Comparative Evaluation of Resin-modified Glass Ionomer Cement, Mineral Trioxide Aggregate, and Calcium Hydroxide When Used as a Direct Pulp Capping Material on Carious Pulp Exposures of Human Permanent Teeth: A Randomized Clinical Trial

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ABSTRACT

Aim and objective: To evaluate the clinical efficacy of resin-modified glass ionomer cement (RMGIC), mineral trioxide aggregate (MTA), and calcium hydroxide (CH) when used as a direct pulp capping (DPC) material on carious exposure of human permanent teeth.

Materials and methods: Forty-five participants in the age group of 15–52 years, with deep carious lesions diagnosed with reversible pulpitis, were selected and divided into three groups, i.e., group I: RMGIC, group II: MTA, and group III: CH. Recall evaluation after 24 hours, 3 weeks, 3 months, and 6 months was carried out for recording self-reports from participants, a clinical inspection of the tooth, evaluating radiographs, testing vitality, palpation, percussion, mobility, and probing depths.

Results: Of the 45 participants, 42 presented without any abnormal signs or symptoms. Three participants presented with symptoms of irreversible pulpitis, which indicated DPC failure. Chi-square test gave a p value > 0.05 .

Conclusion: There was no significant association between different parameters and the DPC materials used in the study.

Clinical significance: Carious pulp exposure poses a challenge to the endodontist and maintaining the vitality of the pulp by DPC is one of the treatment modalities. This study has attempted to compare the efficacy of commonly used pulp capping materials like MTA and CH in addition to RMGIC, which has routinely been used for restorations.

Keywords: Calcium hydroxide, Direct pulp capping, Mineral trioxide aggregate, Resin-modified glass ionomer cement.

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INTRODUCTION

Preservation and maintenance of pulp tissue in a healthy state after it has been affected by caries/the tooth underwent trauma or a restorative procedure is known as vital pulp therapy.¹

In such cases when a biocompatible material is placed directly over the exposed pulp, it is referred to as a direct pulp capping (DPC) procedure, wherein the main aim will be to maintain the vitality and the health of the pulp.² Various materials have been used as pulp capping (PC) materials over the years³ but calcium hydroxide (CH) has been one such material⁴ by which others were judged.

Calcium hydroxide, as a VPT material, has shown acceptable properties but variable outcomes have been observed in long-term studies⁵ as CH has demonstrated cytotoxicity in cell cultures, its inability to stimulate reparative dentin coupled with poor marginal adaptation to dentin and inducing of pulp cell apoptosis.⁶ Favorable pulp responses following the use of mineral trioxide aggregate (MTA)⁷ which is a bioactive silicate cement that is an effective PC material in canine models and non-human primates.^{8,9} Resin-modified glass ionomer cement (RMGIC) has been used for DPC. Resin-modified glass ionomer cements have been reported to be cytotoxic to the pulp¹⁰ found to have a favorable response in a deep cavity as a liner.¹¹ Yet information is scarce about the effects of RMGIC as a DPC material.¹² To date, few clinical studies have investigated the effect of RMGIC as a DPC material.^{13–15} Thus, this study aims to evaluate the clinical efficacy of RMGIC, MTA, and

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CH when used as a DPC material in carious exposures of human permanent teeth.

MATERIALS AND METHODS

Subjects were recruited between June 2015 and June 2016 for this clinical study. Approval for the project was obtained from the Institutional Ethics Committee for Research on Human

Subjects (MGM/DCH/IEC/30/12/2014). The participants were explained the procedure of DPC which included the rationale, the clinical procedure that would be undertaken, and the possible complications of DPC and then informed consent was obtained. The participants were treated in accordance with the Helsinki Declaration. The inclusion criteria being: participants in the age group of 15–52 years, permanent maxillary and mandibular 1st and 2nd molars exhibiting carious pulp exposure. An intraoral periapical radiograph (Fig. 1A) of the tooth in concern was taken, tooth mobility checked, periodontal probing depth recorded, tooth percussed for periapical status, and vitality of the tooth was assessed using cold spray and an electric pulp tester. Those teeth which were diagnosed as having reversible pulpitis were included.

The exclusion criteria were participants with teeth diagnosed as having irreversible pulpitis from their history or clinical examination revealing the presence of a sinus tract or periodontal inflammation, mobility of tooth with poor prognosis, cracked tooth, furcation involvement, resorptive defects, or calcification of the root canal. During the clinical procedure of the participant included in the study, if it was observed that the pulpal hemorrhage could not be controlled and the same lasted for >10 minutes, such teeth were excluded from the study. The medical history of all participants was non-contributory.

A sample size of 45 participants was arrived at (15 participants per group were selected), which set the power of the study at 90% and precision for the study was 9%. All participants were assigned into the three groups with the help of simple random sampling using sealed envelopes. The clinical procedure was carried out by the primary investigator and the participant allocation was done by a neutral investigator, who did not carry out any clinical procedure. The participants did not know which PC material was being placed and the statistician also was unaware of the materials used per group. The primary investigator was aware of the material being placed.

All DPC procedures were carried out under local anesthesia 2% (LOX 2%, NEON, India) and rubber dam isolation (Hygienic, India) (Figs 1A and C).

A sterile carbide bur #245, in a high-speed handpiece, with water coolant was used to remove the undermined and carious enamel.

Large round stainless steel bur in a slow-speed handpiece was used for the excavation of caries. Caries on the pulpal or axial walls were excavated using a spoon or discoid excavators (Fig. 1D), the removal of which resulted in the exposure of the pulp (Fig. 1E), which was ≤ 0.5 mm in diameter. Once the exposure was detected, the cavity was disinfected by irrigating with 3% sodium hypochlorite (NaOCl) (Prime Dental Products Pvt Ltd, India) to remove all the debris and the bleeding from the pulp exposure site was controlled by placing a 3% NaOCl moistened sterile cotton pellet, applying moderate pressure to the exposed pulp for a maximum of 10 minutes to achieve hemostasis. Once the bleeding was controlled, the cavity was irrigated slowly with 1 mL of normal saline (Baxter India Pvt. Ltd., India) to remove any remnants of NaOCl. Finally, the cavity was lightly dabbed with saline moistened sterile cotton pellet to remove excess moisture. In case of uncontrollable bleeding, i.e., >10 minutes, irreversible pulpal damage was assumed and the participant was excluded from the study.

The PC material was then applied according to the manufacturer's instructions (Fig. 1F). The thickness of all three PC materials was a maximum of 1.5 mm over the pulp exposure leaving 1–2 mm of dentin and enamel available circumferentially for the future liner placement. The final restoration included placement of a polycarboxylate liner (Harvard Polycarboxylate Cement, Harvard Dental Intl, Germany) (Fig. 1G) and restoration of the cavity with silver amalgam (ARISTA-ALLOY 21, Cookson Precious Metals Ltd., Birmingham, UK) (Fig. 1H).

For group I: RMGIC (GC India Dental Pvt Ltd) was directly placed over the exposure site and the surrounding dentin using a plastic filling instrument with a small round tip then light-cured for 20 seconds using a visible light curing device (COXO, DB-685, Penguin, Europe) (470 nm wavelength, intensity 1,200 mW/cm²). The light source was placed as close as possible to the cement surface.

For group II: MTA: following manipulation, MTA was placed over the pulp exposure and also the dentin surrounding the exposure, followed by placing a sterile cotton pellet moistened with sterile distilled water, over the MTA, and the tooth was provisionally restored with intermediary restorative material (IRM) (Dentsply, USA) for 24 hours, after which the temporary restoration and the cotton pellet was removed³ and final restoration done as described above.

Figs 1A to H: 36 (A) Preoperative photograph; (B) Preoperative radiograph; (C) Rubber dam isolation; (D) After caries excavation; (E) Pinpoint pulp exposure noted; (F) Placement of RMGIC pulp capping agent; (G) Polycarboxylate base placed; (H) Silver amalgam restoration

For group III: CH: following manipulation, CH (GC India Dental Pvt. Ltd.) cement was placed over the pulp exposure and also the dentin surrounding the exposure. After the complete setting of the CH, the final restoration was done as described above.

Recall evaluation of the following parameters for each participant was at 24 hours, 3 weeks, 3 months, and 6 months:

- Recording self-reports from participants (S)
- Clinical inspection of the tooth (I)
- Evaluating radiographs for normal and pathological changes (R)
- Testing the pulp-capped teeth for vitality by electric and cold tests (V)
- Palpation (PA)
- Percussion (PE)
- Mobility (M)
- Probing depths (PD).

Statistical analysis was done using SPSS software version 16. The Chi-square test was applied to check for an association between different parameters and the groups. In addition, a 95% confidence interval for the success rate for all the 3 groups was calculated. A p value <0.05 was considered statistically significant.

RESULTS

All 45 participants returned for follow-up, 42 were asymptomatic and 03 of them presented with continuous pain, not relieved by medication, which were suggestive of irreversible pulpitis, and were excluded from the study. A consort flow diagram showing the enrollment, allocation, follow-up of all the participants included in this clinical study is as presented in Flowchart 1.

Group-wise comparison of signs and symptoms at the 6-month follow-up period (Table 1) showed that 15 participants from the RMGIC group, 13 participants from the MTA group, and 14

participants from the CH group did not complain of pain (Fig. 2), vitality testing revealed normal findings (Fig. 3). Vertical percussion elicited a negative response. Group-wise comparison of signs and symptoms at 24 hours, 3 weeks, 3 months, and 6 months are presented in Figures 2 to 4. Between the 3rd and 6th month follow-up, two participants from the MTA group and one participant from the CH group showed all signs and symptoms resembling irreversible pulpitis, and a decision was made to initiate endodontic treatment for these three participants (Figs 2 to 4). Since the p value for the Chi-square is >0.05 , indicates no significant association between different parameters and the groups.

DISCUSSION

VPT aims to maintain the coronal and radicular pulp tissue in a viable condition by preserving its vitality.¹ Direct pulp capping is one such procedure in which an exposed dental pulp is covered with a suitable material that protects the pulp from additional injury and permits healing and repair¹⁶ and alternative to root canal therapy or extraction. In group I, RMGIC was the PC material used. Conventional GIC and RMGICs have been used as PC agents since the early 90s.^{13,14,17}

Resin-modified glass ionomer cement combines the main advantages of glass-ionomer cements such as adhesion to the tooth structure, fluoride release, and biocompatibility, with the easy handling of light polymerization.¹⁸ In the RMGIC group, it was observed that none of the participants had any complaint with respect to the pulp-capped tooth at the end of the study period of 6 months. Shameem et al. used Vitrebond™, resin-modified glass ionomer liner and Vitremer™, resin-modified glass ionomer cement (GIC) in comparison with the control group of Dycal® as PC agents in iatrogenic exposures and observed that reparative dentin formed is comparable to that of reparative dentin formed with

Flowchart 1: CONSORT flow diagram

Table 1: Group-wise comparison of signs and symptoms at 6 months

			Groups					
			Rmgic		MTA		Calcium hydroxide	
			Count	Column N %	Count	Column N %	Count	Column N %
1.	S	Present	0	0	0	0	1	7.1
		Absent	15	100.0	13	100.0	13	92.9
2.	I	Normal	15	100.0	13	100.0	14	100.0
		Abnormal	0	0	0	0	0	0
3.	V	Normal	15	100.0	13	100.0	14	100.0
		Abnormal	0	0	0	0	0	0
4.	PA	Positive	0	0	0	0	0	0
		Negative	15	100.0	13	100.0	14	100.0
5.	PE	Positive	0	0	0	0	0	0
		Negative	15	100.0	13	100.0	14	100.0
6.	M	Present	0	0	0	0	0	0
		Absent	15	100.0	13	100.0	14	100.0
7.	PD	Normal	15	100.0	13	100.0	14	100.0
		Abnormal	0	0	0	0	0	0
8.	R	Satisfactory	15	100.0	13	100.0	14	100.0
		Unsatisfactory	0	0	0	0	0	0

Fig. 2: Bar graph depicts presence or absence of pain **Fig. 3:** Bar graph depicts vitality **Fig. 4:** Bar graph depicts presence/absence of tenderness to percussion

time-proven CH.¹⁹ Resin-modified glass ionomer cements have been considered as less biocompatible due to the release of unreacted monomers and other components which has discouraged the materials being used to cap the exposed pulp in human participants. However, Tarim et al.¹² in their animal study on exposed as well as non-exposed pulps in monkeys showed acceptable biological compatibility of the RMGIC for this application in both scenarios, confirming the results of a study done by Felton et al.¹³ using an experimental RMGIC. Vitremer/Vitrebond was the RMGICs used in all the above studies. The material used in the present study, i.e., Fuji II LC differed in its composition from the GICs used earlier like Vitremer/Vitrebond, which is a tri-cured RMGIC containing potential leachable components including unreacted HEMA, camphorquinone (CQ), diphenyliodonium chloride (DC), tricarboxylic acid (TA), potassium persulfate ($K_2S_2O_8$), and ascorbic acid responsible for the cytotoxicity.¹⁷ The photo-activator in Vitremer is DC but Fuji II LC uses *N,N*-dimethylaminoethyl methacrylate²⁰ could be the reason the present study showed no failures.

In group II, MTA was the PC material. Yasuda et al.²¹ compared MTA, Dycal, and adhesive resin cement. Their data indicated that MTA has no cytotoxicity after 72 hours and it not only significantly increases mineralization by stimulating dental pulp cells, but also increases the amount of bone morphogenetic protein-2 (BMP-2) production. Mineral trioxide aggregate as a DPC material has shown promising results³ and when compared with CH, has advantageous properties such as bioactivity with antibacterial and antifungal effect²² good biocompatibility, it is hydrophilic, radio-opaque, highly alkaline pH which makes it bacteriostatic, has the excellent sealing ability, low marginal leakage, and low solubility.⁸ When MTA and CH were used for DPC procedures for evaluating their effectiveness in maintaining long-term pulp vitality in clinical studies the authors observed that compared to CH, MTA appeared to be more effective.^{2,7}

In group III, CH was the PC material used. Considering the alkalinity, biocompatibility, and antimicrobial activity, it seems that CH is a suitable material for PC. However, its sealing ability has been observed to be not as complete as MTA,²³ and solubility in fluids is a problem that requires a good coronal seal. It does not have any inherent adhesive quality. The other drawback of CH is the presence of tunnel defects in the reparative dentin has been observed when CH has been used as a DPC material. A tunnel defect is a passage from the exposure site through the reparative dentin to the pulp which may consist of fibroblasts and capillaries in the defect.²⁴

The success of DPC depends on the ability of the operator to control bleeding after the pulp has been exposed during carious excavation and also before placing the PC material can affect the success of DPC. In the present study, a cotton pellet moistened with 3% NaOCl was used to control the bleeding as it has antibacterial property and controls the hemorrhage efficiently.²⁵ The reason for the failure of the three DPCs could be an inability to control bleeding or the size of the pulpal exposure may have exceeded 0.5 mm.

The limitations of this study were that the sample size was small with a shorter follow-up period and the dentin bridge formation was not evaluated.

CONCLUSION

All the three materials—RMGIC, CH, and MTA when used and evaluated as a DPC material over carious exposure of human permanent teeth provided a favorable result. There was no significant relationship between different parameters and the PC materials used in the study. Resin-modified glass ionomer cement can be recommended for DPC; however, further clinical studies need to be carried out.

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