Dilute Silver Diamine Fluoride (1:10) Versus Light Cure Calcium Hydroxide as Indirect Pulp Capping Agents in Primary Molars – A Randomized Clinical Trial

Nisha Shafi*/ Harsimran Kaur **/ Rishika Choudhary ***/ Ramakrishna Yeluri ****

Aim: *To evaluate the clinical and radiographic outcomes of diluted silver diamine fluoride (1:10) and light cure calcium hydroxide as indirect pulp capping agents in primary molars.* ***Study design:*** *Fifty-six primary molars requiring indirect pulp treatment were randomly allocated to two groups: Dilute SDF (one drop of SDF mixed with 9 drops of distilled water giving a 1:10 dilution) and light cure calcium hydroxide. The indirect pulp treatment was followed by glass ionomer cement restoration and all primary molars received stainless steel crown as full coverage restoration. The teeth were followed up both clinically and radiographically at 1,6- and 12-months' time interval using a pre-determined criterion. The results were statistically analyzed using Chi square analysis. The significance level was set at p ≤0.05.* ***Results:*** *Overall clinical and radiographic success rate of indirect pulp treatment with SDF was 96% and with light cure calcium hydroxide was 91.6% respectively at the end of 12 months but the difference was not statistically significant (p>0.05).* ***Conclusion:*** *Dilute silver diamine fluoride (1:10) can be advocated as potential indirect pulp capping agent in primary molars with deep carious lesions.*

Keywords: *Indirect pulp capping; Light cure calcium hydroxide; Silver diamine fluoride*

INTRODUCTION

Indirect pulp treatment (IPT) is a vital pulp treatment where the deepest caries is left unexcavated to avoid causing a pulp exposure during caries excavation.[1] Calcium hydroxide available in original and altered forms is widely used as IPT agent in paediatric dentistry.[2]Calcium (Ca) and hydroxyl (OH) ions released by Calcium hydroxide; interact with bacteria's cytoplasmic membrane, causing antimicrobial effects and activating tissue enzymes such as alkaline phosphatase which promotes secondary/reparative dentin development in close proximity to the pulp.[3]

Self-curing $Ca(OH)_2$ cement (Dycal) is soluble, raises alkalinity, and forms a necrotic layer at the material–pulp interface, paving to greater chances of microleakage; which can reduce the success rate of preventive pulp therapy.[4] The failure rate of pulp treatment with calcium hydroxide-based materials increase with time in long-term clinical tests,[5]as there seems to be an increase in the amount of cells indicative of inflammation and a small area of pulpal necrosis.[6] Also, the non-adhesive nature of calcium hydroxide and gradual disintegration leads to tunnel formation in newly formed dentin-[7]thereby causing microleakage and entry of bacteria into dentin-pulp complex.[8] Hence, light-cured pulp capping materials have emerged as a promising option in place of self-curing calcium hydroxide. Light-cured $Ca(OH)_2$ cements, claim to release Ca ions for a period of up to 21 days, which is significantly more than Dycal during all the test periods.[4]

From the Department of Pedodontics & Preventive Dentistry, Teerthanker Mahaveer Dental College & Research Centre, Uttar Pradesh, India.
*Nisha Shafi, BDS, Post Graduate Student.
**Harsimran Kaur, BDS, MDS, Former Professor.
***Rishika Choudhary, BDS, MDS, Senior Lecturer.
****Ramakrishna Yeluri, BDS, MDS, Professor and Head.

Corresponding Author:
Ramakrishna Yeluri
Department of Pedodontics and Preventive Dentistry,
Teerthanker Mahaveer Dental College & Research Centre,
Delhi Road, Moradabad – 244102,
Uttar Pradesh, India.
Phone: +91 9997951558
Fax: +91 591 2476823
E-mail: drramakrishnay@gmail.com, kittypedo@yahoo.com

Glass ionomer cement (GIC) owing to its sustained fluoride release, has been cited as the most successful IPT agent.[9] Conventional GICs possess limitations related to their susceptibility to dehydration and poor physical properties, such as high solubility and slow setting rate. Nevertheless, certain of these deficiencies have been overcome by recent modified GIC liners.[10] SDF has also been used as cariostatic agent. It has been demonstrated to be beneficial in the management and prevention of dental caries.[11]SDF assists in the formation of silver phosphate, which restores the content of minerals and cause tooth remineralization.[12]

SDF provides a fluoride hyper-saturated environment, which leads to the development of fluorapatite crystals as compared to the formation of hydroxyapatite crystals by calcium hydroxide. Fluorapatite crystals are larger in size, resulting in a structure that is more densely packed with fewer vacancies resulting in better microhardness rating.[12] SDF's properties are based on chemical interactions and its ability to diffuse into dentin[13] to a depth of 700 microns.[14] Its antibacterial characteristics are due to suppression of enzyme activity and dextran-induced agglutination of a streptococcus mutans cariogenic strains. The oligodynamic activity of silver inhibits the microorganism's development if it invades the dentinal tubules.[15] SDF has been shown in a recent laboratory study to have a restraint impact on matrix metalloproteinases (MMP), which have a significant role in the degradation of collagen in carious lesions. MMP activity is inhibited by SDF which can protect against collagen degradation.[16] When used on artificially demineralized human dentine, Gupta *et al*[12]found that SDF has a stronger remineralization capacity than calcium hydroxide in regards to enhanced mineral content and microhardness value. Sulyanto *et al*[17] indicated that the interaction of SDF with the dentin-pulp complex changes the tooth's physicochemical properties, which contributes to SDF's mechanism of action in caries arrest and desensitization, including tertiary dentin development. In an *in vivo* investigation, Sinha *et al*[18] discovered that SDF resulted in higher phosphate and fluoride ion levels and lower calcium ion levels in residual dentine thickness in permanent molars when compared to calcium hydroxide. These investigations revealed that SDF can be employed as an IPT agent.

Rivastar and Rivastar aqua (SDF+KI) were introduced in the market to be used in a sandwich technique before a base and a restoration to sterilize the lesion and desensitize the tooth prior to restoring it. However, their actions on the pulp complex and as an IPT agent have not been reported in the literature. FAgamin, 38% silver diamine fluoride manufactured by Tedequim SRL, (Cordoba, Argentina) can be applied in deep caries in a diluted ratio of 1:10 with distilled water.[19] Further, studies done by Gupta *et al*[12], Sinha *et al*[18], Korwar*et al*[20] evaluating the remineralizing, antimicrobial and fluoride release efficacy of SDF propagated that it can be utilized as a potential IPT agent in permanent teeth. There are very few studies available in the literature comparing SDF and calcium hydroxide as IPT agents in primary teeth.[21,22] The aim of this randomized clinical trial is to compare the efficacy of diluted SDF (1:10) and light-cured $Ca(OH)_2$ as indirect pulp capping agents in primary molars with deep carious lesions.

MATERIALS AND METHOD

The institutional ethics committee received the study protocol and gave its approval vide Ref. No: TMDCRC/IEC/19-20/PPD5 dated 11/10/2019. Prior to the beginning of the study, legal guardian of the child participant signed the consent form-including the risk, benefits and alternatives of the given procedure. Calculation of sample size was done following power analysis using nMaster2.0 software. A minimum of 20 samples were required in each group to estimate the difference at 95% confidence level and 10% relative precision. The sample size was calculated as per the article by Sinha et al.[18] Teeth with clinically large carious lesion, history of transient pain and, radiolucency approximating pulp and intact lamina dura were included. However, teeth with presence of spontaneous pain, inter radicular or periapical radiolucency, patients with behavioral management issues and/or systemic diseases were excluded.[23] Fifty-six primary molars indicated for indirect pulp capping procedure were included in this study. All the participants were randomly and equally allotted to one of the groups: Group 1 (1:10 Diluted silver diamine fluoride, n=28) and Group 2 (Light-cured calcium hydroxide, n=28). The randomization was carried out by the parent choosing one of the two colored balls from an opaque bag each denoting the name of the procedure (diluted silver diamine fluoride or light-cured calcium hydroxide) with 1:1 distribution ratio. All the procedures were performed and evaluated by a single operator (N.S).

After administration of local anesthesia (Lignox2% A, Indoco Remedies Ltd, Mumbai, India) and adequate isolation using rubber dam, the carious lesion in the tooth was accessed by using a number 4 round bur. The cavity preparation was widened sufficiently to excavate the carious dentine. The soft caries was removed using a spoon excavator until it was believed that further excavation would result in pulp exposure. The prepared cavity was then irrigated with saline and gently dried. If pulp was exposed during excavation, pulpotomy was performed and the tooth was excluded from the study.

Clinical procedure in Group-1

After washing and drying, the floor of the cavity was damped with two or more drops of diluted (one drop of SDF mixed with 9 drops of distilled water giving a 1:10 dilution) silver diamine fluoride using an applicator tip. It was rubbed thoroughly over the tooth for two minutes followed by thorough washing and drying of cavity.[19]

Clinical procedure in Group-2

Light-cured calcium hydroxide (CAL LC, PREVEST DenPro, Jammu, India) was applied directly into the cavity with the tip provided by the manufacturer. The thickness of the material was maintained at 1mm for all the teeth. The material was photo polymerized as per manufacturer's instructions. All the teeth in both groups received glass ionomer cement restoration on the same visit, followed by stainless steel crown on the consecutive day. Stainless steel crown was cemented using luting GIC.

Each and every restored tooth was evaluated clinically and radiographically at 1, 6, and 12-month time intervals to determine the success of the respective treatment. Any tooth exhibiting signs of clinical or radiographic failure during the follow up period was subjected to pulpectomy and was excluded from the study.

Criteria for success[24,25] included presence of an intact tooth with normal periodontium, and intact lamina dura, while criteria for failure included: presence of pain, sensitivity to percussion, intra-oral or extra oral sinus / abscess/ swelling, widening of periodontal ligament space, internal resorption of the root, external resorption of the root, radiolucency in furcal area **(Figures: 1 [A,B,C] & 2 [A,B,C])**. The data was subjected to statistical analysis using SPSS Version 23.0 for windows (IBM SPSS statistics, IBM corp., 2018). Frequency and percentage were included in the descriptive analysis. Chi-Square test was utilized to evaluate the variance between the groups at different intervals. The significance level was predetermined at $p \leq 0.05$.

RESULTS

The data pertaining to eligibility, intervention and number of participants accessed at different time intervals is presented in **Flow chart -1** where 71 patients with reversible pulpitis were screened. Out of that, 59 patients received the intervention, 3 patients who had pulpal exposure during excavation were excluded. Finally, 56 patients were randomly allocated to test groups: SDF and Cal LC, who were followed up for 1, 6, 12 months. The 56 study participants had a mean age range of 5.72 ± 2.18 in males and 5.72 ± 1.83 in females with a total of 56 molars, (one per child) who received indirect pulp capping procedure with either diluted SDF (n=28) or light-cured calcium hydroxide (n=28). **Table -1** shows the mean age and gender distribution of participants. The distribution of teeth in maxillary and mandibular arch is presented in **Table -2**. **Table -3** shows the intergroup comparison of clinical parameters of failure at 1, 6, 12 months respectively. A statistically non- significant difference was observed at different time intervals between the two groups clinically even though failures were observed in both groups.No radiographic failures were observed in either of the groups but those presented with clinical failure were excluded in radiographic follow up as well. **Table -4** shows comparative overall success of SDF and light cured calcium hydroxide groups at 1, 6, 12 months respectively. At the end of 12 months in SDF group out of 28 samples (excluding 3 drop outs) and only one clinical failure, resulted in 96% overall success and CAL LC group out of 28 samples

Figure 1-A: Pre-operative radiograph, B: Immediate post-operative radiograph, C: 12 month follow up radiograph in respect to 84 in Group 1

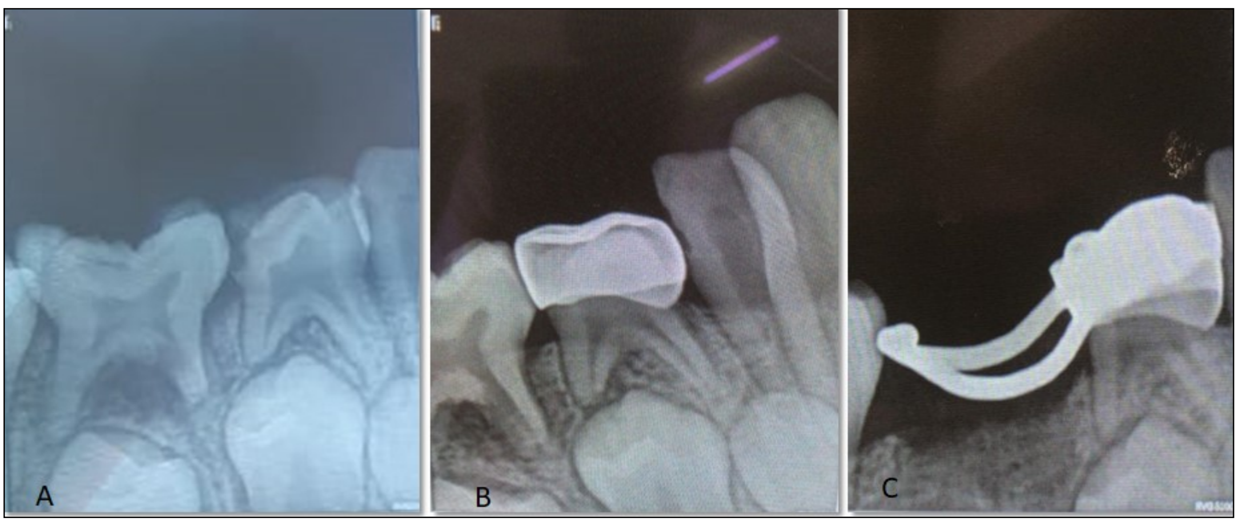
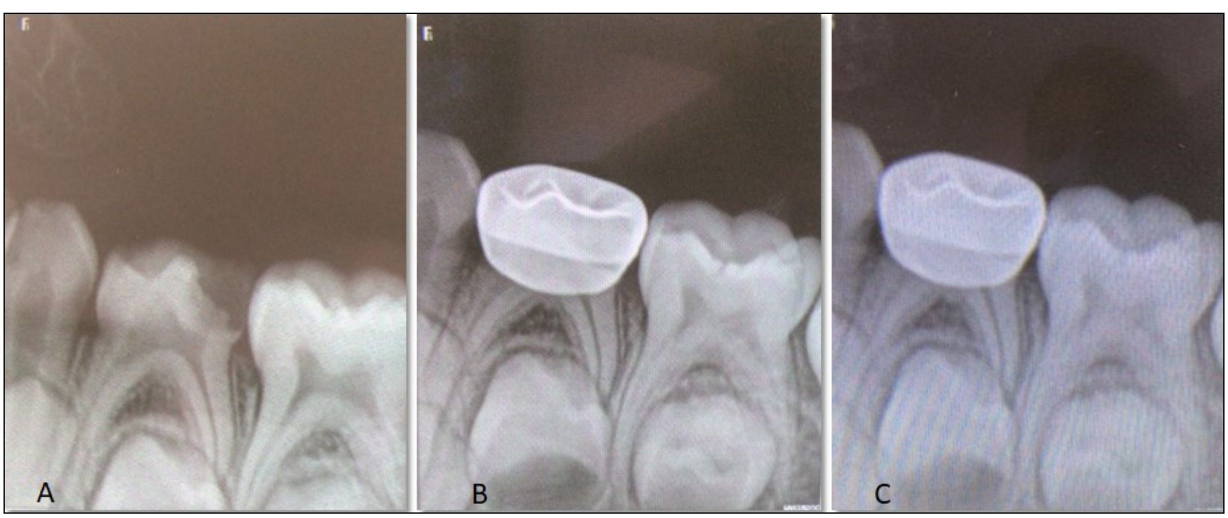


Figure 2-A: Pre-operative radiograph, B: Immediate post-operative radiograph, C: 12 month follow up radiograph in respect to 74 in Group 2



 doi 10.22514/1053-4625-46.4.3

Flow chart 1: Flow chart of the study subjects from baseline to 12-months follow up in accordance to CONSORT guidelines

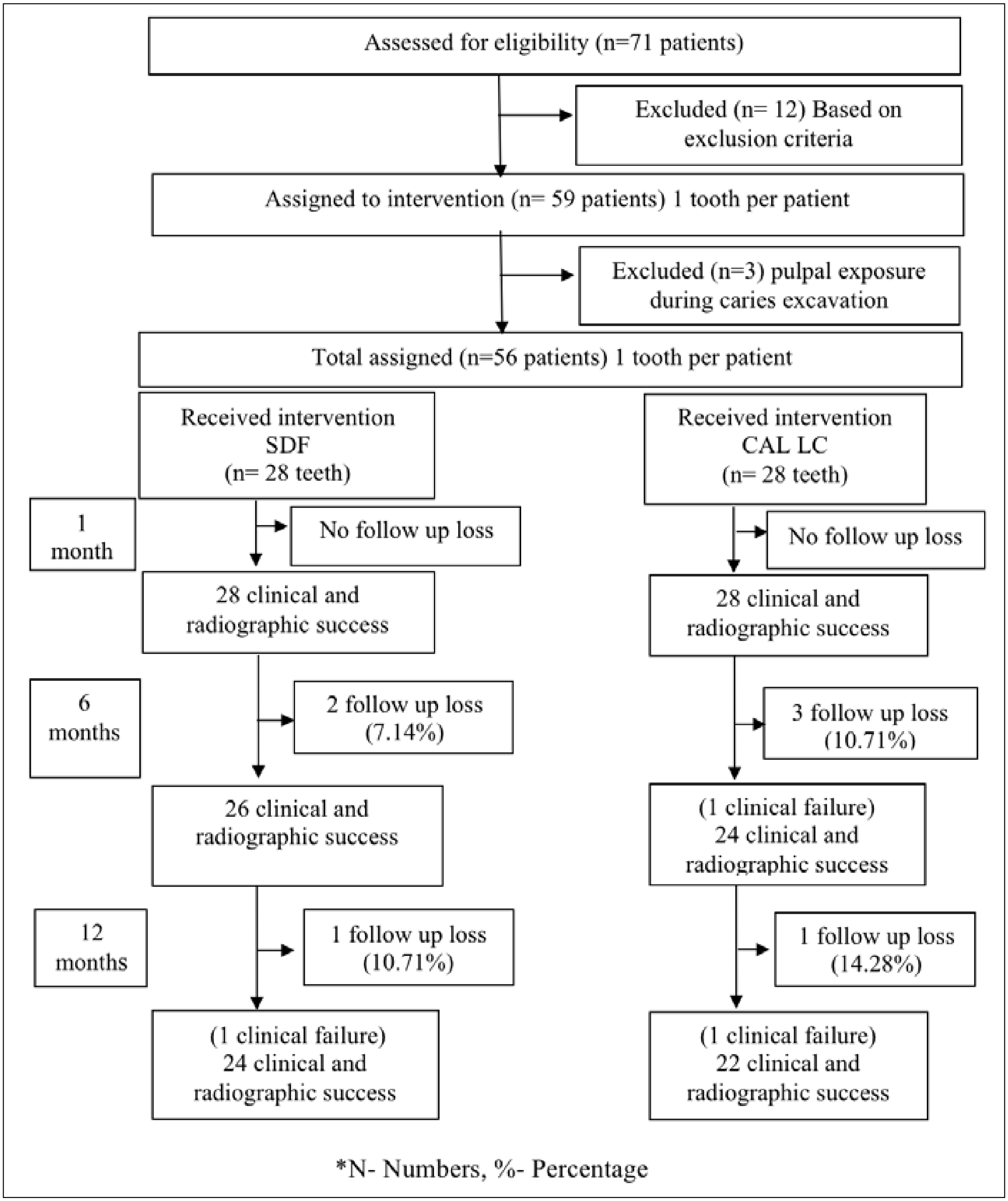


Table 1: Mean age and gender distribution of the study subjects

Sex	N	Mean(yrs)	Std. Deviation
Male	31	5.74 ±2.18	2.1
Female	25	5.72 ± 1.83	1.8

*Std. Deviation – Standard Deviation, yrs- years, N- Numbers.

Table 2: Distribution of teeth in the present study

	Frequency	Percentage
Maxillary	28	50.0
Mandibular	28	50.0
Total teeth	56	100
Primary Ist Molar	35	62.5
Primary IInd Molar	21	37.5
Total teeth	56	100

Table 3: Intergroup comparison of clinical parameters of failure at 1, 6, 12 months.

		History of Pain	Tenderness on percussion	Mobility	Swelling
1 Month	SDF (n=28)	0% Failure	0% Failure	0% Failure	0% Failure
	CAL-LC (n=28)	0% Failure	0% Failure	0% Failure	0% Failure
	Chi Square	0.000	0.000	0.000	0.000
	P value	1.000 (NS)	1.000 (NS)	1.000 (NS)	1.000 (NS)
6 Months	SDF (n=26) (2 lost to follow up)	0%-Failure	0%-Failure	0%-Failure	0%-Failure
	CAL-LC (n=25) (1 clinical failure) (3 lost to follow up)	4.00%-Failure	0% Failure	0% Failure	0% Failure
	Chi Square	1.061	0.000	0.000	0.000
	P value	0.490 (NS)	1.000 (NS)	1.000 (NS)	1.000 (NS)
12 Months	SDF (n=25) (1 clinical failure) (3 lost to follow up)	4.00%-Failure	0%-Failure	0%-Failure	0%-Failure
	CAL-LC (n=24) (2 clinical failure) (4 lost to follow up)	8.33%-Failure	0%-Failure	0%-Failure	0%-Failure
	Chi Square	0.400	0.000	0.000	0.000
	P value	0.609 (NS)	1.000 (NS)	1.000 (NS)	1.000 (NS)

*df- degree of freedom, N- Number, N.S- Not Significant, %- Percentage.

Table 4: Comparative overall success rate of SDF and CAL LC at 1, 6, 12 month interval.

		Clinical success	Radiographic success
1 Month	SDF (n=28)	100%- Success(28)	100%Success(28)
	CAL-LC (n=28)	100%-Success(28)	100%-Success(28)
	Chi Square	0.000	0.000
	P value	1.000 (NS)	1.000 (NS)
6 Months	SDF (n=26) (2 lost to follow up)	100%-Success(26)	100%-Success(26)
	CAL-LC (n=25) (1 clinical failure) (3 lost to follow up)	96%- Success(24)	96%- Success(24)
	Chi Square	1.061	1.061
	P value	0.490 (NS)	0.490 (NS)
12 Months	SDF (n=25) (1 clinical failure) (3 lost to follow up)	96%- Success(24)	96%- Success(24)
	CAL-LC (n=24) (2 clinical failure) (4 lost to follow up)	91.67%- Success(22)	91.67%- Success(22)
	Chi Square	0.400	0.400
	P value	0.609 (NS)	0.609 (NS)

*df- degree of freedom, n- Number, N.S- Not Significant (excluding 4 drop outs) and with two clinical failures, resulted in 91.67% overall success. At the end of 12 months follow up period, no statistically significant differences between the success of diluted SDF and light-cured calcium hydroxide were observed.

DISCUSSION

An indirect pulp treatment procedure not only maintains the vitality of the carious tooth, but also lowers the number of micro-organisms near the pulp and halts the progression of caries. The success rate in the current study was 96.0% in the SDF Group and 91.6 % in the light- cured calcium hydroxide group at the end of 12-month follow up period, and the difference among the groups was statistically not-significant (p>0.05), which is consistent with earlier studies reported by Patil *et al*[21], who found that SDF had a 98 % success rate and calcium hydroxide had an 88% success rate when used as IPT agents in primary teeth.

At the conclusion of the 6 and 12-month periods, SDF had a clinical failure rate of 0% and 4%, respectively. Light-cured calcium hydroxide, on the other hand, had a clinical failure rate of 4% at 6 months and 8.33% at 12 months. The clinical failures due to pain (total 3) in both groups in this study could be ascribed to inaccurate baseline pulp diagnosis, or a pulp reaction to the pulp capping material. However, to quantify the level of pulpal invasion and inflammation, can only be determined after a histological investigation, which was not within the scope of this study. Divyashree[22] examined SDF, MTA, and Dycal as IPT agents clinically and radiographically at 1, 3, and 6 months, reported 0.1533 mm of reparative dentine development with Dycal, 0.116 mm with MTA, and 0.0076 mm with SDF. In an ex vivo investigation, Korwar et al[20] investigated SDF as an IPT agent in permanent teeth and found no inflammation in the pulp treated with SDF and no statistically significant change in tertiary dentine development when compared to GIC.

In this study, after application of the IPT agent, the tooth was restored with GIC, followed by the cementation of stainless-steel crown, which created a hermetic seal and disguised any potential SDF discoloration. The teeth were monitored for 1, 6, & 12 months owing to the highest rate of reparative dentine development in the first month declining gradually up to 9-12 months.[22] Since a stainless-steel crown was used, the tertiary dentine deposition could not be assessed in this study. However, the high success rate could indicate reparative dentine production. The limitations observed in this study includes: inability to gauge the extent of pulpal inflammation based on child's pain history. The extent of discoloration associated with SDF and the penetration of silver ions along the dentinal tubules and into the pulp (if any), could not be evaluated. Additionally, a radiograph is a two-dimensional image of a three-dimensional tooth structure; it cannot portray the exact limits of a carious lesion. A CBCT scan can be used to provide details regarding the extent of reparative dentine production. Based on the results of the current study, 1:10 diluted SDF can be used as an indirect pulp capping agent in primary molars presenting with deep carious lesions; however, long term clinical trials are essential to establish the sustainability of this treatment.

CONCLUSIONS

The conclusions drawn from the present study are:

- Diluted SDF seems to be an effective IPT agent for primary teeth with an overall success rate of 96% at the end of 12 months.
- Light-cured calcium hydroxide was also an effective IPT agent for primary teeth with an overall success rate of 91.67% at the end of 12 months.
- In comparison, diluted SDF was more effective than light-cured calcium hydroxide, but the difference was not statistically significant.

REFERENCES

1. Fuks AB, Peterz B. Pediatric endodontics, current concepts in pulp therapy for primary and young permanent teeth. Israel: Springer;2016.p-44.
2. Rahman B, Goswami M. Comparative evaluation of indirect pulp therapy in young permanent teeth using biodentine and theracal: a randomized clinical trial. J Clin Pediatr Dent. 2021;45(3):158-164.
3. Mohammadi Z, Dummer PM. Properties and applications of calcium hydroxide in endodontics and dental traumatology. Int Endod J. 2011; 44(8):697-730
4. Chaudhari WA, Jain RJ, Jadhav SK, Hegde VS, Dixit MV. Calcium ion release from four different light cured calcium hydroxide cements. Endodontol. 2016;28(2):114-118.
5. Fitzgerald M. Cellular mechanics of dentinal bridge repair using 3H-thymidine. J Dent Res. 1979; 58(D):2198-2206.
6. Accorinte ML, Loguercio AD, Reis A, Carneiro E, Grande RH, Murata SS et al. Response of human dental pulp capped with MTA and calcium hydroxide powder. Oper Dent. 2008;33(5):488495.
7. Mathur VP, Dhillon JK, Logani A, Kalra G. Evaluation of indirect pulp capping using three different materials: A randomized control trial using cone-beam computed tomography. Indian J Dent Res. 2016;27(6):623-629.
8. Sangwan P, Sangwan A, Duhan J, Rohilla A. Tertiary dentinogenesis with calcium hydroxide: A review of proposed mechanisms. Int Endod J. 2013;46(1):319.
9. Metalita M, Tedjoasongko U, Nuraini P. Indirect pulp caping in primary molars using glass ionomer cements. Dent J. 2014; 47(4): 190-193.
10. Modena KCS, Casasapayco LC, Atta MT, Costa CAS, Hebling J, Sipert RR et al. Cytotoxicity and biocompatibility of direct and indirect pulp capping material. J Appl Oral Sci. 2009:17(6):544-554.
11. Crystal YO, Niederman R. Evidence-Based Dentistry Update on Silver Diamine Fluoride. Dent Clin North Am. 2019;63(1):45-68.
12. Gupta A, Sinha N, Logani A, Shah N. An ex vivo study to evaluate the remineralizing and antimicrobial efficacy of silver diamine fluoride and glass ionomer cement type VII for their proposed use as indirect pulp capping materials – Part I. J Conserv Dent. 2011;14(2):113-116.
13. Seto J, Horst JA, Parkinson DY, Frachella JC, DeRisi JL. Silver microwires from treating tooth decay with silver diamine fluoride. bioRxiv. 2017. doi: 10.1101/152199.
14. Shah S, Bhaskar V, Venkatraghavan K, Choudhary P, Ganesh M, Trivedi K. Silver diamine fluoride: a review and current applications. J Adv Oral Res. 2014; 5(1): 25–35.
15. Yamaga R. Diamine silver fluoride and its clinical application. J Osaka Univ Dent Sch.1972; 12(1):1-20.
16. Mei ML, Lo ECM, Chu CH. Arresting dentine caries with silver diamine fluoride. J Dent Res. 2018;97(7):751-758.
17. Sulyanto RM, Kang M, Srirangapatanam S, Berger M, Candamo F, Wang Y et al. Biomineralization of dental tissues treated with silver diamine fluoride. J Dent Res 2021; 100(10):1099–1108.
18. Sinha N, Gupta A, Logani A, Shah N. Remineralizing efficacy of silver diamine fluoride and glass ionomer type VII for their proposed use as indirect pulp capping materials – Part II (A clinical study). J Conserv Dent. 2011; 14(3): 233–236.
19. Tedequim.com. Instruction for use [Internet]. Cordoba Argentina: MiryamDellaVedova. [cited 2021October 17].Available from: http://www.tedequim.com/wp-content/uploads/Instrucciones-FAgamin.pdf.
20. Korwar A, Sharma S, Logani A, Shah N. Pulp response to high fluoride releasing glass ionomer, silver diamine fluoride, and calcium hydroxide used for indirect pulp treatment: an in vivo comparative study. Contemp Clin Dent. 2015; 6(3):288-292.
21. Patil D, Katge F, Jain K, Poojari M, Chimata VK. Comparative evaluation of clinical and radiographic outcomes of indirect pulp treatment with silver diamine fluoride versus calcium hydroxide in primary teeth: a randomized controlled trial. Int J Sci Health Care Res. 2021;6(2):150-155.
22. Divyashree R. Effectiveness of Silver Diamine Fluoride when used as an indirect pulp therapy (IPT) material- A clinical and radiological assessment. Int J Appl Dent Sci. 2021; 7(2): 466-478.
23. Ingle JI, Bakland LK. Endodontics. 5th ed. London: Elsevier Pub; 2002. p 864-868.
24. Farooq NS, Coll JA, Kuwabara A, Shelton P. Success rate of formocresol pulpotomy and indirect pulp therapy in the treatment of deep dentinal caries in primary teeth. Pediatr Dent. 2000; 22(4):278-285.
25. Falster CA, Araujo FB, Straffon LH, Nor JE. Indirect pulp treatment: in vivo outcomes of an adhesive resin system vs calcium hydroxide for protection of the dentin-pulp complex. Pediatr Dent. 2002; 24(3):241-248.