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Efficacy of Calcium Enriched Mixture Cement, Mineral Trioxide Aggregate and Calcium Hydroxide Used as Direct Pulp Capping Agents in Deep Carious Lesion- A Randomized Control Trial

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KEYWORDS
Calcium-Enriched Mixture Cementdental Caries, Mineral Trioxide Aggregate, Pulp Capping

Abstract

Objective- This randomised clinical trial's primary goal was to compare the effectiveness of direct pulp capping (DPC) of deep carious lesions with reversible pulpitis with Calcium Enriched Mixture (CEM) cement, Mineral Trioxide Aggregate (MTA), and Calcium Hydroxide (CH), and its secondary goal was to evaluate the overall effectiveness of DPC in carious exposures. **Methods:** This study comprised 150 individuals with profound carious lesions and a diagnosis of reversible pulpitis. Three groups of patients (n=50) were randomly assigned: Group C: CEM group, Group M: MTA group, and Group D: CH (Dycal) group. Based on positive vitality tests, the absence of clinical signs and symptoms, and PAI scores at 1, 3, and 6 months, patients' outcomes were evaluated as successful, and 18-month follow-up periods. **Results-** Group C had an overall success rate of 86.7%, Group M 77.3%, and Group D 57.9%. After direct pulp capping of deep carious lesions, the total success rate of this trial was 74.8%. Groups C and D showed a statistically significant PAI score difference. **Conclusion:** In teeth with reversible pulpitis, CEM cement was more effective than CH and MTA at preserving pulpal vitality after DPC. DPC could produce positive therapeutic outcomes in deep carious lesions with reversible pulpitis, according to its overall success rate of 74.8%.

Introduction

The goal of vital pulp therapy (VPT) is to keep the dentine-pulp complex healthy and functioning. This prevents the removal of too much hard tissue, which would weaken the tooth, and preserves the pulp tissue, retaining its physiological and protective roles (1). The American Association of Paediatric Dentistry states that teeth with short-term pain that is relieved by analgesics or brushing, but that do not exhibit signs or symptoms of irreversible pulpitis, have reversible pulpitis and are candidates for VPT (2). To preserve the vitality and health of the exposed tooth pulp, a treatment known as direct pulp capping is performed (3). There are debates in the literature on DPC of carious pulpal exposures (4, 5). Nevertheless, numerous recent investigations (6–8) have shown that VPT is effective in carious exposures utilising more modern biomaterials. For essential permanent teeth with pulp exposed to caries, overall success rates for VPT have been reported to range from 72.9 to 99.4% (9). When calcium hydroxide (CH) is employed for pulp capping, studies have shown a decline in success rates (10, 11). Mineral trioxide aggregate (MTA), despite being a promising bioactive material, is expensive, has challenging handling qualities, takes a long time to set, and may stain teeth (15). Calcium-enriched mixture (CEM), a recently introduced bioactive substance, is said to have the required setting time, handling features, chemical properties, colour, and sealing ability (16). Major ingredients in CEM cement powder include 51.75 percent calcium oxide, 9.53 percent sulphite, 8.49 percent phosphorous-pentoxide, and 6.3 percent silica. Minor ingredients include aluminium oxide, sodium oxide, magnesium oxide, and chlorides, which when combined with a water-base solution produce a bioactive calcium- and phosphate-enriched material. CEM can generate hydroxyapatite over the material in ordinary saline solution and has a setting time of less than an hour, greater flow, and a thinner film than MTA (13, 17).

The effectiveness of CEM for DPC of deep carious lesions in adult permanent teeth with reversible pulpitis was not assessed in any randomised clinical trials that we could identify. Our major goal was to test CEM's effectiveness in sustaining pulp vitality when utilised for DPC in deep carious lesions with reversible pulpitis in comparison to MTA and CH, and our secondary goal was

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to evaluate DPC's general effectiveness in carious infections.

Methodology

The Peoples College of Dental Sciences and Research Centre in Bhopal, which houses the Department of Paediatric and Preventive Dentistry, conducted this study. The institutional ethics committee evaluated, approved, and registered the study protocol with the ISRCTN registry. Patients received verbal and written informed permission after being told of the study's specifics. The Declaration of Helsinki was followed in conducting the study (18). In total, 150 patients (Fig. 1) who had severe caries lesions with mature permanent teeth and were clinically diagnosed with reversible pulpitis were included in the study. All of the patients ranged in age from 14 to 60 and were devoid of any systemic illnesses. There was no prior history of the carious tooth experiencing either spontaneous pain or pain on percussion (POP).All the selected teeth showed a positive response to the cold test and electric pulp test (EPT) and a periapical index score (PAI) of one (19, 20).

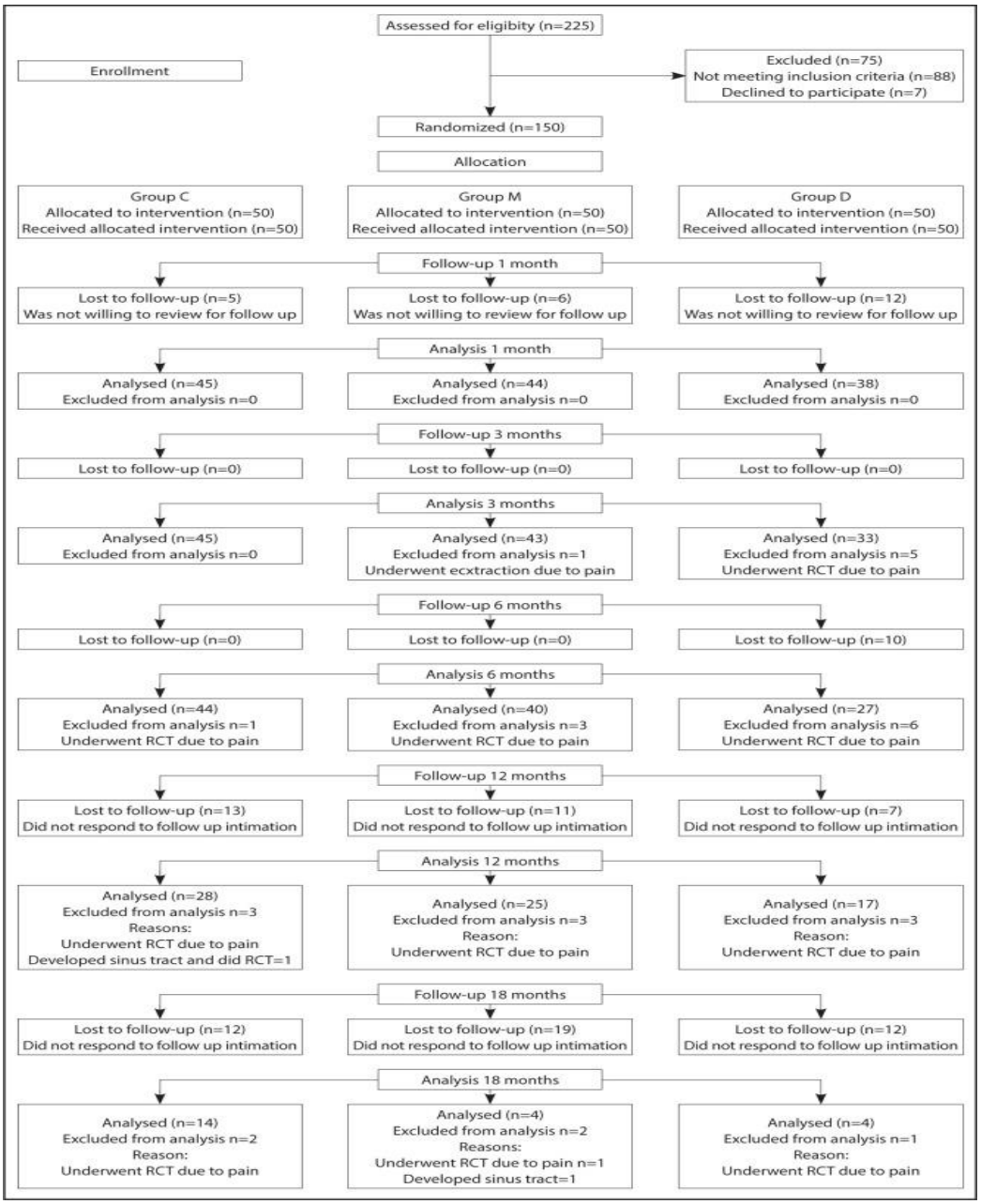

Figure 1-CONSORT flow diagram Group C: Calcium enriched mixture Group, Group M: Mineral trioxide aggregate group, Group D: Dycal group, RCT: root canal treatment

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Teeth subjected to traumatic occlusion, non-carious destructions, developmental defects, mobility, clinical or radiographic evidence of pulp degeneration, symptoms of irreversible pulpitis, profuse haemorrhage from exposure site >5 minutes, presence of serous or purulent exudates from exposure site and pregnant patients were excluded.

A related study (21) found that 60% of CH and 78% of MTA had favourable DPC outcomes. For the sake of this study's sample size calculation, these were used as p1 and p2, respectively. The entire sample was split into three groups: Group C (Experimental Group), Group M (Control Group), and Group D (Control Group), where DPC was carried out using CEM (Bionique Dent Tehran, Iran), white MTA (Proroot, Dentsply, Johnson City, USA), and CH (Dycal, Dentsply, Johnson City, USA), correspondingly. A total of 36 patients were divided among the two groups. However, the sample size was rounded off to 50 in each group to account for any dropouts. Using a straightforward lot procedure, each group was assigned at random to all patients. The individual's information sheet had the patient's demographic information, chief complaint, medical-dental history, findings from the baseline and follow-up exams, and scores were given for the clinical and radiographic categories.

Figure 2-Preoperative view after peripheral caries removal

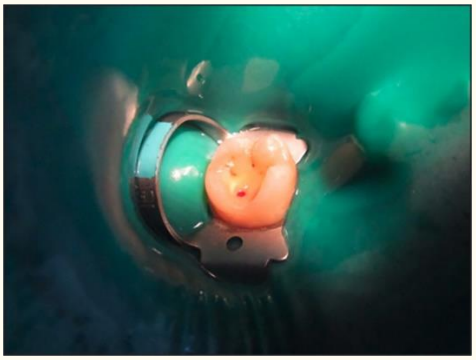

Figure 3-Pulp exposure site after complete caries removal

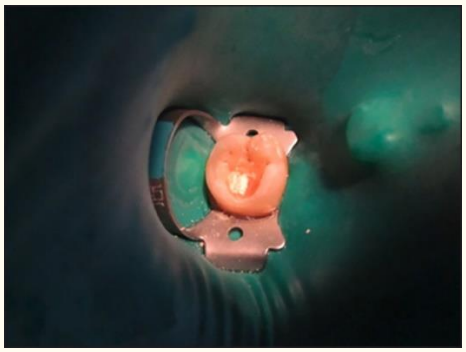

Figure 4-Direct pulp capping agent applied to the exposure site

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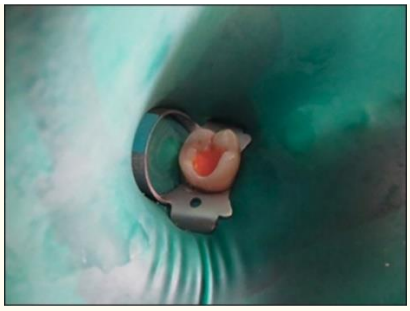

Figure 5-Capping agent covered with Glass ionomer liner

Figure 6-Immediate Restoration with direct composite resin

Following surgery, evaluations were conducted at 1, 3, 6, and 18 months (Fig. 7a–e), and results were recorded on the patient information sheet. Success criteria were a positive vitality test response, the lack of clinical complaints, and PAI 1. Whenever follow-up exams reveal any of the following: PAI score > 1, POP, negative vitality test results, sinus tract, mobility, RCT, or extraction of the pulp-capped tooth, the outcome is said to have failed.

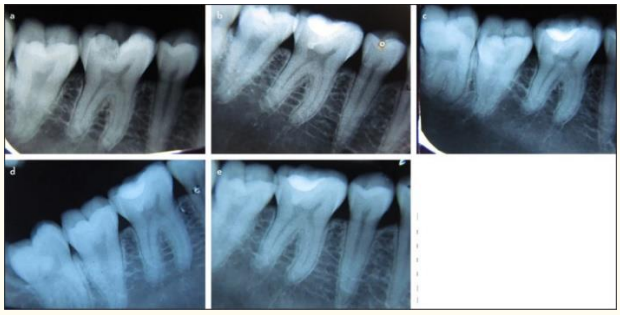

Figure 7-(a) Preoperative radiograph. (b) 1 month follow-up after DPC with CEM. (c) 6 months follow-up after DPC with CEM. (d) 12 months follow-up after DPC with CEM. (e) 18 months review after DPC with CEM

Statistical Analysis

The ANOVA test is used since the goal is to compare the effectiveness of three different treatments for deep pulpal caries by evaluating the quantitative PAI scores. To ascertain the experiment-wise error rate, an ANOVA is used as a post hoc approach, followed by a Bonferroni test. Qualitative factors that also affect the overall success rate include "pain on percussion" and "response to vitality tests.

Results

127 patients were used in the final analysis and interpretation (Fig. 1). In this study, there were 79 female participants and 48 male participants. A p-value of 0.374 was found in the chi-square test of the sex distribution across the three groups, which was not statistically significant ($p>0.05$). Group C had a mean age of 29.00, Group M of 28.61, and Group D of 30.53. The p-value for the ANOVA test was 0.728, which was statistically unimportant (p 0.05). Only at the 1-month follow-up (Table 1), when four patients in Group D had severe POP, was a difference in POP observed that was statistically significant.

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TABLE 1-Comparison of pain on percussion and response to vitality tests at different follow-up periods among the groups using the chi-square test. (Number of cases and percentages)

Pain on percussion	**Group C: CEM**		**Group M: MTA**		**Group D: Dycal**		**p**	**Response to vitality tests**	**Group C: CEM**	**Group M: MTA**	**Group D: Dycal**	**p**
	n	**%**	**n**	**%**	**n**	**%**			**n**	**n**	**n**	
1 month												
Mild	0	0	0	0	1	2.6	0.029*	Negative	0	1	5	0.012*
Moderate	0	0	1	2.3	0	0		Positive	45	43	33	
Severe	0	0	0	0	4	10.5						
3 months												
Mild	1	2.2	1	2.3	1	3	0.212	Negative	1	3	6	0.038*
Moderate	0	0	1	2.3	3	9.1		Positive	44	40	27	
Severe	0	0	1	2.3	2	6.1						
6 months												
Mild	0	0	0	0	1	3.7	0.481	Negative	2	4	3	0.530
Moderate	2	4.5	1	2.5	1	3.7		Positive	42	36	24	
Severe	0	0	2	5	1	3.7						

TABLE 2-Comparison of Periapical index score among the three groups using ANOVA followed by Bonferroni *Post hoc*

Periapical index score	**Groups**	**N**	**Mean**	**SD**	**P**	**Between the2 groups**	**p**
1 month	CEM	45	1.00	0.000	0.015*	C-M	1.000
	MTA	44	1.02	0.151		C-D	0.022*
	Dycal	38	1.21	0.622		M-D	0.052
3 months	CEM	45	1.02	0.149	0.058	C-M	p-values are not relevant as no statistically significant difference was obtained between the three groups
	MTA	43	1.14	0.639		C-D	
	Dycal	33	1.33	0.777		M-D	
6 months	CEM	44	1.05	0.211	0.393	C-M	p-values are not relevant as no statistically significant difference was obtained between the three groups
	MTA	40	1.15	0.483		C-D	
	Dycal	27	1.15	0.456		M-D	
12 months	CEM	28	1.11	0.416	0.946	C-M	p-values are not relevant as no statistically significant difference was obtained between the 3 groups
	MTA	25	1.16	0.800		C-D	
	Dycal	17	1.12	0.485		M-D	
18 months	CEM	14	1.21	0.802	0.661	C-M	

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	MTA	4	1.00	0.000		C-D	p-values are not relevant as no statistically significant difference was obtained between the three groups
	Dycal	4	1.50	1.000		M-D	

*: p<0.05 statistically significant. ANOVA: Analysis of variance, CEM: Calcium enriched mixture, MTA: Mineral trioxide aggregate, SD: Standard deviation

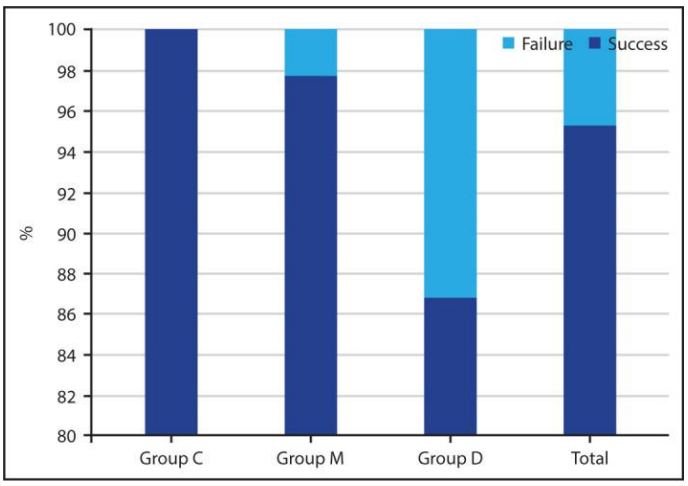

Figure 8-Success versus failure at one month, p=0.012<0.05=Statistically significant

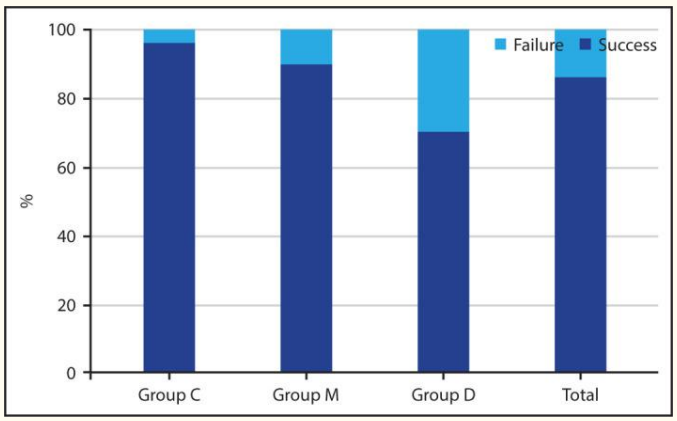

Figure 9-Success versus failure at three months, p=0.001<0.05=Statistically significant

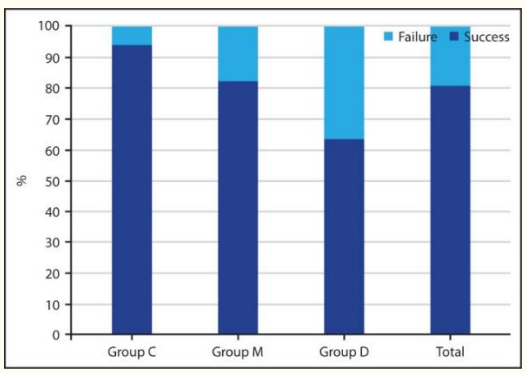

Figure 10-Success versus failure at six months , p=0.003<0.05=Statistically significant

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TABLE 3-Intergroup comparison of overall success versus failure

Compared group	Comparing groups	p
Group C	Group M	0.72
	Group D	0.01*
Group M	Group C	0.72
	Group D	0.18
Group D	Group C	0.01*
	Group M	0.18

Discussion

The results of the research demonstrate the effectiveness and superiority of calcium-enriched bio-mixtures in the treatment of deep pulpal caries. The lack of an accurate technique to measure the advancement of inflammation to the pulp makes it difficult to assess the pulpal condition. The pulpal condition is a critical factor in deciding whether vital pulp therapy is successful or not (9). At 18 months, this group's overall success rate was 86.7%, which was much greater than that of other groups. The 18-month follow-up was selected because it is the best period to identify direct pulp capping operations that have failed (24). The evaluation period is still up for debate. According to a study by Matsuo et al. (25) three months were enough time to assess the success of vital pulpal therapy, as the success rates at three and eighteen months were similar. In our investigation, the success rate gradually decreased from 1 to 18 months of follow-up. This can be explained by the follow-up loss we experienced in our study at the 3, 6, and 12 month follow-up periods. Pre-existing clinical results had no impact on the treatment's success rate, according to the literature (25). The efficacy of vital pulpal therapy is thus dependent on the type of capping material (26). Materials for direct pulp capping ought to be able to prevent bacterial growth, provide a good seal, and promote mineralization and root growth (27). Calcium hydroxide and mineral trioxide aggregate (MTA) were often used materials (27). Due of the exceptional characteristics of the compound, CEM, an endodontic cement made of calcium compounds, has just been released.

Conclusion

Following DPC, CEM cement is just as effective as MTA at preserving pulpal vitality. Compared to CEM and MTA, CH has the lowest efficacy in preserving pulpal vitality. When follow-up time was extended after DPC of deep carious lesions, the capacity to sustain pulpal vitality decreased noticeably for the CH group compared to the CEM and MTA groups. The overall efficacy rate of 74.8% shows that DPC in risky exposures might produce beneficial results.

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