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Original Article

Comparison Of the Post-Operative Pain and Vitality Status of Direct Pulp Capping Using Calcium Hydroxide and Biodentine in Deep Carious Permanent Teeth

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ABSTRACT

Objective: To compare the postoperative pain and symptoms after direct pulp capping with Calcium Hydroxide and Biodentine in a deep carious permanent tooth.

Study Design: Prospective Comparative Study.

Place and Duration of Study: Operative Department, Armed Forces Institute of Dentistry, Rawalpindi Pakistan, from Oct 2019 to Mar 2020.

Methodology: Patients presenting to the OPD were considered for the study using randomized consecutive sampling. Patients ranging between 18 and 30 years, diagnosed with symptoms of reversible pulpitis, were divided into 2 groups, each with 31 participants. Group-A was given Calcium Hydroxide, while Group-B was administered Biodentine. Post-operative evaluation of pain was done after 24 hours, 3 days, and 7 days by visual analog scale, and the success rate was evaluated at 1 month, 3 months, and 6 months.

Results: A total of 62 patients (31 in each group) were enrolled in this study. The mean age of the patients was 20.4±4.9 and 20.0±4.1 years. Calcium Hydroxide Group had 18 males (58.0%), and Biodentine Group had 20(64.5%). Similarly, in Calcium Hydroxide group, there were 13 females (42.0%), and in Biodentine Group, 11 females (35.5%). Comparison of visual analogue score between two groups, Calcium Hydroxide (Group-A) and Biodentine(Group-B) demonstrated as follows: on the first postoperative day, Calcium Hydroxide group revealed 18 patients (58.1%) had mild pain score (3-5), 12 patients (38.7%) reported moderate pain (6-8) and 1 patient (3.2%) had severe pain (9-10). In Biodentine group, on the 1st post-operative day, 15 patients (48.4%) presented with no pain (0-2) while 16 patients (51.6%) reported a complaint of mild pain (3-5). The difference between the two groups on 1st postoperative day was statistically significant (p<0.001). On the 3rd postoperative day, Calcium Hydroxide group showed 10 patients (32.3%) reported no pain (0-2), while 21 patients (67.7%) reported mild pain (3-5). In Biodentine group, 31 patients (100%) reported no pain (0-2) (p<0.001). On 7th postoperative day, in Calcium Hydroxide group, 23 patients (74.2%) demonstrated no pain (0-2) while 8 patients (25.8%) had mild pain (3-5). In the Biodentine group, 31 patients (100%) reported no pain (0-2) (p<0.001). Stratification with regard to age and gender was also carried out, and no association was found with pain score (p>0.005).

Conclusion: Biodentine results in less post-operative pain as compared to Calcium Hydroxide as a direct pulp capping agent.

Keywords: Biodentine, Calcium Hydroxide, Direct Pulp Cap, Permanent Molar, Reversible Pulpitis.

How to Cite This Article: *Shah PJA, Rana MJA, Baig NJ, Akhtar F, Aslam M, Wahid M. Comparison of the Post-Operative Pain and Vitality Status of Direct Pulp Capping Using Calcium Hydroxide and Biodentine in Deep Carious Permanent Teeth. Pak Armed Forces Med J 2026; 76(Suppl-5): S723-S728. DOI: https://doi.org/10.51253/pafmj.v76iSUPPL-5.6813*

INTRODUCTION

Caries is the localized, acidic, pathological tooth destruction of dental hard tissue as a byproduct of bacterial fermentation of dietary carbohydrates.[1] Clinical management of an infective deep carious lesion can be done either by preserving the vitality of pulp tissue (vital pulp therapy) or by performing root canal treatment.[2] Direct pulp capping is the procedure in which a dental material or dressing is placed directly over the exposed pulp (either by trauma or by mechanical instrumentation) to preserve its vitality.[3] The material should be biocompatible and produce anti-inflammatory effects on the pulpal tissue. The material should induce stem cell differentiation to form tertiary dentine. The rationale of direct pulp capping is to promote pulp self-healing and form a protective Dentine calcified barrier.[4]

Vital pulp therapy helps in regulating the normal pulp cell function in teeth in which pulpal exposure has occurred. Vital pulp therapy includes direct pulp capping and pulpotomy for the preservation of pulpal tissues and to ensure continuous growth of the roots.[5] Some of the new materials for direct pulp capping are Calcium Hydroxide, Zinc Oxide Eugenol Cement, Polycarboxylate Cement, Corticosteroid, Inert Materials (Isobutyl Cyanoacrylate and Tricalcium

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Received: 31 May 2021; revision received: 26 Mar 2023; accepted: 27 Mar 2023

Phosphate Ceramic), Bonding Agents, and Glass Ionomer Cement. Mineral trioxide aggregate (MTA), Biodentine, Stem Cells, and Propolis are novel endodontic cements.[6]

Calcium Hydroxide has been considered the gold standard medication for vital pulp therapy. Calcium Hydroxide is basic in nature and has antibacterial and bioactive properties. It causes pulp repair and dentin remineralization. The material loses its antibacterial property by neutralization of tissue fluid before its action on the activity of the bacterial cell due to a decrease in its acidic pH. In response to Calcium Hydroxide, bacterial by-products can readily penetrate the newly formed hard-tissue bridge and can cause serious pulpal damage.[7]

Biodentine, a new Tricalcium silicate-based material. It can be used for deep tooth decay, restoration of deep cervical and root carious lesions, as a root perforation repair, and a root-end filling material with good mechanical and excellent bioactive properties. Biodentine has several advantages over MTA, such as a short setting time of 12 minutes and no tooth discoloration.[8,9] In a study by Brizuela *et al.*, the response of MTA, Biodentine, and Calcium Hydroxide as a direct pulp capping agent was compared, and concluded that calcium silicate-based materials are better than Calcium Hydroxide as a pulp capping agent.[10]

There are a limited number of studies available to evaluate the outcome of Biodentine and Calcium Hydroxide as a direct pulp capping agent. The purpose of this study is to compare the post-operative pain and symptoms of using Calcium Hydroxide and Biodentine material as direct pulp capping materials in deep carious permanent teeth.

METHODOLOGY

The Prospective comparative study was conducted at Operative Department of the Armed Forces Institute of Dentistry, Rawalpindi Pakistan, from Oct 2019 to Mar 2020 after obtaining approval from the ethical committee(905/Trg-ABP1K2). Sample size calculation was done using an OpenEpi calculator. The confidence interval was kept at 95%, and the ratio exposed to unexposed was 1:1. The values 2.3% and 6.7% were incorporated into the risk/prevalence ratio and risk prevalence difference of the population under study,[10] the sample size came out to be 62. Two groups were made, Group-A (Calcium Hydroxide group) and Group-B (Biodentine group), comprising 31 patients each.

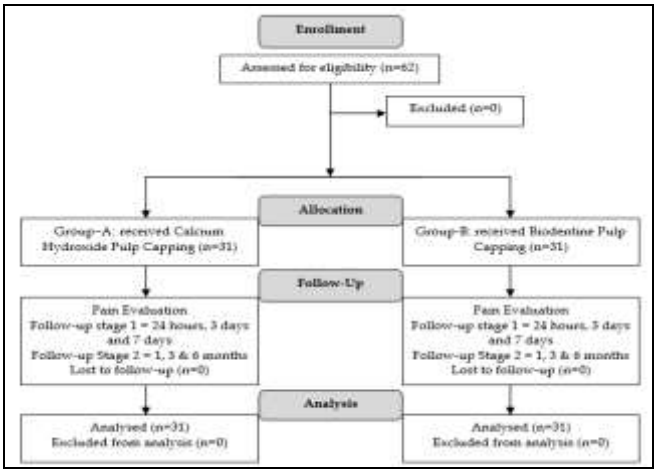

Figure: Patient Flow Diagram

The patients were divided into two experimental groups by randomized consecutive sampling. For Group-A, the pulp capping material used was $Ca(OH)_2$ (Dycal), in Group-B Biodentine was applied as a pulp capping material

Inclusion Criteria: Patients of either gender, from 10 to 30 years of age with closed apices of roots; carious lesions extending to half the thickness of dentine radiographically; no pain on biting; sensitivity to cold lasting for less than 5 seconds; no associated swelling; no pus discharge; and no abnormal mobility were included in the study.

Clinical diagnosis of reversible pulpitis was made on the reaction to the cold test by Ethyl Chloride spray. Radiographic inclusion criteria consist of the presence of caries without the involvement of pulp chamber; no furcation involvement; absence of root resorption and calcification/or pulp canal obliteration.

Exclusion Criteria: Patients with psychological illness, deciduous teeth, no pulp exposure after caries removal, teeth with irreversible pulpitis (spontaneous pain) or pulp necrosis, presence of periapical pathology, periodontal involvement, cracked tooth syndrome, internal or external resorption, or non-restorable tooth were excluded from the study.

The tooth was isolated by using a rubber dam. The cavity was prepared using sterile round diamond burs at high-speed underwater cooling. After gaining suitable access, caries was removed using a steel bur at a low speed to avoid pulp exposure. If required, a local anesthetic was administered. After caries removal, disinfection of the exposed pulp was done with 2.5% sodium hypochlorite. After achieving hemostasis, materials were applied according to the

instructions of the manufacturer. In the Calcium Hydroxide group, Calcium Hydroxide (Dycal) was placed according to the manufacturer's instructions and applied over the exposure site.

In Group-B, Biodentine was mixed according to the manufacturer's instructions and applied to the exposed pulp. It was placed as a pulp dressing and allowed to set for 12 minutes. A base of light-cure GIC was then applied over it. 37% phosphoric acid etchant was applied to the tooth for 30 seconds, and a one-bottle adhesive system, Prime and Bond, was applied for 15 seconds and then cured. Micro-filled Hybrid Composite Resin material was then added to the cavities and light-cured for 20 seconds. Using the paralleling technique, a periapical radiograph was taken immediately after the procedure to serve as a baseline for future follow-ups. The pre-operative pain and radiograph were used as the baseline for comparison with the post-operative pain and radiographs.

To measure the outcome of the procedure, postoperative pain intensity was recorded on the 1st, 3rd, and 7th days after treatment. On the 1st, 3rd, and 7th days after the procedure, patients were instructed to score their pain using the VAS. On the visual analog scale, patients were asked to rate pain intensity as no pain (0-2), mild (3-5), moderate (6-8), and severe (9-10). Patients were recalled after 24 hours to evaluate pulp vitality by assessing the pulp response to thermal, electrical, and tactile tests and by noting the presence or absence of any swelling. Patients were recalled after a week for clinical assessment.

Patient records were analyzed for clinical and radiographic recall data at intervals of 1, 3, and 6 months. The data comprising pain after treatment, cold test, radiographic signs of periapical pathology, and dentin bridge formation were assessed. A tooth that remained asymptomatic with the positive response to sensibility/cold tests and/or radiographic evidence of hard tissue bridge formation with no radiographic signs of periapical pathology and widening of the periodontal ligament space was considered successful treatment.

Data was analyzed by using Statistical Package for Social Sciences (SPSS) 22.00. Quantitative data was represented using mean ± standard deviation and qualitative data was represented by using percentage and frequency. Chi square test was applied and p-value of ≤ 0.05 was considered as statistically significant.

RESULTS

A total of 62 patients (31 in each group) were enrolled in this study. Group-A was given Calcium Hydroxide, while Group-B was administered Biodentine. Patients ranged between 14 and 30 years of age. The mean age of the patients was 20.4±4.9 and 20.0±4.1 years. It was noticed that Group-A had 18 males (58.0%) and 13 females (42.0%), while Group-B had 20 males (64.5%) and 11 females (35.5%). Males were predominant in both groups.

Table-I: Demographic Profile of the Patients (n=62)

Variables	Group-A (Calcium hydroxide)		Group-B (Biodentine)		*p*-value
	No.	%	No.	%	
Age (Year)					
14-25	25	80.6	27	87.12	0.490
26-30	06	19.4	04	12.9	
Total	31	100.0	31	100.0	
Mean±SD	20.4±4.9		20.0±4.1		
Gender					
Male	18	58.0	20	64.5	0.602
Female	13	42.0	11	35.5	
Total	31	100.0	31	100.0	

Table-II: Comparison of Visual Analogue Score (n=62)

Pain score	Group-A (Calcium hydroxide)		Group-B (Biodentine)		*p*-value
	No.	%	No.	%	
Pain on 1st postoperative day					
0-2	0	-	15	48.4	<0.001
3-5	18	58.1	16	51.6	
6-8	12	38.7	0	-	
9-10	01	03.2	0	-	
Total	31	100.0	31	100.0	
Pain on 3rd postoperative day					
0-2	10	32.3	31	100.0	<0.001
3-5	21	67.7	0		
6-8	0	-	0	-	
9-10	0	-	0	-	
Total	31	100.0	31	100.0	
Pain on 7th postoperative day					
0-2	23	74.2	31	100.0	0.002
3-5	08	25.8	0		
6-8	0	-	0	-	
9-10	0	-	0	-	
Total	31	100.0	31	100.0	

Comparison of visual analogue scores between two groups, Calcium Hydroxide (Group-A) and Biodentine (Group-B), is as follows: On the first postoperative day, Group-A showed that 18 patients (58.1%) had mild pain (3-5), 12 patients (38.7%) reported moderate pain (6-8), and 1 patient (3.2%) had severe pain (9-10). In Group-B, on the 1st postoperative day, 15 patients (48.4%) presented with no pain (0-2), while 16 patients (51.6%) reported mild pain (3-5). The difference between the two groups on the 1st postoperative day was statistically significant (p<0.001). On the 3rd postoperative day, Group-A

showed that 10 patients (32.3%) reported no pain (0-2), while 21 patients (67.7%) reported mild pain (3-5). In Group-B, 31 patients (100%) reported no pain (0-2) (p<0.001). On the 7th postoperative day, in Group-A, 3 patients (74.2%) demonstrated no pain (0-2), while 8 patients (25.8%) had mild pain (3-5). In Group-B 31 patients (100%) reported no pain (0-2) (p<0.001). Stratification with regard to age and gender was also carried out, and no association was found with pain score (p>0.005).

Table-III: Age-wise Stratification (n=62)

Pain score	Group-A (Calcium hydroxide)		Group-B (Biodentine)		*p*-value
	Age (Year)		Age (Year)		
	14-25	26-30	14-25	26-30	
Pain on 1st postoperative day					
0-2	0	0	13	2	0.068
3-5	12	6	14	2	
6-8	12	0	0	0	
9-10	01	0	0	0	
Total	25	6	27	04	
Pain on 3rd postoperative day					
0-2	08	2	27	4	0.950
3-5	17	4	0	0	
6-8	0	0	0	0	
9-10	0	0	0	0	
Total	25	6	27	100.0	
Pain on 7th postoperative day					
0-2	18	5	27	4	0.569
3-5	7	1	0	0	
6-8	0	0	0	0	
9-10	0	0	0	0	
Total	25	6	27	4	

Table-IV: Gender-wise Stratification (n=62)

Pain score	Group-A (Calcium hydroxide)		Group-B (Biodentine)		*p*-value
	Gender		Gender		
	Male	Female	Male	Female	
Pain on 1st postoperative day					
0-2	0	0	10	5	0.324
3-5	12	6	10	6	
6-8	06	6	0	0	
9-10	0	1	0	0	
Total	18	13	20	11	
Pain on 3rd postoperative day					
0-2	8	02	20	11	0.088
3-5	10	11	0	0	
6-8	0	0	0	0	
9-10	0	0	0	0	
Total	18	13	20	11	
Pain on 7th postoperative day					
0-2	14	9	20	11	0.592
3-5	4	4	0	0	
6-8	0	0	0	0	
9-10	0	0	0	0	
Total	18	13	20	11	

DISCUSSION

The findings of the study have signified that Direct Pulp Capping with Biodentine demonstrated a higher clinical and radiographic success rate compared to Calcium Hydroxide. The post-operative pain of a patient with Biodentine pulp capping subsided within 48 hours. On the 7th postoperative day, no pain was reported in patients treated with Biodentine. Hence, it signifies that Teeth treated with Biodentine showed superior dentin bridge formation with better quality and fewer tunnel defects. Post-operative sensitivity and pulp inflammation were reduced, and above all, Biodentine exhibited improved sealing ability and biocompatibility, contributing to enhanced pulp healing.

Vital pulp therapy is one of the most critical treatment options to cover the exposed pulp and to ensure the continuous growth and proliferation of pulpal tissues. Since the 19th-century Calcium Hydroxide has been used to cover the pulpal tissue after exposure. It is available in various forms as Dycal, Pulpdent, and Hydrex solution, commonly.[11] A new variety of Calcium Hydroxide is also available nowadays, known as light cure Calcium Hydroxide (Prisma VLC Dycal), which is thought to induce dentinal bridge formation without the initiation of mummification of an external layer of the pulp.[12] The quality of dentinal bridge formation is crucial to the healing of the underlying pulpal tissues and is highly affected by the type of material used for pulp capping. In a study by Araújo *et al.*, it was suggested that the hard tissue substrate formed by MTA and Biodentine is far superior to that formed by Calcium Hydroxide.[13] Calcium hydroxide-containing pastes cause the superficial necrosis of pulpal tissues by hydroxyl ions, which lead to a low irritation reparative response by the pulpal tissues, leading to mesenchymal cells migration and formation of reparative tissue.[14]

One of the studies carried out by Jalan *et al.*, concluded that MTA, Biodentine, and Calcium Hydroxide three maintain the viability of pulpal tissue, but the stem cells of human exfoliated primary dentition (SHED) migrated towards MTA and Biodentine as compared to Calcium Hydroxide, leading to quicker tissue healing and reparative response.[15] Biodentine and a light-cure tricalcium silicate cement were compared for hydration properties and setting reaction by Caruso *et al.*, and concluded that normal set Biodentine converts into Calcium Hydroxide upon hydration, while the light-cure silicate cement (Theracal) has an unknown setting reaction, although with an increased release of calcium ions.[16]

Al-Subait *et al.,* in a study, concluded that pulp capping with Biodentine resulted in thicker dentine formation, which is also more continuous with less pulpal inflammation; these findings are consistent with our results, as Biodentine resulted in less post-operative pain and inflammation.[17] Fasoulas *et al.,* study concluded that Biodentine, when tested as a dentine replacement material as compared to glass ionomer and resin-modified cement, resulted in a loss of ions after etching with 37% phosphoric acid and an increase in leakage at the Biodentine and composite filling interface.[18] One of the studies conducted by Gomez *et al.,* in their study after pulpotomy of deciduous teeth using Calcium Hydroxide and Biodentine, concluded that the success of Calcium Hydroxide was 85.5% after 09 months while that of Biodentine was 94% after 09 months, which is consistent with the results of our study.[19]

Coll *et al.,* studied MTA and Biodentine as pulp capping materials, and results showed a 100% success rate in both groups with evidence of dentinal bridge formation at a 6 to 12-month period. These results are the same as the findings of our study, which showed 100% success rate in Biodentine Group-B.[20] Biodentine is an equally efficient replacement of MTA, and it leads to dentinal bridge formation of adequate thickness and with no leakage points, so Biodentine can be used safely as a direct pulp capping agent in many clinical scenarios.

In addition to the inherent limitations posed by the relatively small sample size and the single-center design, the study's scope was further constrained by the inclusion of teeth without specific classification or stratification. This lack of specification regarding tooth type may introduce variability that could affect the generalizability of the findings. Moreover, oral hygiene parameters, which are known to significantly influence pulp healing and dentin bridge formation, were not systematically assessed or controlled in the study.

Furthermore, future research should aim to address these gaps by conducting multicenter studies with larger, well-characterized patient populations. It would also be valuable to investigate the quality and longevity of dentin bridge formation in individuals with systemic comorbidities, such as diabetes or immunocompromising conditions, to better understand the long-term restorative capacity of these materials in diverse clinical scenarios.

CONCLUSION

Direct pulp capping with Biodentine demonstrates a higher success rate compared to calcium hydroxide in preserving pulp vitality. It promotes the formation of a more uniform and higher-quality dentin bridge with fewer structural defects. The material also reduces postoperative sensitivity and supports a more favorable pulpal healing response. Its superior sealing ability and biocompatibility contribute to improved clinical outcomes. Overall, Biodentine is a more reliable and predictable option for vital pulp therapy than calcium hydroxide.

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

PJAS & MJAR: Data acquisition, data analysis, critical review, approval of the final version to be published.

NJB & FA: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MA & MW: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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