

## Effect of Prior Application of 2% Calcium Dobesilate on Direct Pulp Capping with Mta- A Preliminary Randomized Clinical Trial



### MEDICAL SCIENCE

**KEYWORDS :** Calcium dobessilate , Direct pulp capping, Mineral Trioxide Aggregate

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### ABSTRACT

*AIM OF THE STUDY:* To observe the effect of prior application of calcium dobessilate on direct pulp capping with MTA.

*OUTLINE OF METHODOLOGY:* Clinically and radiographically confirmed cases of direct pulp exposed teeth were randomly stratified into two groups; Group I- Pulp capping done with MTA with prior application of calcium dobessilate and Group II- Pulp capping done with MTA without prior application of calcium dobessilate.

*The experimented teeth were evaluated clinically and radiographically for 6 months post operatively.*

*RESULTS:* All the teeth that were followed showed favourable outcomes on the basis of radiographic appearance, subjective symptoms and cold testing. Group I showed faster results as compared to Group II.

*CONCLUSION:* Prior application of calcium dobessilate has shown to increase the efficacy of MTA as a direct pulp capping agent.

### Introduction

The consequences of pulp exposure from caries, trauma or tooth preparation misadventure can be severe, with pain and infection the result. The morbidity associated with treating pulp exposures is consequential, often requiring either extraction or root canal therapy. An alternative procedure to extraction or endodontic therapy is pulp capping in an attempt to maintain pulp vitality. A number of materials have been suggested for use in direct pulp capping. Interestingly, no one material seems to enjoy a significant preference among practitioners. In a survey in which private practitioners were asked what direct pulp capping material they use, the respondents listed different materials like Calcium Hydroxide, Mineral Trioxide Aggregate (MTA), Adhesive systems and RMGIC/GIC with none being preferred by a clear majority of users.<sup>1</sup> Although many products have been suggested, a recent Cochrane Review found that evidence is lacking as to the most appropriate pulp capping material.<sup>2</sup> MTA has been described very recently as "the material of choice" in pulp capping procedures, particularly in permanent teeth as compared to Calcium hydroxide in long term studies<sup>3</sup>. Calcium dobessilate is a vasoactive drug with presumed effects on endothelial integrity, capillary permeability and blood viscosity. It is often recommended for venous disorders, and also prescribed for diabetic retinopathy and other microvascular disorders.<sup>4,6</sup> Till now there is no reported use of this drug in dentistry for direct pulp capping. In this study it was used as a local application in direct pulp capping along with MTA.

### AIM OF THE STUDY

To clinically observe the effect of prior application of calcium dobessilate on direct pulp capping with MTA.

### SELECTION CRITERIA

A total of 40 patients were randomly selected from the undergraduate out patient within the age group 18 to 34 years. Teeth presented with caries in close proximity to the pulp in relation to mandibular molars with no signs of extra oral or intraoral swelling or sinus tract formation were selected. All teeth were negative to percussion and palpation tests and the mobility was within normal limits. The research protocol and informed consent were reviewed and approved by an institutional research committee (IRC) prior to study initiation. All patients were informed about the procedure and informed consent was obtained.

### Group Distribution

For blinding purpose each subject was asked to select a sealed pouch ( total 40 pouches) labeled with unique number which was required for investigation research. Selected cases were then

divided into following groups: Group I- Pulp capping with Calcium dobessilate + MTA (n=20) Group II- Pulp capping with MTA only (n=20) as per the unique number selected.

### PREPARATION OF CALCIUM DOBESSILATE SOLUTION

Manual grinding of 500mg Calcium dobessilate monohydrate tablets (Ranbaxy, India) was done in mortar and pestle until fine grains were obtained. 1 ml of normal saline (9 g/L Sodium Chloride) , USP (NaCl) with an osmolarity of 308 mOsmol/L was added to obtain 2% calcium dobessilate solution (20mg/ml) W/V.

### Treatment Protocol

The initial treatment plan was removal of the carious lesion followed by clinical evaluation of the pulp exposure. Direct pulp capping with MTA ANGELUS –WHITE (Angelus Indústria de Produtos Odontológicos BRASIL) was planned for the anticipated pulp exposure with and without application of Calcium dobessilate solution. Patients were informed about the procedure and consent was obtained along with the information about the potential need for root canal therapy in case of abnormal signs and symptoms. Following administration of local anaesthesia, teeth were isolated with rubber dam. Caries removal was performed using a no. 4 sterile round bur on a low speed handpiece with copious water irrigation. During or after removal of caries, exposure of pulp with moderate bleeding was observed. A sterile cotton pellet moistened with saline was used to apply moderate pressure to the exposed pulp for 5 min and haemostasis was achieved. The cavity was lightly dabbed with a moist pellet to remove the excess moisture.

### Group I (n=20)

In this group 0.5 ml solution 2% calcium dobessilate was applied on the exposure site with the help of disposable calibrated syringes (Dispovan, Single use insulin syringes). Immediately 1-2 mm thick layer of MTA was placed over the exposure site and adjacent dentinal surface with a plastic filling instrument. The mix was then padded with a moist cotton pellet to ensure optimum contact of MTA with exposed pulp tissue. IRM (Caulk, DENTSPLY) was placed over the MTA. A light cured Glass Ionomer Cement (GC Light cured universal restorative) was used as a permanent restoration.

**Group II (n=20)** In this group 1-2 mm thick layer of MTA was placed over the exposure site and restored with same procedure as Group I.

Patients were scheduled for 1 week, 1 month, 3 months and 6 months follow up in order to monitor for any signs or symp-

toms. Patients were asked to call and inform if any pain or discomfort occurred. In follow up visits clinical examination was done to evaluate an intact restoration and absence of any abnormal signs or symptoms. Teeth were tested for vitality by various vitality tests (heat test, cold test, electric pulp test). Periapical radiographs were taken to evaluate any periapical changes.

Criteria for success was based on subjective and objective responses. It was on the ability to show response of a normal pulp at earliest possible time frame.( 1 week,1 month,3 months and six months) as compared to persistent abnormal pulpal symptoms.s and six months) as copmresponse of a normal pulp at earliest possible time frame.( 1 week,1 month,3 months and six mont

## RESULTS AND OBSERVATIONS

**Table 1: statistical analysis**

Time Period	Group No.	Number of patients reported	Normal Response	Reversible Pulpitis	Chi-Square values	Level of Significance
After 7 days	Group 1	20	18	2	3.5842	p= 0.05833 Significant p< 0.10
	Group 2	20	18	7		
After 1 month	Group 1	19	19	0	4.2343	p = 0.039615 Significant P < 0.10
	Group 2	20	16	4		
After 3 months	Group 1	18	18	0	0.9243	p=0.0336342 Not significant at p <0.10
	Group 2	20	19	1		
After 6 months	Group 1	16	16	0	0 Not significant at p <0.10	
	Group 2	17	17	0		

All the teeth that were followed showed favourable outcomes on the basis of radiographic appearance, subjective symptoms and cold testing.( Total 33 patients at the end of 6 months, 1 patient undergone RCT in Group II after 3 months follow up). Inter group comparison was done with chi -square test. No significant differences were observed radiographically between both the groups. Group 1 showed faster results as compared to Group II in the early phase of treatment ( $\pm 1$  months).

## DISCUSSION

Calcium dobesilate (C<sub>6</sub>H<sub>5</sub>O<sub>5</sub>S) 2,5-dihydroxybenzene sulfonate, Molecular Weight :418.41) is an orally administered angioprotective agent which promotes venous blood flow. Calcium dobesilate has three main indications: chronic venous disease, diabetic retinopathy and the symptoms of hemorrhoids. It acts on the capillary walls by regulating its impaired physiological functions-increased permeability and decreased resistance. It increases erythrocyte flexibility, inhibits platelet hyper aggregation and reduces plasma and blood hyper viscosity, thus improving blood rheological properties and tissue irrigation and contributes to reduce edema. These effects allow to correct capillary dysfunctions either of functional origin or caused by constitutional or acquired disorders. Rarely in sensitive persons some nausea or gastric discomfort may occur but this rapidly disappears.<sup>6-7</sup> The prevalence of calcium dobesilate-induced agranulocytosis estimated as 0.32 cases per million treated patient.It has extremely low toxicity . In case over dosage is suspected it is recommended that vomiting be induced or gastric lavage be performed, and such symptomatic supportive therapy be administered as appears indicated.<sup>7</sup> In our study 0.5 ml of 2% concentration of Calcium dobesilate used as a local application and none of the patients reported any side effects.

In our study a faster healing was observed with calcium dobesilate and found to be statistically significant ( $p < 0.10$ )in the early phases ( $\pm 1$  month) of treatment which may be attributed to effect of Calcium Dobesilate on the impaired capillary functions the involved pulp.

MTA has been compared with various capping materials including calcium hydroxide. The deficiencies of calcium hydroxide include poor adherence to dentin, inability to form a long-term seal against bacterial microleakage and a porous dentinal bridge formation.<sup>8</sup> Pulp capped with MTA consistently demonstrated complete tubular bridge formation and lack of pulpal inflammation. The dentinogenic effects of MTA can be attributed mainly to its sealing ability and biocompatibility with subjacent tissues, which facilitates restoring normalcy to the pulpal and periradicular tissues.<sup>9</sup> In this study MTA Angelus- White was used as it has faster setting time (10 -15 minutes) hence restoration is possible on same visit.

Being a preliminary clinical trial it needs further studies with a larger sample size aiming at the histological extent and degree of inflammation and related changes in pulp due to calcium dobesilate and for a longer follow-up period. The current study included factors that are believed to give indications of the health and healing capacity of pulpal tissue prior to treatment i.e. age of the patient, size of exposure and radiographic appearance. Each of these factors has been cited in the literature as having some relevance in the ability of the pulp to recover from a pulp exposure (cariou or otherwise),<sup>10-12</sup> but none has been shown to be reliably predictive in our study.

The true "gold standard" of pulp status is histological analysis which is an invasive procedure. Unfortunately, the true state of pulp health or pathology cannot be determined by clinical signs, symptoms or radiologic appearance Clinicians have relied on assessments, such as the application of hot or cold temperatures, an electric current, percussion of the tooth, changes in the appearance of associated soft tissues and patient reports of symptoms. However, numerous studies including histological analysis have demonstrated a chronically inflamed pulp, but the patients reported no symptoms, the investigators discerned no signs and no apical or radicular pathology were noted on radiographs.<sup>11-15</sup> It must also be kept in mind that most studies that include histological analysis are of quite a short duration, typically two to four months. Maintaining a consistent methodology within the study in direct pulp capping cases are extremely difficult. This can hamper interpreting the results, since it is difficult to determine whether differences in the pulp status are the result of the pulp cap regimen or the restorative procedure or other factors. Although no studies were carried out targeting dental pulp but large number of studies including clinical trials have established calcium dobesilate as a vasoactive and angioprotective drug for micro circulation disturbances in structures like human retina. Moreover as the present clinical trial was purely based on subjective responses which is practically possible only in human subjects.

Some studies have shown that a tooth is more likely to survive direct pulp capping if the initial exposure is due to mechanical reasons rather than caries. Caries penetration to the pulp will result in bacterial invasion of the pulp, resulting in pulpal inflammation. This leaves the pulp less able to respond and heal, compared to a mechanical exposure in which preexisting inflammation is not present. A logical explanation of this is that teeth that are asymptomatic and exhibit no clinical or radiologic signs of pathology at the time of pulp capping tend to fare better than those teeth with such factors present<sup>16</sup> but in reality we encounter more of the carious exposure cases which were considered for the present study.

**CONCLUSION:**

Within the limitation of this preliminary clinical trial it was observed that 2% solution of Calcium dobesilate significantly improved the healing rate of injured dental pulp along with the sealing and dentinogenic effects of MTA. Further clinical studies are suggested including histological analysis of the tissue changes during its application.

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