ORIGINAL RESEARCH

Combination of Silver Diamine Fluoride and Hall Technique for Caries Management in Primary Molars: A Randomized Controlled Trial

Meenu Mittal[1], Radhika Chopra[2], Ashok Kumar[3], Ibadat P Kaur[4]

Abstract

Aims and background: Combination of different noninvasive caries arresting approaches may improve the effectiveness and success rate of individual procedures for caries management. The purpose of this study was to evaluate clinical and radiographic success rate of a combination of 38% silver diamine fluoride (SDF) application and Hall technique (HT) for the management of dentinal caries in primary molars and compare it with conventional stainless steel crown (SSC) restoration.

Materials and methods: Children aged 4–8 years, having carious primary molars with the International Caries Detection and Assessment System (ICDAS) score of 5 or 6, were randomly assigned to treatment group A or B. Treatment group A ($n = 25$) received 38% SDF application and Hall crown, while group B ($n = 25$) received conventional SSC restoration. Follow-up was done at 1 month, 3, 6, 12, 24, and 30 months intervals.

Results: There was one case of major failure in group A (93.5% successful) while no case of major failure in group B (100% successful) and the difference was not statistically significant ($p > 0.05$). For minor failure (loss of SSC), the success rate was 91.3% in group B and 84.2% in group A, wherein the difference was not statistically significant ($p > 0.05$).

Conclusion: Conservative management of dentinal carious lesions with SDF and HT showed a similar success rate as compared to conventional operative procedures.

Clinical significance: This protocol can help reduce the clinical chair time and the need for deep sedation/general anesthesia in young children suffering from deep carious lesions with reversible pulpitis.

Trial registration number: CTRI/2020/07/026877, Clinical Trial Registry—India.

Keywords: Caries management, Hall technique, Primary molars, Silver diamine fluoride.

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Introduction

The management of dentinal caries continues to be challenging for children despite the advances made in dentistry. Restorative interventions for young children can be difficult and complex because of their young age and inability to cooperate. Traditionally, dental caries has been treated by nonselective (complete) removal of all carious dentine. There have been concerns of overtreatment and requirement of general anesthesia for conventional dental treatment in children which has led to the development of minimally invasive biologically based treatment strategies in recent times. This conservative approach emphasizes preserving healthy and remineralizable tissue so that the risk of pulp exposure is reduced and pulpal health can be maintained.

For medical management of active caries in primary teeth, topical application of silver diamine fluoride (SDF) has been shown to be effective. SDF application is a noninvasive technique that is affordable and simple to use and has minimal requirement of personnel time and training. It simultaneously halts the cariogenic process and prevents caries.[1] SDF has been recommended for difficult-to-treat lesions, and in patients with high caries risk including those with medical or behavioral complications, requiring multiple dental visits, or lacking access to dental care.[2] Semiannual application of SDF in 38% concentration is recommended.

The Hall technique (HT) is commonly used for sealing caries in primary molars. This technique might arrest or at least slowdown caries progression in primary teeth. Local anesthesia is not required for HT, thus increasing the operator's comfort and child's compliance, which creates less traumatic dental experience for the child.[3]

If lesions are not restored after SDF application, its ability to arrest caries may reduce especially in posterior teeth due to constant food lodgment. This also increases the need for reapplication of SDF periodically. Some researchers have also raised questions regarding the fate of the residual carious lesion left behind when using HT.

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Conflict of interest: None

In order to overcome these drawbacks and also to improve the success rate, a combination of different noninvasive caries arresting approaches has been suggested.

A PubMed search conducted using the keywords SDF and HT resulted in 17 articles of which two matched the citation. Only one of these two articles was a randomized clinical trial with only 1-year follow-up, while the other was a narrative review just mentioning about combination of SDF with HT as a treatment option. When searched on Google, in addition to the above two articles, two registered clinical trials and a few videos depicting the technique of SDF combined with HT were found.

The aim of the present study is to evaluate clinical and radiographic success rate of application of 38% SDF combined with HT for management of dentinal caries in primary molars.

Materials and Methods

Ethics

Ethical clearance was taken from Institutional Ethics Committee (F.No.115-E-13/12/01/2011/Estt. DC). The trial was registered with Clinical Trial Registry—India, (CTRI/2020/07/026877) and the protocol is available at the trial registry. Before enrolling study participants, written informed consent was obtained from each child's parents.

Study Design, Settings, and Participants

Children in the age-group of 4–8 years, reporting to the pediatric dentistry department for dental needs during the period from August to September 2020, were examined, and those fulfilling the following inclusion criteria were enrolled in the study.

Inclusion criteria were: (1) healthy and cooperative children aged 4–8 years, (2) clinical presence of cavitated carious lesion involving dentin and having soft caries in primary molar without pulp exposure [International Caries Detection and Assessment System (ICDAS) 5 or 6], (3) radiographically, teeth with radiolucency involving dentin, (4) intact lamina dura radiographically, (5) radiographic absence of calcification in the pulp canal, (6) restorable tooth, and (7) absence of furcation/interradicular radiolucency.

Exclusion criteria were: (1) history of spontaneous pain, (2) tenderness to palpation or percussion, (3) presence of abscess or fistula, (4) presence of abnormal mobility, and (5) radiographic evidence of internal root resorption or periapical pathosis.

After clinical examination and radiologic assessment of the intraoral radiographs, children were randomly assigned to either of the treatment groups A or B by lottery method by an investigator who was not part of the study and was blinded to the treatment methods.

Sample Size Calculation

The power analysis of data obtained from the literature survey was done by software G*Power version 3.1.[4] The effect size was 0.725 and the power was 95.20%. Therefore, for α error probability 5 and 95% confidence interval, the total sample size was 38 and 19 for each group. To compensate for loss to follow-up we took 25 in each group.

Interventions

The two groups divided were as follows—group A (SDF–HT): ($n = 25$) SDF application and tooth restoration with HT; group B (control-conventional SSC): ($n = 25$) complete removal of carious dentin and restoration with stainless steel crown (SSC).

The treatment was carried out in steps as follows:

Group A (SDF–HT): Separators were placed mesially and distally 3–4 days prior to the appointment for Hall crown. During the second appointment, gross debris from cavitation was removed but no caries removal was done. A protective coating was applied on the lips and skin. Isolation of the tooth was done with cotton rolls and tooth was dried using three-way syringe. One drop of SDF (FAgamin, AKV enterprises, Hyderabad, India) was applied with microbrush on carious dentin for 1 minute and again dried with a gentle stream of air. Isolation with cotton rolls was maintained for 3 minutes. It was followed by SSC placement using HT.

Group B (control-conventional SSC): Gross debris from cavitation as well as carious dentin was removed and the tooth was restored with glass ionomer cement (GC Fuji II), followed by SSC.

All treatments for groups A and B were provided by a single pediatric dentist (first investigator).

Participants' Follow-up and Assessment

The follow-up of treatment was done at intervals of 1 month, 3, 6, 12, 24, and 30 months and treatment outcome was determined by a combination of clinical and radiographic findings by an independent pediatric dentist (second investigator) who was blinded to the treatment groups. Radiographs were taken at 3, 6, 12, 24, and 30 months follow-up visits. The second investigator was trained and calibrated for recording ICDAS scoring, clinical evaluation, and assessment of intraoral periapical (IOPA) radiographs on a group of 15 patients who were not a part of the study. Disagreement if any was discussed until full agreement was achieved. These records were excluded from the study. Interevaluate κ values for the second investigator was 0.8.

Clinical determinants of success were as follows.

Primary Outcome: Successful

- SSC intact, no loss, or perforation of crown.
- Absence of clinical signs or symptoms of pulpal pathology: lack of pathologic tooth mobility, lack of parulis, no complaint of sensitivity, and lack of pain (such as spontaneous pain or pain on percussion).
- Tooth exfoliated without minor or major failure.
- Radiographic criteria: lack of periapical or interradicular pathology, intact lamina dura, and lack of internal or pathological external root resorption.

Primary Outcome: Minor Failure

- Loss/perforation of SSC.
- Complaint of sensitivity.

Secondary Outcome: Major Failure

- Irreversible pulpitis (history of spontaneous pain or pain on percussion) and/or presence of parulis; requiring pulpectomy or extraction.
- Radiographic criteria: presence of interradicular or periapical pathology, loss of continuity of lamina dura, and presence of internal or pathological external root resorption.

Data Analysis

Data from both groups was entered into MS Excel and statistically analyzed using the statistical software SPSS 16.0. The descriptive statistics like mean, median, standard deviation, standard error mean, and frequency distribution *N* (%) of data were calculated. The significance of parameters between the two groups was tested by

Pearson's Chi-squared test. The 95% CI and 5% level of significance were used for the analysis of data.

Results

Participant Flow and Baseline Characteristics

The total number of children who participated in group A (SDF–HT) was 25, of which 19 (76%) were males and 6 (24%) were females. In group B (control-conventional SSC), the total number of children were 25, of which 16 (64%) were males and 5 (36%) were females. The mean age of children in group A was 5.96 ± 1.4 and 6.19 ± 1.6 in group B.

Figure 1 shows the dropouts and failure cases at the follow-up visits for both groups.

Four children of group B did not turn up after the initial treatment visit and had to be excluded from the study.

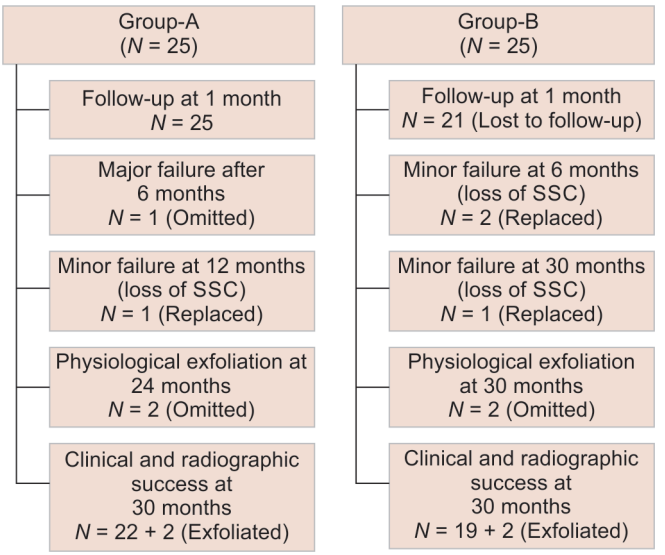

Fig. 1: Flowchart depicting clinical and radiological outcomes

Outcomes and Estimation

Groups A and B Clinical Evaluation

In group A, at 6 months follow-up, there was one case of major failure with pain and periapical abscess and the tooth had to go in for extraction (Table 1 and Fig. 2). At 12 months follow-up, there was one case of minor failure with loss of SSC which was replaced. At 24 months follow-up, two teeth had undergone physiological exfoliation. At the end of 30 months, all the remaining 22 teeth were healthy and met all the criteria of clinical success.

Of 21 cases (four were lost to follow-up) in group B, there were two cases of minor failure with loss of SSC at 6 months which were replaced. At 30 months follow-up, one more case of minor failure with loss of SSC was recorded. Two teeth had exfoliated physiologically and the rest of the teeth were clinically sound at 30 months follow-up.

Radiological Evaluation

In group A, at 6 months recall, there was one case of major failure with the presence of periapical radiolucency, widening of lamina dura, and evidence of root resorption (Table 2 and Fig. 3). At 30 months recall visit, all the 22 teeth were found to be successful radiologically.

In group B, none of the 21 teeth showed any signs of radiographic pathology during the whole duration of 30 months.

Combining clinical and radiological results for major failures, there was one case of major failure in group A (93.5% successful) while no case of major failure in group B (100% successful), the difference was not statistically significant ($p > 0.05$); while for minor failure (loss of SSC), 91.3% were successful in group A, and 84.2% successful in group B, the difference was not statistically significant ($p > 0.05$).

Discussion

The current practice of dentinal caries management in primary molars is shifting toward minimally invasive biological treatments as these procedures offer several advantages over conventional

Table 1: Clinical evaluation

	Group A	*Group B*	*Group A*	*Group B*	*Group A*	*Group B*	*Group A*	*Group B*	*Group A*	*Group B*
	Intact SSC		*Lack of tooth mobility*		*Lack of parulis*		*No complaint of sensitivity*		*Lack of pain*	
1 Month	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	NA		NA		NA		NA		NA	
3 Months	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	NA		NA		NA		NA		NA	
6 Months	25 (100%) (*n* = 25)	19 (90.47%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.0%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.0%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	0.1146		NA		0.3541		NA		0.3541	
12 Months	23 (92.00%) (*n* = 25)	19 (90.47%) (*n* = 21)	24 (96.0%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.0%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.0%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.0%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	0.8550		0.3541		0.3541		0.3541		0.3541	
24 Months	21 (91.30%) (*n* = 23)	19 (90.47%) (*n* = 21)	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)
p-value	0.9239		0.3337		0.3337		0.3337		0.3337	
30 Months	21 (91.30%) (*n* = 23)	16 (84.21%) (*n* = 19)	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19))	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19)	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19)	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19)
p-value	0.4798		0.3576		0.3576		0.3576		0.3576	

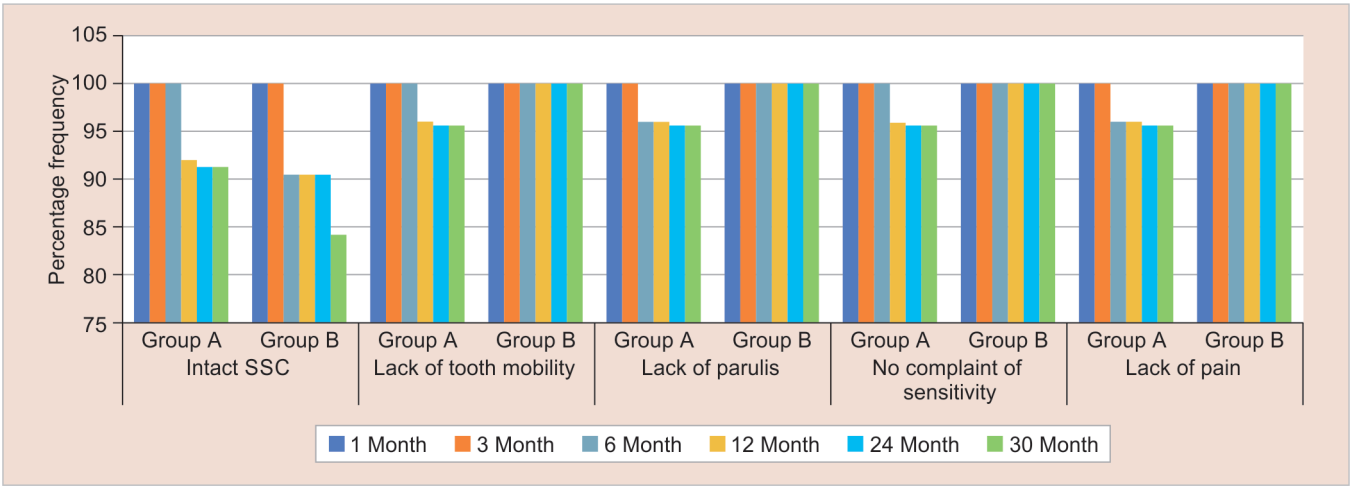

Fig. 2: Graphical representation of clinical evaluation

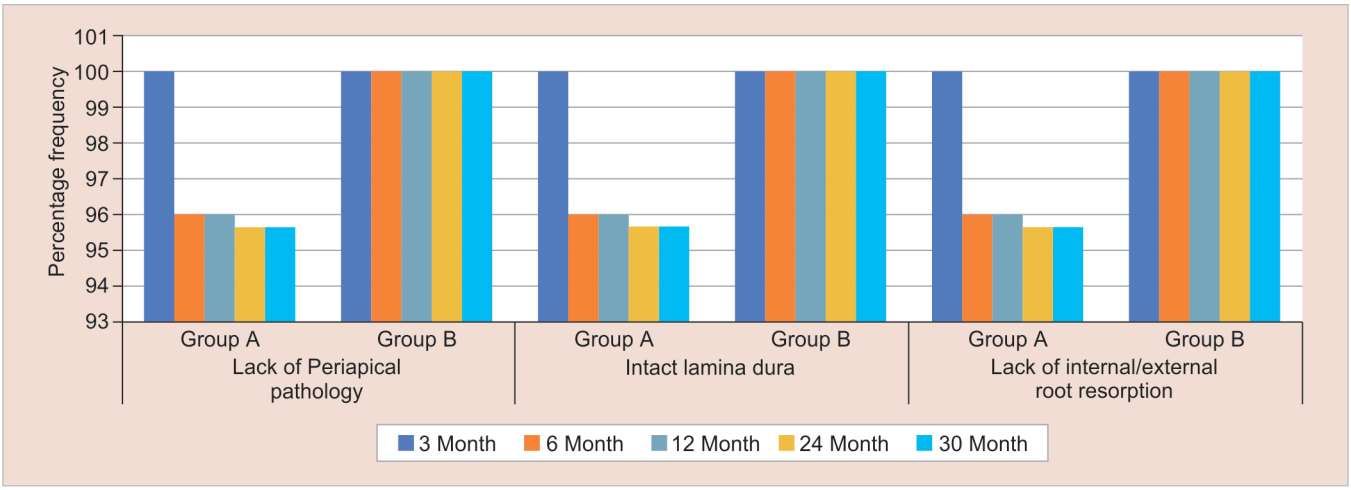

Fig. 3: Graphical representation of radiological evaluation

Table 2: Radiological evaluation

	Group A	*Group B*	*Group A*	*Group B*	*Group A*	*Group B*
	Lack of periapical pathology		*Intact lamina dura*		*Lack of internal/external root resorption*	
3 Months	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)	25 (100%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	NA		NA		NA	
6 Months	24 (96.00%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.00%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.00%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	0.3541		0.3541		0.3541	
12 Months	24 (96.00%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.00%) (*n* = 25)	21 (100%) (*n* = 21)	24 (96.00%) (*n* = 25)	21 (100%) (*n* = 21)
p-value	0.3541		0.3541		0.3541	
24 Months	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)	22 (95.65%) (*n* = 23)	21 (100%) (*n* = 21)
p-value	0.3337		0.3337		0.3337	
30 Months	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19)	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19)	22 (95.65%) (*n* = 23)	19 (100%) (*n* = 19)
p-value	0.3576		0.3576		0.3576	

dental surgical management. These minimally invasive treatments (MID) are simple procedures that are less traumatic for the child and have shown reliable outcomes. As these procedures are usually conservative and do not require high speed drills, the frequency of administration of local anesthesia and general anesthesia is significantly reduced. This in turn leads to better behavior shaping of the patient, reduction of the cost of treatment, and better acceptance by the parents.[5,6]

Two of the most commonly used MID methodologies are SDF and HT. These techniques do not require expensive equipment or infrastructure[7,8] and can be used in fields without electricity.[9] These are frequently used when a shorter duration of treatment is essential such as for uncooperative children or when access to dental care is limited.[9]

Silver diamine fluoride is a medical noninvasive treatment protocol for carious primary molars. For SDF application, no caries excavation or removal is necessary but the tooth surface needs to be free of food debris so that SDF solution can come in direct contact with dentin.[3,10] Hammersmith et al.[11] in their study reported caries arrest with SDF in majority of cases; and in cases where caries progressed, it progressed slowly.[11,12]

Hall technique involves seating an SSC on a carious primary molar, without any local anesthesia, caries removal, or tooth preparation.[6,13] The crown margins are not cut and no marginal crimping or finishing is done.[13] The concern over excess overbite with HT was observed to resolve at 6–12 months of recalls.[14] Both HT or SSC placed by conventional technique, provide effective, low-maintenance seal around the whole perimeter of restoration, particularly for class II restorations.[15,16] According to Kidd,[17] there is no need to remove soft, wet dentine and the caries process can be arrested by simply sealing it in place. In HT, the superficial layer of plaque biofilm is not removed and sealed along with the carious lesion.[3] This stops caries progression or at least slows it to a degree that it is of no concern.[3] Since conventional techniques of proven efficacy are available; there have been several published concerns about clinical outcomes and short-term as well as extended histopathological implications of diseased tissue left in the Hall crown.[13,18,19]

However, this concern can be alleviated by applying SDF directly on the carious lesion before placement of the Hall crown. Application of SDF occludes the dentinal tubules and makes the environment for cariogenic bacteria and plaque biofilm unfavorable.[20] Placement of crown after SDF application increases the chances of sealing carious lesion successfully.[20] It will also improve the survival of SDF application, which has been reported to be 76% by Raskin et al. when SDF is used alone without any restoration.[21] In these cases, SDF usually has to be reapplied 6 monthly for the caries arrest process to continue,[10] but with the combination method, reapplication would not be required.

The purpose of the present study was to minimize the limitations of both SDF and HT and maximize the chances of carious lesion arrest by using a combination of antibacterial effects of SDF and excellent sealing ability of Hall crowns.

Conventional SSCs were used as restoration in control group following removal of carious dentin and tooth restoration with glass ionomer cement, which is the standard treatment for restoration of primary molars. For multisurface lesions, definitive treatment with SSC following complete caries removal has been proven to be a better alternative as compared to multisurface intracoronal restorations in children at high risk of caries.[14,22,23] Hall crown is another treatment option for primary molars with multisurface lesions.[14]

The current study resulted in no significant difference between the conventional SSC and SDF–HT groups at recall visits for major and minor failures (there was one case of major failure in SDF–HT group and no major failure in conventional group). Only one randomized controlled clinical trial is available in the literature by Salem et al. which compared HT with SDF–HT combination and reported SDF–HT to be more successful than HT, but the difference was not statistically significant.[24] They compared SDF–HT with HT, instead of conventional SSC as was the case in the present study. Soni et al. also achieved clinical and radiographic success using SDF under Hall crown, although they used it in a single case only.[25]

Elamin et al.[9] and Ludwig et al.,[26] compared HT with conventional SSC and found similar results, but they did not use SDF. A study by Innes et al. reported less failures with HT as compared with conventional restorations comprising GIC and other intracoronal restorations as control rather than SSC.[16] Similarly, Fontana et al. concluded level 2 evidence for the HT.[22]

As per reviews by Natarajan[27] and Al-Yaseen et al.,[20] the silver modified atraumatic restorative technique (SMART) arrests and remineralizes the carious lesion, enhances pulp vitality, and preserves tooth structure. SDF–HT will provide a better seal than SMART, as there would be more chances of loss of intracoronal restorations as compared to SSC.

Although we did not analyze the duration of the procedure among the groups, it was observed by the clinician that SDF–HT could be performed quickly with better behavior outcomes as compared to conventional SSC. These observations can obviously be explained by the elimination of local anesthesia and high-speed drill for SDF–HT. Nevertheless, requirement of additional appointments for placement of separators in SDF–HT group cannot be overlooked as a disadvantage.

There has been a paradigm shift in the management of dental caries, where dental care for children has moved from traditional "drill and fill" approach to minimally invasive methods such as HT and SDF. These minimally invasive techniques have achieved similar success repeatedly, while in addition, reducing child discomfort. Both SDF application and HT have additional advantage of being nonaerosol generating procedures.[20]

For any treatment to be successful, accurate detection, assessment, and diagnosis of the status of dental caries and the tooth is mandatory.[20] Direct application of SDF on pulp can cause necrosis of the tissue. Indirect application has been found to be generally biocompatible with a mild inflammatory response. Thus, a proper clinical and radiographic diagnosis of reversible pulpitis with the presence of a dentinal barrier is crucial for the success of SDF application.[28]

Both conventional caries removal and restoration with SSC or combining SDF with Hall crown have the common goal of trying to stop the progression of carious lesion to dental pulp and thus avoiding pain and/or pulpal infection before primary tooth exfoliation. SDF being bactericidal, its combination with HT might make the residual microorganisms nonviable and improve caries management in primary teeth. This is however the limitation of the present study that histopathological evaluation of pulp–dentin complex after SDF and Hall crown could not be performed and this aspect needs further research for better clarification.

As per Innes et al., the care index for 5-year-olds remains at 10% level.[6] The requirement of these simpler, cost-effective, efficient,[27] and noninvasive techniques remains essential in children who do not have access to high-quality treatment. This protocol can help in reducing the clinical chair time and the need for deep sedation/

general anesthesia in young children suffering from deep carious lesions with reversible pulpitis. Clinicians should discuss any modification of standard treatment with MID such as HT, SDF with the parents, or care givers of children[20] and make an informed decision.

Conclusion

Conservative management of deep carious lesions with SDF combined with HT showed a similar success rate as compared to conventional operative procedures after a follow-up of 30 months. Further long-term studies are needed to validate the usage of this strategy in routine dental clinics.

Clinical Significance

Silver diamine fluoride combined with HT is a minimally invasive technique, achieving success similar to traditional approaches to dentinal caries management. This protocol can help in reducing the clinical chair time and the need for deep sedation/general anesthesia in young children suffering from deep carious lesions with reversible pulpitis.

Presentation

Presented as part of a guest lecture at SAAPD conference from 8th to 11th February, 2024 held at Hyderabad.

Author Contributions

Concepts: Dr Meenu Mittal.
Definition of intellectual content: Dr Meenu Mittal, Dr Ashok Kumar, Dr Radhika Chopra, Dr Ibadat Preet Kaur.
Design: Dr Meenu Mittal, Dr Ashok Kumar.
Literature search: Dr Meenu Mittal, Dr Radhika Chopra.
Clinical work: Dr Meenu Mittal, Dr Ashok Kumar, Dr Ibadat Preet Kaur.
Manuscript preparation: Dr Meenu Mittal.
Manuscript editing: Dr Radhika Chopra.
Manuscript review: Dr Ashok Kumar, Dr Radhika Chopra, Dr Ibadat Preet Kaur.
Guarantor: Dr Meenu Mittal.

Declaration

The manuscript has been read and approved by all the authors, the requirements for authorship as stated earlier in this document have been met, and each author believes that the manuscript represents honest work.

Availability of Data and Materials

The data is available with the corresponding author and can be submitted if required.

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