



Comparison of Clinical Success between Three Different Materials- Direct Pulp Capping of Carious Molars- An *In-vivo* Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To evaluate the clinical success of Calcium Hydroxide (CH), Mineral trioxide aggregate (MTA) and Biodentine as pulp capping materials for Direct pulp capping in carious molars.

Materials and Methods: Thirty-six molars of thirty-six patients with deep caries lesions, diagnosed with reversible pulpitis were subjected to direct pulp capping treatment. They were randomly divided into three groups, Biodentine (12 teeth) or MTA group (12 teeth) or CH group (12teeth). Simple randomization of three was employed to allocate the treatment materials. Patients were recalled at one, three and six months to evaluate the clinical success of the treatment outcome.

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Results: In clinical trial/study, the pulp capping materials gave different success rate, 91.67% success in the Biodentine group, 75% success in the MTA group and 41.67% success in Calcium Hydroxide group.

Conclusion: In our study the materials tested at 1 month, 3 month and 6-month follow-up, Calcium Silicate materials are better than calcium hydroxide and comparably Biodentine is better than MTA for Direct pulp capping.

Clinical Significance: The findings of this clinical trial could promote the reliability of pulp capping materials for treatment of deep carious lesions by conservative approach rather than opting endodontic management.

Keywords: Biodentine; direct pulp capping; MTA; Calcium hydroxide.

1. INTRODUCTION

The treatment widely practiced for exposed dental pulp is pulpectomy as healing of the pulpal tissue is unpredictable and unfavourable. Stanley in 1989 reported about the regeneration potential of dental pulp and positive approach towards exposed pulp than the traditional belief. For pulp exposure caused by dental caries, trauma or while preparing cavity, Direct Pulp Capping is advised and practiced to preserve the vital pulp tissue [1]. Deep carious lesions are treated with the aim of resolving inflammation and preserving the pulp vitality [2]. Many materials have been used for this type of therapy [3].

Direct pulp capping is defined as wound dressing of exposed vital pulp tissue. The exposure can occur due to caries excavation or trauma. Commonly exposed pulpal injuries are managed with pulp capping agent to heal the pulp dentin complex, initiate formation of reparative dentin and to preserve the vitality of pulp tissue.

The primary goal of direct pulp capping is to promote pulpal tissue healing [4-6]. Possible outcomes after several months following direct pulp capping are:

- Inflammation-free pulp tissue with a continuous deposition of reparative dentine.
- Chronic inflammation with infiltration in pulp mixed with presence of tunnel fissures and thin porous line of reparative dentin.
- Pulp tissue that is severely inflammatory and has a defective, insufficient, or lacking induction of reparative dentin or thick collagenous tissue scar over the injured pulpal zone.
- Pulpal necrosis with or without any symptoms.

The first outcome is considered as successful treatment due to the survival and regeneration of pulpal tissue encountered after damages by injury and irritants [7].

Several materials were used and are being used for pulp capping over several years but still there is debate over the ideal material for direct pulp capping. In search of a compatible and suitable has led to trials with a plethora of dental materials. Materials researched for pulp capping are calcium hydroxide (CH), calcium phosphate, zinc phosphate, zinc oxide, and polycarboxylate cement, calcium tetracycline chelate, antibiotics and growth factor mixture, emdogain, bioglass, cyanoacrylate, hydrophilic resins, calcium phosphate ceramics, hydroxyapatite, Glass ionomer cement and calcium silicate material based mineral trioxide aggregate (MTA) [8].

In 1920s, Herman introduced calcium hydroxide which made a significance in history of dental pulp therapy by illustrating with a mixture of calcium hydroxide induced bridge between the pulpal tissue and dentin [1]. Calcium hydroxide known to have antibacterial properties, which produce an environment that is more favourable for healing. Calcium hydroxide has been shown to hydrolyse bacterial lipopolysaccharide under conditions that are similar when used in root canal treatment. Thus detoxification of residual lipopolysaccharide may be one of the mechanisms whereby this agent exerts its beneficial effects in clinical endodontics [9]. Furthermore, it has also been suggested that the effectiveness of calcium hydroxide may be due to its high pH or the hydroxyl ions [10]. Although Ca (OH)₂ has been widely used as the material for pulp capping, many disadvantages are there, low adherence towards dentine, time dependant dissolution and manifold tunnel defects in the formed dentine bridge [11].

Mineral trioxide aggregate (MTA) is suggested to be a possible replacement for calcium hydroxide since the reparative dentin stimulation is better and formation of bridge is quicker, promoting pulpal wound healing and expressed better successful clinical outcome. Calcium silicate material based Mineral Trioxide Aggregate is biocompatible, bioactive with antibacterial properties that has outstanding sealing and stability properties [12]. Due to its prolonged setting time, inappropriate handling characteristics, higher price and possibility for discolouration, practitioners [13]. Slower setting and staining of dental tissues were seen in use of white Mineral Trioxide Aggregate, which was used to compensate for grey MTA's discoloration potential [14,15]. Nonetheless, when a two-visit treatment strategy was followed, MTA was proved as a predictable pulp capping material for pulp exposures [16].

Mineral Trioxide Aggregate is a good choice for direct pulp capping operations, arguing in opposition to the continued use of calcium hydroxide as the gold standard material for pulp capping treatment procedures. Mineral Trioxide Aggregate is the first calcium silicate material introduced and has a few disadvantages, longer setting time, handling difficulties and discolouration of teeth [17-19].

More calcium silicate-based materials have been introduced and in them Biodentine is a better calcium silicate material reported with better mechanical properties and good biocompatibility with bioactive behaviour [20,21]. Biodentine sets initially in twelve minutes and with no risk of tooth discolouration in future [22]. Since Biodentine is a recent material, research is needed for use as a suitable and biocompatible material for direct pulp capping and should be compared with Mineral trioxide aggregate and calcium hydroxide. The research reported comprised a randomized clinical trial for evaluation of the clinical success and efficacy of Biodentine, Mineral Trioxide Aggregate and calcium hydroxide as direct pulp capping materials for vital pulp therapy in carious molars.

2. MATERIALS AND METHODS

2.1 Study Design and Participants

The randomized clinical trial was designed with three experimental groups. The trial was performed between October 2017 and October 2020. The selected patients were adults with age

between 19 to 40 years. All patients were explained about the benefits, value of treatment, risks, and other treatment options before enrolling in the study. The clinical procedures and follow up of patients were done in Department of conservative Dentistry and Endodontics, Karpaga Vinayaga Institute of dental sciences, located in Chengalpet district, Tamilnadu, India.

2.1.1 Inclusion criteria

- Patients between 19 and 40 years of age.
- Carious exposure less than two millimetres in a molar.
- Pulpal response on diagnostic tests should be with adjunct to healthy tooth or pulp in reversible pulpitis.

2.1.2 Exclusion criteria

- Patients with systemic diseases.
- Tooth having signs and symptoms of pulpal diseases other than reversible pulpitis.
- Tooth with calcifications in pulp region or internal resorption seen in radiograph.
- Restoration contraindicated or not possible for the tooth.
- Uncontrolled and excessive bleeding in the pulpal exposure site.

2.1.3 Sample size determination

Sample size was fixed to 12 per group as described by Steven A. Julious, the minimum sample size required for a pilot design is estimated to be 12. Overall, 36 participants were enrolled (20 male and 16 female) [23].

2.2 Clinical Procedure

42 patients with deep caries were diagnosed with deep dental caries and 36 patients were selected for the trial. Pulp sensitivity test for the teeth was performed and evaluated by Cold Test (Endo Ice) and electrical pulp test (Digitest II, Parkell, USA). Preoperative radiograph, RVG was taken to assess periodontium and hard tissue. 2% Lidocaine hydrochloride with epinephrine 1:80,000 (Lignospan, Septodont, France) given as infiltration buccal to Maxillary teeth or Infra alveolar nerve block for Mandibular teeth for achieving anaesthesia for the teeth included in trial. Isolation was done with rubber dam and saliva ejector for all cases. Spoon excavator was used to remove the caries and was completely

removed with sterile BR 31 ball bur (Mani Inc, Japan) attached to handpiece. Dental caries was removed till resistance was felt over dentin while using spoon excavator or bur. 2*2 mm exposure with bleeding occurred during this procedure due to pulp exposure. The pulp exposed tooth was incorporated for the study. If there was no pulpal exposure and bleeding, the case was not included in the study. Pulpal bleeding was managed with 2% Lidocaine with adrenaline. If bleeding persisted for 10 minutes and more, the case was excluded from the study. The prepared cavity was cleansed and sterilised with 2% chlorhexidine and Distilled water. In this stage, pulp exposed tooth was assigned to a group randomly by simple randomization technique using Excel table (Microsoft Corp).

2.3 Experimental Groups

Group - 1, Dycal (Dentsply, USA) was mixed on a paper pad given by the manufacturer. Manipulated material was placed over the pulp exposure region in pulpal floor of cavity with a Plastic filling Instrument.

Group - 2, Mineral Trioxide Aggregate (Angelus, Brazil, White MTA) was manipulated according to the instructions given by manufacturer in a paper pad with cement spatula and placed with MTA carrier in the floor of cavity as it was done in the Group – 1.

Group - 3, Biodentine (Septodont, France) was manipulated according to instructions given by manufacturer by placing capsule filled with powder and liquid in mechanical amalgamator and then placed in prepared cavity with plastic filling instrument.

The materials were placed approximately 2*2 mm over the pulp exposed area. Provisional restoration with IRM was completed by placing above the capping material and covering it. After one month, patient was recalled and the pulp capped tooth was restored with Glass ionomer cement (GC gold label IX, GC corporation, Japan), and occlusion was checked.

Patients were recalled at 1 month, 3 months and 6 months for review and evaluation. The pulp capped tooth was subjected to pulp sensitivity test, pain was recorded in Visual analog scale and was also assessed with RVG at every follow up.

Clinical success was defined as a tooth with no pain, normal sensitivity tests, no facial edema, no

internal or external resorption, no periradicular disease, periodontal ligaments of normal width, and no fistula.

Pulp capped tooth was defined clinically successful if the tooth had no pain and responded to sensitivity tests within normal limits.

Treatment was revised and performed for Tooth with symptoms or failure.

2.4 Statistical Analysis

Data was compiled in Microsoft excel sheet and subjected to statistical analysis using SPSS (Statistical package for the social sciences software) version 21. Chi-Square test was applied. The level of significance was kept as < 0.05.

3. RESULTS

36 patients were selected and incorporated for the study (18 male and 8 female). Details of the patients selected for the study is shown in Fig. 1. 36 molars of 36 patients diagnosed with deep dental caries were selected for the study. 36 molars were divided into three groups, 12 teeth in group 1 pulp capped with Calcium Hydroxide, 12 teeth in group 2 pulp capped with Mineral trioxide aggregate and 12 teeth in group 3 pulp capped with Biodentine. Baseline characteristics of the teeth included for the study are shown in Table 1. In the 36 selected molar teeth, 10 were maxillary molars and 26 mandibular molars.

Failures occurred at various intervals for different materials and the failure rate is shown in table 2. There was no failure at one month follow up showing 100% success for all the three materials. In three months follow up and evaluation, calcium hydroxide - group 1 had three failures, Mineral trioxide aggregate - group 2 had one failure and Biodentine - group 3 didn't have any failure. In six months follow up and evaluation, calcium hydroxide group 1 had five failures, Mineral trioxide aggregate - group 2 had two failures and Biodentine - group 3 had one failure. Table 3 reveals success rate of the three pulp capping materials in three months and Table 4 reveals success rate of the three pulp capping materials in six months. Table 5 reveals the overall success rate of the three pulp capping materials. The treatment undergone by the failure cases in different groups are shown in Table 6.

4. DISCUSSION

Protection of the pulp is of foremost importance for multiple reasons; initiation of reparative dentin and bridge formation in between the pulpal tissue and pulp capped material by odontoblasts and to carry on pulp functioning. The study principally focused over the various dental materials used for direct pulp capping for preserving vitality and functions of the pulp. This study was done for evaluation of the clinical success and efficacy of calcium hydroxide, Mineral trioxide aggregate

and Biodentine used for pulp capping of carious molars by clinical follow up and assessment during six months duration. Calcium hydroxide is still being used for pulp capping procedures and pulpectomy procedures as it is the gold standard material in this field for nearly a century old. Even though calcium hydroxide is used in conventional practice, it also has several disadvantages. Few of them are poor adhesion towards dentin, tunnel like defects in the formed dentin bridge and time dependant dissolution [12,24].

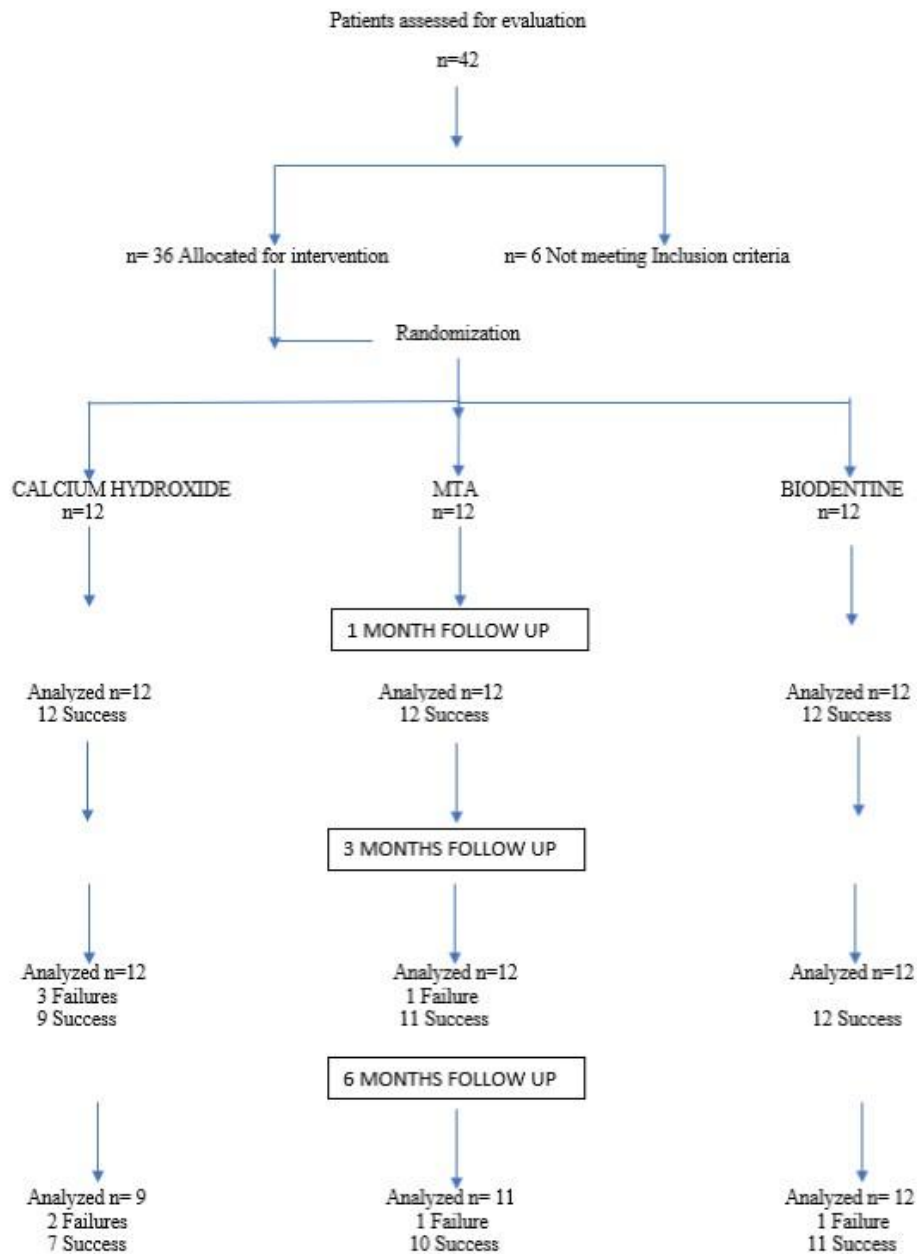


Fig. 1. CONSORT Flowchart of patients registered for the trial

Table 1. Baseline characteristics of the patients and teeth included for trial

| Variables | | Calcium hydroxide (n=12) | Mineral trioxide aggregate (n=12) | Biodentine (n=12) |
|-----------|-------------------|--------------------------|-----------------------------------|-------------------|
| Gender | Male | 9 (75%) | 9 (75%) | 10 (83%) |
| | Female | 3 (25%) | 3 (25%) | 2 (17%) |
| Tooth | Maxillary | 3 (25%) | 4 (33%) | 3 (25%) |
| | Molars | | | |
| | Mandibular molars | 9 (75%) | 8 (67%) | 9 (75%) |

Table 2. Showing failure rate of materials at different time period

| | Calcium hydroxide | Mineral trioxide aggregate | Biodentine |
|------------------------|-------------------|----------------------------|--------------|
| 3 month follow up time | 3 (25%) | 1 (8.33%) | 0 (0 %) |
| 6 month follow up time | 5 (55.55%) | 2 (18.18%) | 1 (8.33%) |

Table 3. Showing Success rate of materials at 3 months' time period

| | Calcium hydroxide | Mineral trioxide aggregate | Biodentine | P value * |
|------------------------|-------------------|----------------------------|---------------|-----------|
| 3 month follow up time | 9 (75%) | 11 (91.67%) | 12 (100 %) | 0.14 |

Table 4. Showing Success rate of materials at 6 months' time period

| | Calcium hydroxide | Mineral trioxide aggregate | Biodentine | P value * |
|------------------------|-------------------|----------------------------|----------------|-----------|
| 6 month follow up time | 4 (44.44%) | 9 (81.82%) | 11 (91.67%) | 0.014 |

*p value - <0.05- statistically significant

Table 5. Success rate of pulp capping materials

| Calcium hydroxide | Mineral trioxide aggregate | Biodentine |
|-------------------|----------------------------|----------------|
| 5 (41.67%) | 9 (75%) | 11 (91.67%) |

Table 6. Description of Treatment Done after Failure of the Pulp Capping Procedure

| Revision treatment | Calcium hydroxide | Mineral trioxide aggregate | Biodentine | Total |
|----------------------|-------------------|----------------------------|------------|-------|
| Extraction | 2 | 1 | 0 | 3 |
| Endodontic treatment | 6 | 2 | 1 | 9 |

However, there is a paradigm shift in the preference of clinicians for pulp capping materials from calcium hydroxide to Mineral trioxide aggregate due to its predictable treatment outcome [20]. Min et al reported that Mineral trioxide aggregate is better than calcium hydroxide in initiation of reparative dentin formation by odontoblastic activity [25]. Few authors reported that the frequency and

thickness of dentinal bridge formed is superior for mineral trioxide aggregate than calcium hydroxide [26,27]. Mineral trioxide aggregate also has few disadvantages, some of them are longer setting time preventing completion of treatment procedure in single visit, bismuth oxide incorporated in powder content as radiopacifier is reported as a reason for tooth discolouration and it has handling difficulties [28,29].

Newer CSMs have been developed and introduced to overcome the drawbacks of mineral trioxide aggregate. Biodentine was introduced by septodont, newer calcium silicate material with increased bioactivity and biocompatibility, clinically acceptable setting time, better mechanical properties, good dentin adhesion, can be easily manipulated and handled with ease [30-32].

In our study, we compared the clinical success between three different pulp capping materials Calcium hydroxide, Mineral trioxide aggregate and Biodentine. The results of our clinical study are; 91.67% success in the Biodentine group, 75% success in the MTA group and 41.67% success in Calcium Hydroxide group. Claudia Brizuela et al has reported similar study with resembling results for Mineral trioxide and aggregate [33]. Many trials have been done on caries free healthy teeth, it is well known that bacteria are causing dental caries and pulpal infection [34]. In our study we have attempted to assess the efficacy of three different pulp capping materials in a more challenging clinical scenario where the outcome is unpredictable because of variability in the bacterial load, virulence and diversity.

Research should try to find the factors that facilitate favourable and better result for pulp capping procedures in an original clinical scenario rather than doing trials with artificial exposures of pulp in a sound tooth with good dentin [35]. Precise mechanisms of Calcium Silicate materials promoting dentin bridge development is unknown [27]. Although they do discharge calcium hydroxide as a by-product, Calcium Silicate materials don't dissolve over time like calcium hydroxide and are stable, induce dentin bridge formation, and predictably effective of sealing the damaged pulpal tissue [36,37]. These compounds cause inflammation that is only temporary, less intense, and less widespread than the inflammation caused by Calcium Hydroxide [38]. Although the study's primary disadvantages include a small sample size and a brief assessment time, it was conducted in permanent molars diagnosed with deep dental caries and were clinically assessed. Our results showed statistically significant difference between the three pulp capping materials evaluated during the trial duration. MTA and Biodentine are better than calcium hydroxide and comparably Biodentine is better than MTA for direct pulp capping. Future research trials should be focused on qualitative analysis of the

dentin bridge formed by the pulp capping materials.

5. CONCLUSION

In our study the materials were clinically assessed and evaluated at 1 month, 3 month and 6-month follow-up. Calcium Silicate materials are better than calcium hydroxide and comparably Biodentine is better than MTA for Direct pulp capping.

The findings of this clinical trial could promote the reliability of pulp capping materials for treatment of deep carious lesions by conservative approach rather than opting endodontic management in conventional practice.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

ETHICAL APPROVAL & CONSENT

The study was assessed and approved by ethical committee board members of Karpaga Vinayaga Institute of dental sciences KIDS/IRB/3-2017/001 and it was formulated in line with CONSORT regulations 2010.

The willing participants were selected for the study after recording their sign in Informed consent form.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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