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"COMPARATIVE EVALUATION OF THE EFFICACY OF LIGHT CURE CALCIUM HYDROXIDE AND THERACAL LC AS INDIRECT PULP CAPPING MATERIALS IN PATIENTS WITH DEEP CARIOUS LESION- AN INTERVENTIONAL STUDY"

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Abstract
Background- Indirect pulp capping (IPC) is one procedure that helps to sustain pulp vitality by enabling healing/repair of pulp. Our main aim of the study is to carry out IPC using TheraCal LC and light cure Calcium hydroxide in tooth of patients having deep carious lesion. Also, to check for the preservation of vitality of the same tooth and to compare and find out which among them is the most suitable material for IPC.

Material and Methods- 28 patients will be randomly divided into one test group and one control group consisting of 14patients in each group. The test group will be managed by TheraCal LC while the control group will be treated with light cure calcium hydroxide. Clinical examination will be done to check for postoperative pain, tenderness, neural sensibility and radiographical examination will be done to check for PDL space widening, presence of calcific barrier and periapical radiolucency at patient recall of 21days, 3 month and 6 months. The primary and secondary outcome variables will be based on clinical and radiographical success rates noted from the 6 month follow-up that will be conducted. Result- The expected result is that TheraCal LC will give better results in comparison to light cure Calcium hydroxide as pulp capping agent.

Conclusion- This study will provide the most suitable material for Indirect Pulp Capping that we can put to use in clinical practice which will help in maintaining pulp vitality as we need a material that has better efficacy and is cost effective as Indirect Pulp Capping agent.

Keywords- Indirect pulp capping, TheraCal LC, light cure Calcium hydroxide, Deep carious lesion.

INTRODUCTION

Indirect pulp capping (IPC) is one procedure that helps to sustain pulp vitality by enabling healing/repair[1] of pulp. Treating deep carious lesions approximating a healthy pulp has been quite challenging in most situations. Indirect pulp treatment (IPT) or IPC is a choice of procedural modality for teeth in such cases with no signs or symptoms of pulpal degradation. The main principle for this method is that dental pulp can produce dentin‑like matrix (reactionary or reparative dentin) which repairs the dentin‑pulp complex. IPT aims is to check the progressing caries. It promotes dentinal sclerosis and stimulates the formation of reparative dentin. This arrests demineralization of carious dentin and at the same time preserves pulp vitality. Different materials are used as IPC agents for managing vital teeth with deep carious lesions.

The gold standard pulp capping agent is Calcium hydroxide. It's use was first described by Zander in 1939. It leads to forming of a reparative dentin via differentiation of cells, extracellular matrix secretion, & is followed by mineralization. But there are various disadvantages associated with it. This includes gradual disintegration leading to forming of tunnel defects in the newly formed dentin. This is seen with calcium hydroxide after long follow-ups[2]. This led to the usage of many other pulp capping materials like calcium silicate based materials for IPC which includes TheraCal LC.

TheraCal LC is a calcium silicate-based material available in syringe in paste form. It has a dual purpose of that of a pulp capping agent, and in direct restorations it is used as protective liner[3]. Based on the chemistry of calcium silicate cements, TheraCal LC is classified as 4th generation calcium silicate material[4]. According to ISO 9917-2017 part 2 clause 4.1, TheraCal LC is a class 2 cement material “in which the setting reaction of the polymerizable component is lightactivated"[3].

Several studies stated the variation in success rates following usage of calcium hydroxide as pulp capping material in permanent teeth, but so far there has been no clinical study that have compared the efficacy of the 2 materials(i.e., light cure Calcium Hydroxide and TheraCal LC) in deep carious lesions. Thus, the target of our study is clinical evaluation of postoperative pain, tenderness, neural sensibility, and to check radiographically periodontal ligament(PDL) space widening, periapical radiolucency and the presence of calcific barrier

which will be performed at 21 days, 3 months and 6 months after IPC with light cure Calcium Hydroxide and TheraCal LC in permanent teeth with deep carious lesion.

AIM

To evaluate and compare the efficacy of light cure Calcium Hydroxide and TheraCal LC as Indirect Pulp Capping Materials in patients with deep carious lesion.

OBJECTIVES

Objectives of study are:

1. To evaluate efficacy of TheraCal LC as IPC agent clinically by checking postoperative pain, tenderness, neural sensibility, and radiographically by checking PDL space widening, presence of calcific barrier and periapical radiolucency.
2. To evaluate efficacy of light cure Calcium Hydroxide as IPC agent clinically by checking postoperative pain, tenderness, neural sensibility, and radiographically by checking PDL space widening, presence of calcific barrier and periapical radiolucency.
3. To compare efficacy of TheraCal LC and light cure Calcium Hydroxide as IPC material in relation to the above mentioned parameters.

This interventional study is a Randomized, Parallel Group Trial and has a superiority framework with allocation ratio of 1:1.

This study will be conducted in Department of Conservative Dentistry and Endodontics, Sharad Pawar Dental College and Hospital, Sawangi(Meghe), Wardha. The recruitment of study participants will be from the patient group reporting to the OPD. Country for data collection will be India only. The patients will made aware about the importance of Indirect Pulp Capping. Patients would be made aware of the involved benefits, risks, and other possible treatment options before enrolling them in this trial. They would be made to give signed consent before the start of the treatment.

INCLUSION CRITERIA:

To be eligible for the study, the participant should meet the following criteria:

1. Age group should be 17–40 years.
2. Tooth should be a mature permanent tooth showing a closed apex on periapical radiograph.
3. Tooth should have carious penetration in dentin in more than half (or three-quarters) the thickness of its dentin bulk as seen in periapical radiograph and diagnosed as reversible pulpitis.
4. Should have a positive response to Cold test that will confirm Neural sensibility.

EXCLUSION CRITERIA:

The following are the exclusion criteria for the study:

1. Deciduous teeth*
2. No pulpal exposure post completion of caries removal
3. Teeth with necrosed pulp**

4. Teeth diagnosed with irreversible pulpitis with or without periapical lesion as diagnosed from radiograph
5. Teeth affected by periodontitis
6. Cracked tooth
7. Teeth showing internal or external resorption
8. Calcified canals
9. Failure to achieve pulpal hemostasis after accidental pin point exposure of pulp
10. Patients having systemic disease or is immunodeficient
11. Patient in pregnancy
12. Patient on antibiotic or analgesic course within a week prior to the start of treatment

* Deciduous tooth have varying root structure because of which pulp therapy is mostly unsuccessful in such tooth.[5]

** A necrosed pulp is avoided because tissue healing and remodelling is dependent on blood supply of tissue[6], without which there would not be a calcific barrier formation.

Studies conducted in past showed that any systemic or oral disease specifically neoplasms of oral cavity have led to the lowering of function among the survivors. Therefore, only Healthy Human Volunteers without any signs of systemic or oral diseases are chosen for the study.[7]

Sample Size

Based on the results of previous studies, depending on the basis of percentage of success of direct Pulp Capping with Mineral Trioxide Aggregate as 80%[8] versus Calcium hydroxide as 33.3%[10] using α=5% with power of 80%, the sample size was calculated which came out to be 14 for each group. Since there are 2 groups, a total of 28 samples are required for this study.

STUDY DESIGN:

This is an interventional type of study having a randomized, parallel group trial type of study design. It is a double blinded study where neither the participants nor the experimenter shall know the particular pulp capping material that is being used on them for their treatment of pulpal exposure. Sequence generation is done by computer generated randomization. There will be a centralised allocation of the materials to the patients for the study. There are total 2 groups which will have 14 patients in each group. There is 1 test group that will be treated with TheraCal LC and the control group shall be treated with light cure Calcium Hydroxide.

METHODS AND MATERIAL:

Materials used for the study are:

TYPE OF MATERIAL	**BRAND NAME**
TheraCal LC	Bisco, USA
Light cure Calcium Hydroxide	Prevest DenPro, Belgium
3% Sodium hypochlorite	Parcan, Septodont, India
2% Chlorhexidine gluconate	Safe Plus, India
Light cure Glass Ionomer Cement	Prevest DenPro, Belgium
Composite	Spectrum Micro hybrid composite (Dentsply), USA
LED curing light	Woodpecker , China
Endo-Ice	Coltene-Whaledent, USA

The steps to be undertaken are:

- Patient will be made to give a detailed case history. And shall be thoroughly examined both clinically and radiologically.
- The subjects chosen for the study should have mature permanent teeth having deep carious lesion approximating the pulp.
- Local anesthesia (2% lignocaine HCl with epinephrine[*]) is given to the patient to deter anticipated unpleasant sensitivity during caries excavation. This also results in less post operative pain or sensitivity.[9]
- Tooth to be treated is isolated using rubber dam.
- Under slow speed, the top layer of the carious tooth structure is excavated using a round bur. Care must be taken to preserve as much as healthy naturally remaining tooth structure to increase the retention form of the restoration.[10]
- The tooth will be disinfected with 2% Chlorhexidine followed by irrigation with saline.
- The remaining soft carious tooth structure left in the bottom-most layer is excavated with care using a spoon excavator. The cavity is then disinfected using 3% NaOCl.
- The cavity is then washed with saline to remove sodium hypochlorite. The excess is soaked with cotton pellet to achieve a dry cavity.
- The two different pulp capping materials will be placed in different patients as per their assigned group according to manufacturer's instructions.
- Light cure Glass Ionomer Cement (Prevest DenPro, Belgium) is then placed as a base in the cavity.
- This is followed by direct composite restoration(Spectrum Micro hybrid composite Dentsply, USA) [**] . Composite as final restorative material provides a better bond strength and solubility resistance and has lesser incidence of secondary caries as compared to Glass Ionomer Cement[11].
- The final restoration must be finished to achieve a smooth surface to decrease plaque accumulation and to prevent potential discolouration[12] or gingival inflammation in case the restoration is extending subgingivally which may harness specific Periodontogens leading to Peiodontitis.[13]
- Instantly after completion of the treatment we take an IOPA of the same tooth which is taken as a baseline for any follow up in future.

* Lignocaine has a shorter duration of anesthesia (≥60minutes) but has a faster onset of action than Bupivacaine. So to suit our procedure, lignocaine is the preferred anesthetic here.[14]

**The most common resin based cement used these days are Microhybrids which provide good strength and good smoothness.[15]

- Clinical examination is done to check for postoperative pain, tenderness, neural sensibility and radiographical examination is done to check for PDL space widening, presence of calcific barrier and periapical radiolucency at patient recall of 21days, 3 month and 6 months.
- The primary and secondary outcome variables will be based on clinical and radiographical success rates noted from the 6 months follow-up that will be conducted.
- Successful primary outcome will be defined by the presence of calcific barrier below the restoration.
- Successful secondary outcome will be indicated by the absence of postoperative pain, tenderness on percussion, positive neural sensibility tests; and no radiographic signs of PDL space widening and absence of periapical radiolucency.
- Pain experienced by patients will be scored using Visual Analogue Scale(VAS).
- Patients will be asked to score the pain before and after the procedure.

Recall examinations will include clinical assessment for-

- Postoperative pain- Scoring of pain felt by patients will be done using the Visual Analogue Scale(VAS).
- Tenderness- this will assessed by vertical percussion of the treated tooth
- Neural sensibility- this will be assessed by Cold test using Endo-Ice (Coltene-Whaledent, USA)

Recall examinations will also include radiographic assessment using IOPA taken at 21 days, 3 months, and 6 months. The following parameters are assessed in radiographic examinations-

- to check for PDL space widening
- periapical radiolucency
- the presence of calcific barrier below the restoration

The data used will be analysed using SPSS software. The Mean and standard deviation will be calculated for all the parameters. Chi Square test & ANOVA test will be used for the statastical analysis.. The level of significance will be set at $p<0.05$.

Study protocol has been approved by the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences(Deemed to be University) having the Reference Number of-DMIMS(DU)/IEC/Dec-2019/8562.

Informed consent shall be taken from each subjects by principal investigator and confidentiality related to the participants shall be maintained. There is no conflict of interest for the principal investigator.

EXPECTED RESULT:

The expected result is that TheraCal LC will give better results in comparison to light cure Calcium Hydroxide as indirect pulp capping agent. It has its clinical implication in maintaining pulp vitality as we need a material that has better efficacy and is cost effective as Indirect Pulp Capping agent which we can put to use in clinical practice.

DISCUSSION:

Dental pulp has the natural tendency of repairing damaged tissue. This leads to forming of reparative dentin. It forms a hard tissue barrier after an Indirect pulp capping (IPC) procedure. IPC is a treatment method where a deep carious lesion approaching pulp is treated with a biocompatible pulp capping material to keep pulp vital by preventing bacterial invasion by stimulating a calcific barrier formation at the same site. Variations in outcomes is seen which is contributed by different factors like age, gender, the location of the exposure site, the nature of exposure, i.e., whether it is iatrogenic or carious, the type of pulp capping agent being used, etc. To avoid anomalies of results, certain inclusion and exclusion criteria are laid down. Studies conducted by Matsuo et al. 1996 showed that the patients below the age of 40 years had shown a higher success rate to pulp therapy than the ones above the same group[16].

Mathur et al. 2016 studied IPC using Calcium hydroxide in 94 patients. Objective of this study was to find out the most appropriate material for indirect pulp treatment (IPT) to be put to use in clinical practice. Also, the study intended to find out the thickness (in mm) and type of tissue in terms of radiodensity (in Hounsfield units [HU]) formed following IPC using CBCT. The study concluded that success rate for IPC was 96.85%. A marked difference in values was seen in the average thickness of reparative dentin at a 6‑month postoperatively in calcium hydroxide group. This suggested distinct bridge formation. Similarly notable readings were recorded in radiodensity of barrier formed (in HU). The material was thus, stated suitable as IPC agent suggesting mineral gain.

CONCLUSION:

This study will provide the most suitable material for Indirect Pulp Capping that we can put to use in clinical practice. It has its clinical implication in maintaining pulp vitality as we need a material that has better efficacy and is cost effective as Indirect Pulp Capping agent which we can put to use in clinical practice.

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