, and between 55 and 65 years) as described by **Nikki Foruk**.^[22] Children less than 4 years of age were not included in the study because as emphasized by **Mc Granth A, 1987**^[23] only the children over 5 years of age are able to use self assessment pain scales like Visual Analogue scale and

Verbal Pain Scale in a reliable and valid manner to describe their pain perception. In the present study two independent peered clinicians who did not participate in our clinical study and were unaware of the caries excavation method evaluated the 'Need for further treatment'. This protocol was taken in accordance to the study conducted by **Maarouf et al.**^[17] who conducted a study to evaluate caries removal efficacy by polymer bur and control group.

In Group 2, all the carious lesions were arrested. Dark color and hardness on probing over the carious lesion showed that the SDF did help to arrest the carious process. The results were also in accordance with clinical study conducted by **Zhi et al. 2012**^[19] which reported that SDF arrested 90% of the existing carious lesion (measured by explorer probing of the carious lesion) at 6 months, while fluoride arrested 70% lesions.

However in Polymer bur group in 13.3% cases, need to excavate more carious dentin was felt. In these cases cutting might have been limited to superficial layer of affected dentin leading to incomplete caries removal and thus need for further caries removal was felt. Moreover, removal of carious tissue using polymer bur is a subjective phenomenon as there is no limit to number of burs being used. Our results were similar to a study conducted by **El. Nasri et al in 2015**^[13] which concluded that smart bur had significantly lower caries removal efficiency when compared to hand excavation and CMCR.

In carie care group also, in 13.3% cases, need to excavate more carious dentin was felt, although carie care chemically softens the carious dentin which is then excavated with spoon excavator, in order to preserve maximum tooth structure insufficient caries removal might have occurred during the study. **Venkatraghavan K et al. 2013**^[7] conducted a study to review chemomechanical caries removal efficacy of carie care which also concluded that Carie care gel (CMCR) may not be able to replace the use of traditional instruments (drill) for caries removal but can be used as an alternative to children who are highly anxious about dental treatment.

On inter group comparison between Group 1 and Group 2 for pain, no pain was observed in SDF group since there was no excavation of carious lesion as SDF application is completely painfree and simple to use in young children (**AAPD**).^[24] Our findings are consistent with the various studies conducted on silver diamine fluoride which reveal that Silver diamine fluoride application is completely painfree (**Silveria JM et al, 2015**^[25] and **Clemens J et al, 2017**).^[10]

Further when Group 1A and 1B were compared for SEM scale, the distribution of SEM scale score comfort was significantly more among Group 1B compared to Group 1A. Although polymer bur is also one of the least painful minimal excavation approaches (**Silva N.R.F.A et al 2006**)^[26], mild pain might have occurred because of the sensation of scarping of the decay and by vibration, noise,

overheating and excessive pressure caused by polymer bur. Moreover, the patient compliance also becomes less, since the bur wears off quickly as soon as it contacts the affected dentin and it needs to be replaced by new ones (**Maarouf et al 2009**).^[17]

Kumar K.V.S et al, 2016^[13] found that Carie-Care was the least painful and most acceptable method followed by polymer bur and ART. In our study in Group 1 some of the samples showed mild pain/discomfort. The Chemomechanical caries removal method used in Group1B is considered one of the most conservative and convenient caries removal approaches. Also, carie care used in present study has clove oil in it which is known to possess anti inflammatory, anesthetic and analgesic properties (**Venkatraghavan K et al.2013**).^[7]

SDF is a non invasive method that is also efficient, cost effective and can be used on deciduous teeth. However, the main drawback of SDF is the formation of dark stains on tooth surface. The results of our study suggested that many parents are open to compromise esthetics in favour of using a Non invasive approach which is easy and completely painfree for their child. This is consistent with the study conducted by **Crystal Yo, et al. 2017**^[27] who concluded that staining on posterior teeth was more acceptable than staining on anterior teeth and most parents preferred this option to advanced behavioral techniques such as sedation or general anesthesia.

In the present study on clinical evaluation, all (100%) the samples were found to be asymptomatic postoperatively at the end of three months. Absence of clinical symptoms (pain, tenderness, secondary caries and sinus formation) could be attributed to complete caries arrest and no further caries extension in Group 2 patients. It is well known from literature sources that 38% SDF contains high amount of Fluoride concentration (44, 800 ppm). Fluoride causes remineralisation and thus caries arrest. A literature review of SDF suggested that 38 % silver diamine fluoride (SDF) can be effective in preventing new caries and arresting dental caries in primary teeth of children (**Chu C et al, 2008**).^[9]

Postoperatively all the samples in Group 1A and 1B were asymptomatic which could be attributed to reduction in bacterial flora and remineralisation of the affected dentin. In a study conducted by **Aswathi KK, et al. 2017**^[28] it was found that compared to the base line microbial count, the total viable count after caries excavation using polymer bur and chemomechanical caries removal method showed statistically significant reduction. Moreover, since restorative material used in both Group1A and Group1B were fluoride releasing, they possess an inherent cariostatic property. **Forsten L, 1990**^[29] reported that Glass Ionomer Cements act as fluoride reservoirs and it is suggested that they are clinically cariostatic

In terms of radiographical findings, all (100%) the samples were found to be asymptomatic indicating that in all the three groups there was absence of

release of bacteria and their toxins to pulp and periapical tissues via apical foramen. Moreover, all the samples were vital. The above observation highlights success of both the interventions “less invasive approach” and “Only arrest and no excavation” approach.

CONCLUSION

Both the “LIA” (using SmartPrep burs or Carie Care) and “OANE” (using 38% Silver Diammine Fluoride) were found to be painless and comfortable for the pediatric patients with SDF taking the lead followed by Carie Care and polymer burs. Significant difference were seen in favour of Carie Care approach in comparison to polymer bur when compared for pain/ discomfort using SEM scales. Caries removal efficacy was also found to be more in Carie Care group as compared to polymer bur group though statistically insignificant. In SDF group as all the lesions were arrested and some of the participants were not comfortable with the SDF discoloration and its taste.

However, more studies with larger sample size and longer study period are required to validate the results of the present study..

CONFLICTS OF INTEREST

There are no conflicts of interest.

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