

EVALUATION OF CALCIUM HYDROXIDE, TRIPLE ANTIBIOTIC PASTE, MINERAL TRIOXIDE AGGREGATE AND BIODENTINE AS PULP CAPPING AGENTS IN DEEP CARIOUS TEETH

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ABSTRACT

INTRODUCTION

Deep caries management (DCM) with a reliable biomaterial is considered an alternative to root canal treatment (RCT) provided the pulp is vital. Calcium hydroxide (CH) and mineral trioxide aggregate (MTA) are relatively more popular as pulp capping agents. Triple antibiotic paste (TAP) has been proposed for lesion sterilization and tissue repair (LSTR). Biodentine is relatively new biomaterial currently explored for vital pulp therapy.

MATERIAL AND METHODS

A total of 100 cases confirmed eligible for pulp capping were randomly assigned to either CH, TAP, MTA or biodentine group (25 teeth per group). The allocated pulp capping agent was applied followed by glass ionomer cement. Permanent restoration was done with composite at 3rd week. Clinical and radiographic evaluations were performed at 3 weeks, 3 months, 6 months and 1 year. Teeth presenting with severe pain or no response to pulp sensibility tests or demonstrating periapical changes in the radiograph were considered failures.

RESULTS

Biodentine and MTA had 22 (31.9%) successful cases each. CH had 13 (18.8%) successful cases and TAP had 12 (17.4%). There was statistically significant difference in the pain score between biodentine and CH, between biodentine and TAP at 6 months. There was statistically significant difference in the vitality of the teeth for the pulp capping materials at 3 weeks while no significant difference in the radiographic findings.

CONCLUSION

Biodentine and MTA showed better outcome than CH and TAP based on subjective symptoms, pulp sensibility tests and radiographic findings. Thus, Biodentine and MTA can be used as replacement for CH and TAP as pulp capping material.

KEYWORDS

Biodentine, Calcium hydroxide, MTA, Pulp capping, Triple antibiotic paste

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INTRODUCTION

DCM of adult permanent dentition is considered an ultraconservative treatment modality in contemporary endodontics.¹ DCM includes the application of a protective agent to an exposed pulp or retaining a thin layer of dentin over a nearly exposed pulp to allow the pulp to recover and maintain its normal status and function.² It should not be mandatory to perform RCT just because the caries is approximating the pulp or pulp exposure occurred during caries excavation. Besides, endodontically treated teeth have higher incidence of root fracture due to loss of proprioceptive function, damping property and tooth sensitivity.³ DCM is hence aimed to seal the pulpal wound to facilitate reparative dentin formation and maintenance of pulp vitality.⁴

CH is considered the gold standard for vital pulp therapy, but long-term study outcomes have been variable.⁵ It is reported to display antibacterial properties owing to its dissolution into calcium and hydroxyl ions.⁶ However, it has high solubility and produces tunnel defects in dentin bridge.⁷ According to Hosino et al, TAP contains 200 mg of ciprofloxacin, 500 mg of metronidazole and 100 mg of minocycline (3Mix) in the ratio 1:1:1 which is then added in macrogol (M) ointment and Propylene Glycol (P).^{8,9} Local application of TAP is expected to cause disinfection of bacteria in dentinal, pulpal and periapical lesion.^{10,11} MTA, composed of tricalcium silicate, dicalcium silicate, tricalcium aluminate and bismuth oxide is a bioactive cement with excellent sealing ability.¹² It activates the migration of progenitor cells from central pulp to the injury site and promote their proliferation and differentiation into odontoblast like cells thus stimulating reparative dentinogenesis.¹³ The shortcomings of MTA are difficult handling characteristics, long setting time and potential of discoloration. Biodentine introduced by Septodont in 2010 is specifically designed as a dentin replacement material.¹⁴ It is claimed to have predictable outcome as pulp capping agent as it causes early mineralization by releasing transforming growth factor (TGF- β 1) from human dental pulp cells thereby stimulating the formation of tertiary dentin.¹⁵

The pulp capping treatment has been refined by newly developed materials and protocols that are rapidly replacing long accepted treatment strategies. Therefore, this study intends to compare the outcomes of CH, TAP, MTA and biodentine.

MATERIAL AND METHODS

This in vivo longitudinal study was aimed to evaluate and compare the outcome of CH, TAP, MTA and Biodentine after DCM based on pain intensity, pulpal status and radiographic changes in the teeth. It was conducted with the approval of Institutional Review Committee (UCMS/IRC/197/18) in department of conservative dentistry and endodontics, Universal College of Medical Sciences, Bhairahawa, Nepal from October 2018 to August 2020. The study was conducted in accordance with the Declaration of Helsinki protocol and ethics. Written informed consent was obtained from each patient enrolled in the study. Informed consent of the participants for participation in the study and publication was according to the Institutional Review Committee which comes under National regulation of Nepal.

The sample size was calculated before patient recruitment using $n = z^2 pq / e^2$. Considering the total cases in the department of Conservative Dentistry and Endodontics per year was 6120 and total cases of deep caries management was 360, the prevalence of cases of deep caries management was calculated to be 0.06 from our previous hospital data records. Hence, the estimated sample size was approximately 86.67. Considering the 10% drop out rate, the sample size taken in this study was 100.

The inclusion criteria included patients in the age group 18-40 years with deep dentinal caries penetrating more than half the thickness or more into dentin in maxillary and mandibular molars and premolars, non-tender teeth on percussion showing positive response to thermal and electrical tests. The exclusion criteria included teeth exhibiting tenderness on percussion, no response on electric pulp test (EPT) and/or cold test, presence of any periapical radiolucency on radiographs, failure to control pulpal hemorrhage and immunocompromised patients.

Written informed consent was taken from each participant after the purpose and methodology was explained in full. Purposive sampling method was applied. Patients were screened for inclusion criteria by taking detailed history, thorough clinical examination, performing sensibility tests (cold tests by Endo Frost Spray (Coltene) and Electric Pulp Tester (Pac-Dent International, Inc.)) and evaluating the intraoral radiographs. Preoperative pain was recorded by the numeric pain rating scale (McCaffery M, Pasero C. 1999).¹⁶ The diagnosis indicating reversible pulpitis were recruited in the study. Randomization of the patients using concealed color-coded envelopes was done for allocation to each group of the pulp capping agent. The study was not operator blinded because of the different clinical consistency and appearance of the materials. A different investigator evaluated the clinical and radiographic parameters during the follow up to reduce bias.

A single operator performed the pulp capping procedure. Local anesthesia (2% lignocaine with adrenaline 1:200000 dilution) was administered. Rubber dam (GDC) isolation was done. Caries was removed using a high-speed round diamond bur followed by low-speed tungsten carbide bur with continuous water irrigation and a spoon excavator.¹⁷

The cavity was disinfected with 5% Sodium hypochlorite (Pyrex Exports) and predetermined pulp capping agent either CH (Septocalcine ultra) or TAP or MTA Angelus (Angelus Londrina, PR, Brazil) or Biodentine (Septodont) was applied to patient belonging to respective group followed by temporary restoration with GIC (Type II Restorative Sofu). In case of pulp exposure, a cotton pellet moistened with 5% sodium hypochlorite was placed over the exposure site followed by GIC restoration. Failure to stop bleeding or cases requiring more than ten minutes to control bleeding were excluded from the study.

At 3rd week, radiograph was taken followed by pain score and vitality test. The GIC restoration was reduced to base leaving 1-2 mm of free dentin and enamel. The permanent restoration was done using composite (Luna). Follow up was scheduled at 3 months, 6 months and 1 year where pain score was recorded, vitality was confirmed, and radiographs were evaluated.

A different investigator (post graduate student) evaluated the follow up visits to reduce the bias. It was verified by two investigators (endodontists). Any discrepancies were resolved by mutual consensus. Clinical examination was performed followed by sensibility tests (EPT and cold test) and radiographic assessment.

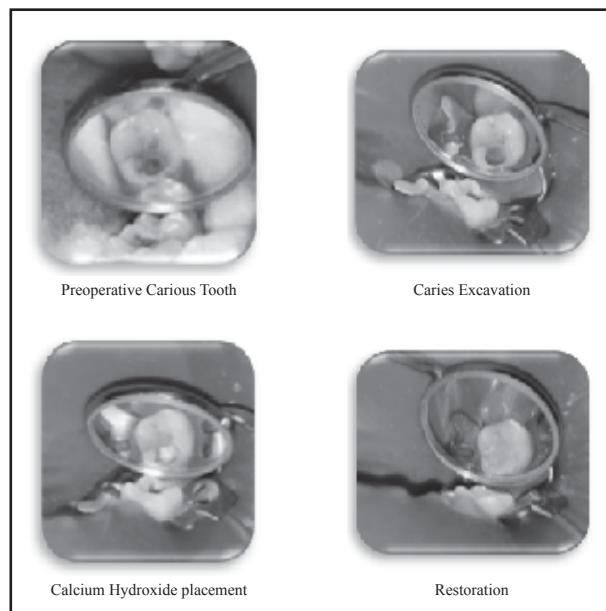


Figure 1. Clinical procedure of Calcium Hydroxide

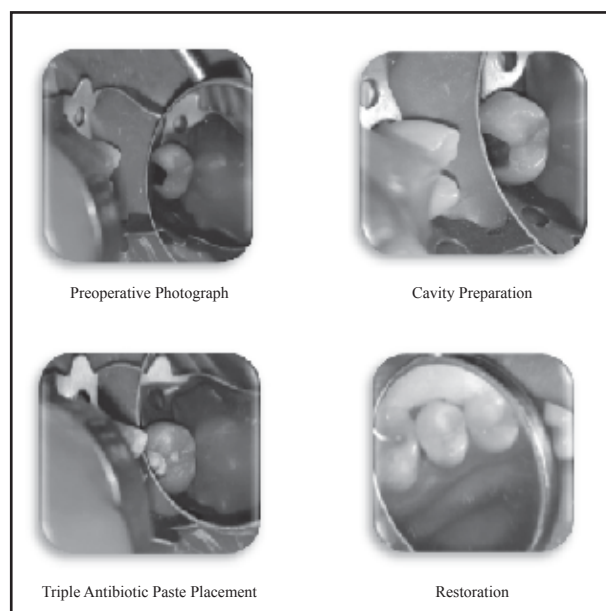


Figure 2. Clinical procedure of triple antibiotic paste

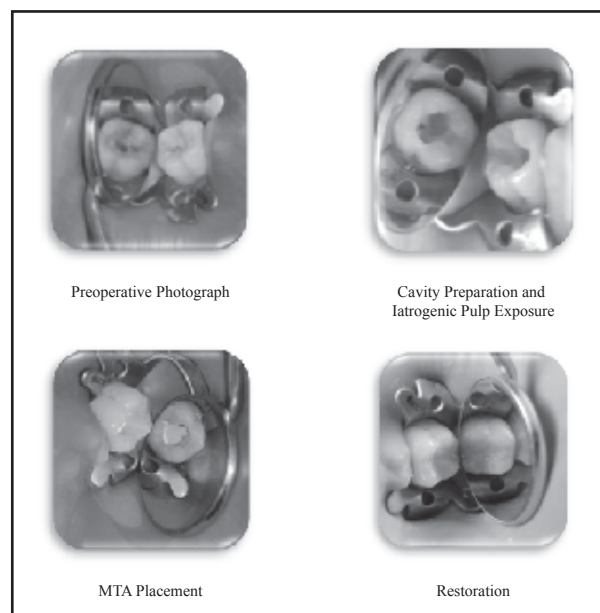


Figure 3. Clinical procedure of mineral trioxide aggregate (MTA)

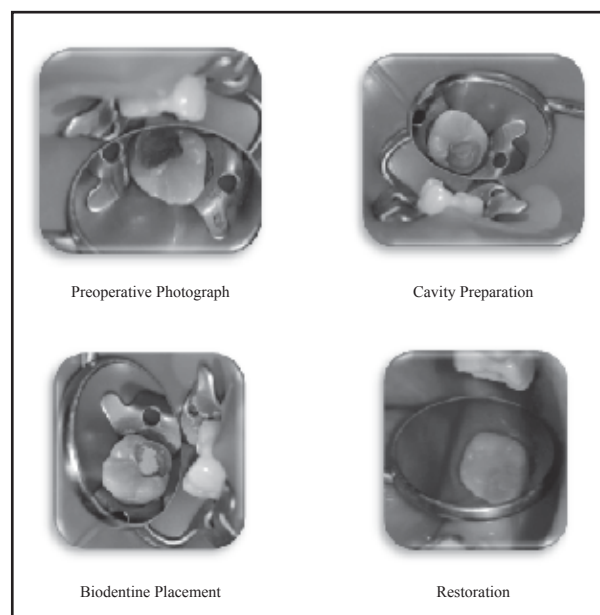


Figure 4. Clinical procedure of biodentine

Treatment was considered successful based on the presence of all the following features:

1. Absence of signs and symptoms of pulpal pathology
2. Lack of pain and tenderness on percussion
3. Absence of periapical rarefaction, internal or external resorption, root canal obliteration
4. Normal pulp vitality

Treatment was considered failure based on any one of the following features:

1. Severe pain (pain score 7 or more than 7 in the numeric rating scale)

- Non-vital pulp (no response on EPT and cold test)
- Periapical changes in the radiograph (widened PDL space, obliterated lamina dura or periapical radiolucency).

Kolmogorov-Smirnov test was done to determine the normality of the data, which was found to significantly deviated from a normal distribution (p value < 0.001). Thus, the rank of the pain in Numeric Rating Scale was analyzed using the nonparametric test; independent sample Kruskal Wallis Test followed by post hoc Bonferroni Correction. The vitality, radiographs and outcome of the pulp capping materials were analyzed with chi square test; p value < 0.05 with 95% confidence interval was considered statistically significant.

RESULTS

A total of 100 patients were included however 11 patients missed the follow up. Hence, 89 patients underwent statistical analysis.

Preoperatively, the median pain score was 3 each. However, it was 1 for CH and TAP while it was 0 for MTA and Biodentine at 3 weeks. The median pain score was 0 for pulp capping material at 3 months, 6 months and 1 year. Independent Kruskal Wallis test was applied to decide whether to retain or reject the null hypothesis based on p value of the pain score for CH, TAP, MTA and Biodentine preoperatively, at 3 weeks, at 3 months and 1 year (Table 1).

Table 1. Decision to retain or reject the null hypothesis based on the p value of the pain score preoperatively, at 3 weeks, at 3 months, at 6 months and 1 year for CH, TAP, MTA and Biodentine by Kruskal Wallis Test

Null Hypothesis	p -value	Decision
The distribution of P0 is same throughout the four groups of pulp capping agents	0.119	The null hypothesis is retained.
The distribution of P3W is same throughout the four group of pulp capping agents	0.001	The null hypothesis is rejected.
The distribution of P3M is same throughout the four group of pulp capping agents	0.013	The null hypothesis is rejected.
The distribution of P6M is same throughout the four group of pulp capping agents	0.021	The null hypothesis is rejected.
The distribution of P1Y is same throughout the four group of pulp capping agents	0.131	The null hypothesis is retained.

The distribution of pain score was similar preoperatively for the four group of pulp capping materials pertaining to non-significant p -value of 0.119. However, there was significant difference in the pain score for the pulp capping materials at 3 weeks (p value=0.001), 3 months (p value=0.013) and 6 months (p value=0.021). Thus, the null hypothesis that the distribution of pain score was similar for all the pulp capping materials is rejected at 3 weeks, 3 months and 6 months. At 1 year, the null hypothesis is retained as the p value was statistically non-significant (p value=0.131). Therefore, post-hoc Bonferroni correction analysis was done for the pain score at 3 weeks, 3 months and 6 months. On pairwise comparison of pain score of the pulp capping material, significant difference in pain score was found between Biodentine and CH (p value=0.011) and between Biodentine and TAP (p value=0.010) (Table 2).

Table 2. Pairwise comparison of pain score of the pulp capping material at 3 weeks

Material 1-Material 2	p -value
Biodentine-MTA	1.000
Biodentine-CH	0.011
Biodentine-TAP	0.010
MTA-CH	0.112
MTA-TAP	0.100
CH-TAP	1.000

At 3 months, there was not any significant finding. At 6 months, significant difference in pain score was found between Biodentine and Triple Antibiotic Paste (p value=0.030) (Table 3).

Table 3. Pairwise comparison of pain score of the pulp capping materials at 6 months

Material 1- Material 2	p -value
Biodentine- MTA	1.000
Biodentine-CH	0.491
Biodentine-TAP	0.030
MTA-CH	1.000
MTA-TAP	0.103
CH-TAP	1.000

There was significant difference in the vitality rates among the four pulp capping materials at 3 weeks (p value=0.044), no significant difference at 3 months (p value=0.163), at 6 months (p value=0.165) and at 1 year (p value=0.121) (Table 4).

Table 4. Comparison of vitality among four group of pulp capping materials preoperatively, at 3 weeks, at 3 months, at 6 months and 1 year

Vitality	Group	CH	TAP	MTA	Biodentine	p -value
Preoperative	Vital	22	22	23	22	
Vitality (V0)		(100%)	(100%)	(100%)	(100%)	
	Non-vital					
Vitality at 3 weeks (V3W)	Vital	18 (81.8%)	19 (86.4%)	23 (100%)	22 (100%)	0.004
	Non-vital	4 (18.2%)	3 (13.6%)	0 (0.0%)	0 (0.0%)	
Vitality at 3 months (V3M)	Vital	16 (88.9%)	17 (89.5%)	23 (100%)	22 (100%)	0.163
	Non-vital	2 (11.1%)	2 (10.5%)	0 (0.0%)	0 (0.0%)	
Vitality at 6 months (V6M)	Vital	14 (87.5%)	14 (82.4%)	22 (95.7%)	22 (100%)	0.165
	Non-vital	2 (12.5%)	3 (17.6%)	1 (4.3%)	0 (0.0%)	
Vitality at 1 year (V1Y)	Vital	13 (92.9%)	12 (85.7%)	22 (100%)	22 (100%)	0.121
	Non-vital	1 (7.1%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	

As teeth having no periapical changes were included in the study, the radiographs were normal at periapical region preoperatively. There was no significant change in the radiographs at the subsequent follow up visits.

On comparing the success and failure of the pulp capping materials, there was significant difference in the outcome of the different pulp capping agents (p value < 0.001) (Table 5).

Table 5. Comparison of outcome of Calcium Hydroxide, Triple Antibiotic Paste, MTA and Biodentine

Pulp Capping Materials	Outcome		p-value
	Success	Failure	
CH	13 (18.8%)	9 (45.0%)	0.000
TAP	12 (17.4%)	10 (50.0%)	
MTA	22 (31.9%)	1 (5.0%)	
Biodentine	22 (31.9%)	0 (0.0%)	
Total	69 (100%)	20 (100%)	

DISCUSSION

The primary aim of pulp capping materials is to induce specifically hard tissue formation by pulp cells that seal the exposure site and contributes to continued pulp vitality.¹⁸

There was a significant reduction in postoperative pain score when compared to preoperative pain score irrespective of the pulp capping material used. This is attributed to the fact that pulpal inflammation adjacent to carious lesion subsides after complete excavation of caries and placement of pulp capping material that subsequently harnesses the natural regenerative capacity of the pulp-dentin complex.¹⁹ However, there was significant difference in pain score of Biodentine and TAP (p value=0.010) and between Biodentine and CH (p value=0.011) at 3 weeks and Biodentine and TAP (p value=0.030) at 6 months. The cases presenting with severe pain could be due to the stimulation of affected dentin that produces pain, or it may occur because of pulp undergoing necrosis followed by apical periodontitis. Pain may also occur due to chemical composition of the materials.¹⁹ The result is in accordance with Baskaran et al¹⁷ and Sultan et al.²⁰ However, Kundzina et al²¹ reported slightly more pain in the MTA group compared with the CH group.

In our study, there was significant difference (p value=0.004) in the pulpal status of the teeth at 3 weeks. There was no significant difference in vitality status among pulp capping agents at 3 months, 6 months and 1 year. The pulp cells migrate to the site of injury within 2 weeks of medicament placement and reparative dentin bridge are formed by 3 weeks.¹⁹ MTA and Biodentine being bioactive and bioinductive have stimulating effect on pulp dentin complex regeneration by locally increasing TGF β -1 secretion from injured pulp tissue.^{15,17} Baskaran et al¹⁷ reported a similar result between Biodentine and MTA. Our result on pulpal status is quite contrary to the result by Awawdeh et al.²²

Kundzina et al²¹ compared the success of DPC using MTA and CH in mature permanent molars and presented a similar result to our study. The success rate was 93% for the MTA group and 69% for the CH group with a statistically significant difference ($p<0.05$). Both CH and MTA have an alkaline pH of 10 and 12 respectively, but the pH of CH drops promptly in approximation with dentin inhibiting its antimicrobial activity. CH tends to dissolve over time, but the byproducts formed during setting of MTA contribute to a sustained alkaline pH. The result of our study is in contrast with Awawdeh et al,²² who reported more successful cases with MTA (88.89%) and less with biodentine (81.48%). This might be because MTA which has longer setting time provides ion release for a longer time.

However, there are certain limitations to this study such as small sample size, shorter follow up period, lack of pulp vitality tests like Laser Doppler Flowmetry and no evaluation of the dentin bridge in radiographs.

CONCLUSION

Hence, it can be implied that DCM with CH, TAP, MTA and Biodentine is a reliable treatment. MTA and biodentine can be used as replacement for CH and TAP to overcome the drawbacks possessed by them as pulp capping agents.

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CONFLICT OF INTEREST

None

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