Treatment Outcomes of 4 Vital Pulp Therapies in Mature Molars

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Abstract

Introduction: Vital pulp therapy (VPT) is a biological approach to minimally invasive endodontics. This randomized clinical trial aimed to evaluate and compare clinical and radiographic success of 4 VPTs (indirect pulp capping [IPC], direct pulp capping [DPC], miniature pulpotomy [MP], and full pulpotomy [FP]) using calcium-enriched mixture cement for deep caries management of mature permanent molars including teeth with clinical signs of irreversible pulpitis and the presence of apical periodontitis. **Methods:** Blinded participants (N = 302) were randomly allocated to 4 study arms. Random allocation was disregarded when visible pulp exposures did not happen after complete caries removal and the tooth was transferred to the IPC arm. Pre- and intraoperative data including vitality test results, pulpal/periapical status, and exposure type/location were recorded. Pain was measured using a numeric rating scale before treatment initiation up to 1 week postoperatively. Participants were followed up for 1 year. **Results:** The groups were homogenous in terms of age, sex, marital status, education, and practitioner; pre- and intraoperative conditions were similar in all arms and did not affect the long-term success. Preoperative pain and apical periodontitis were significantly different among arms ($P < .05$); however, it was not the case when the IPC group was excluded. After baseline pain adjustment, pain relief was continuous with similar patterns in all treatment groups. The 3- and 12-month success rates of the VPT techniques were comparable in the IPC (98.7% and 100%, respectively), DPC (98.4% and 94.7%, respectively), MP (98.4% and 91.4%, respectively), and FP (93.5% and 95.5%, respectively) arms, respectively ($P > .05$). **Conclusions:** In deep caries management of mature permanent molars, the 4 VPTs were associated with favorable/comparable clinical and radiographic outcomes. The pulpal and periapical status as well as pulpal exposure type/location had no effect on treatment outcomes. (*J Endod 2018;■:1–7*)

Key Words

Calcium-enriched mixture, CEM cement, endodontics, periapical periodontitis, pulp capping, pulpitis, pulpotomy, randomized controlled trial

Significance

For the first time, this randomized clinical trial has provided evidence that various VPTs had a similar promising performance in the management of vital mature teeth with clinical signs of irreversible pulpitis and/or the presence of apical periodontitis. These biological approaches as realistic alternatives in endodontics were highly effective and can be recommended for universal practice. In addition, CEM biomaterial can be used for such treatments.

The aims of vital pulp therapy (VPT) include the maintenance of vitality and preservation of the remaining pulp for adequate structural/functional healing of the pulp-dentin complex (1, 2). The key point in the success of VPT is continued vitality of the tooth, especially the presence of sufficient blood supply to advance (3). Vital permanent teeth irrespective of their signs/symptoms of irreversible pulpitis and the presence of apical periodontitis may indeed be candidates for VPT (4–6).

In clinical practice, VPT is an umbrella term for pulp capping (direct/indirect) or pulpotomy (miniature/partial/complete) (7, 8). Indirect pulp capping (IPC) administers a capping material covering the affected dentin over the unexposed pulp; during direct pulp capping (DPC), the covering agent is placed over the exposed pulp. Pulpotomy involves the removal of a minute amount (miniature pulpotomy [MP]) of the coronal pulp up to complete amputation of the coronal pulp (full pulpotomy [FP]) followed by direct coverage of the remaining pulp tissue.

Pulp capping agents should provide a suitable environment to promote regeneration of the dentin-pulp complex and be biocompatible, nontoxic, and antibacterial (9) to induce differentiation of odontoblastlike cells (10). In the new millennium, calcium silicate–based biomaterials such as mineral trioxide aggregate (MTA) and calcium-enriched mixture (CEM) cement have been widely used because of their biocompatibility and adequate properties (2, 11, 12).

CEM as a calcium silicate–based cement is a hydraulic and tooth-colored endodontic biomaterial. The cement has similar clinical applications but dissimilar chemical, physical, and biological properties as MTA (12). CEM is inexpensive and user-friendly and has no discoloration potential (13). *In vitro* studies on MTA and CEM cement have revealed that both endodontic biomaterials are capable of inducing hard tissue formation (ie, cementogenesis [14], dentinogenesis [15], and osteogenesis [16]).

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Randomized controlled trials have reported favorable clinical outcomes for FP with CEM cement in primary and permanent dentitions (12, 17). In a 5-year trial, FP with CEM cement also showed comparable outcomes with root canal therapy (RCT) in mature permanent teeth with irreversible pulpitis (18). In a recent case series, 4 CEM/VPT techniques were examined in 94 teeth for a mean period of 12.3 months. Only 1 radiographic failure was detected in the DPC group, and the remaining cases were successful (19); however, the level of evidence for this study is IV (20). In the absence of a clinical trial with a high level of evidence (ie, a well-designed randomized controlled trial) to compare the effectiveness of different VPT techniques, this clinical trial aimed to evaluate and compare the clinical and radiographic success of 4 VPTs (ie, IPC, DPC, MP, and FP) using CEM cement for deep caries management of mature permanent molars including teeth with clinical signs of irreversible pulpitis and the presence of apical periodontitis. In addition, the secondary objective of the study was to assess the influence of pre- and intraoperative factors on clinical/radiographic success.

Materials and Methods

This randomized controlled trial identified as NCT01561183 at clinicaltirals.gov was approved by the Ethics Committee of Shahid Beheshti Research Institute for Dental Sciences, Tehran, Iran. The trial was conducted in compliance with the ethical principles of the Helsinki Declaration. The trial was a 12-month randomized, parallel-group, open-label trial to evaluate the effectiveness of 4 VPT techniques (ie, IPC, DPC, MP, and FP) with CEM cement. The recruitment of participants was done in March 2012 through March 2013.

Patient/Subject Participants

Eligible participants were 12–75 years old and presented with 1 vital mature (ie, closed-apex) permanent molar characterized by deep caries in close proximity to the dental pulp. The teeth were restorable by direct restoration. Opposing teeth were present, and each tooth had at least 1 proximal contact. The pulp status was normal, reversible (pain caused by cold testing without lingering/spontaneous pain), or irreversible pulpitis (prolonged response to cold testing). The vital teeth with asymptomatic as well as symptomatic apical periodontitis (painful response to biting and/or percussion/palpation) were considered eligible. The patients selected had no systemic diseases or persistent chronic periodontal problems. After history taking, clinical/radiographic examination, and the prediction of pulp exposure after caries removal, the patients were informed about the trial, and the volunteers signed an informed consent form. The subjects were then randomly allocated to 1 of the 4 intervention groups.

Practitioner Participants

Practitioner participants (PPs) of the trial were dentists of the operative dentistry department of Imam Khomeini Dental Clinic, Tehran, Iran. The PPs received training in VPT methods, the use of CEM cement, and resin-bonded restoration (sandwich technique) to guarantee standardization among the practitioners.

Sample Size Calculation

In this trial, $\alpha = 0.05$ and power = 90% were determined. Based on the results of a previous review showing a success rate of 72.9%–99.3% for different VPTs (21), the proportion in population 1 (P1) and the proportion in population 2 (P2) were determined to be 99% and 73%, respectively (the most/least success rates; ie, FP/DPC). Using the equivalency formula for calculating the sample size, each arm should have had 27 participants. However, the superiority design of this study (ie, a study showing that one treatment is superior to another) dictated that with a delta of 0.05, 41 participants were needed for each study arm. Assuming an ~20% loss for recall during the 1-year follow-up, the number of study teeth was finally calculated to be 50 in each arm (sample size = 200). Because of convenient access to the pool of patients, 302 participants were recruited.

Interventions

FP. After anesthesia (lidocaine with 1/80,000 epinephrine), complete caries removal, isolation, and pulp exposure, the pulp chamber was unroofed with a sterile bur, and the pulp was then completely removed with a round-end sterile bur on high speed with very low pressure and copious irrigation. After irrigating the chamber with normal saline, a sterile cotton pellet soaked in 0.2% chlorhexidine was gently left over the orifices for ~5 minutes to achieve hemostasis. If bleeding continued, a sterile cotton pellet soaked in 5.25% sodium hypochlorite was placed to achieve hemostasis. The capping agent (CEM cement; BioniqueDent, Tehran, Iran) was then prepared according to the manufacturer's instructions and placed over the orifices with a thickness of approximately 2–3 mm. The cement was then covered by a layer of light-cured glass ionomer (Vitrebond; 3M ESPE, Irvine, CA), and the remaining cavity was then restored with resin-bonded composite (Filtek, 3M ESPE).

MP. After pulpal exposure, an ~1-mm-deep cavity was prepared with a round-end sterile diamond bur. Irrigations, hemostasis, pulp covering, and restoration were similar with the FP group.

DPC. The exposure area was directly covered with a layer of CEM cement. Irrigations, hemostasis, and restoration were similar with the FP group.

IPC. The caries closest to the pulp were removed, without any visible pulpal exposure. Approximately 2-mm thickness of the CEM cement was placed over the pulpal wall; restoration was similar with the FP group.

Randomization/Allocation Concealment/Blinding

Block randomization was conducted, and sealed pockets were used for allocation concealment. The only medical/ethical exception was prescribing IPC in the absence of pulp exposure after complete caries removal. Patients were unaware of the treatment option in this single-blind trial. It was not feasible to blind the PPs to the VPT techniques.

Data Collection

Demographic data including age, sex, marital status, and education level as well as universal tooth number undergoing treatment were registered. Pre- and intraoperative data including the electric pulp test (EPT, examined by a 0–10 scale) and binary variables including the cold test, pulpal/periapical status, and exposure type/location were also registered. Pain was measured using a pain numeric rating scale with ratings between 0 and 9 at pretreatment; at 6, 12, 18, 24, 36, 48, and 60 hours; and at 3, 4, 5, 6, and 7 days posttreatment. The EPT and cold test were repeated at the 1-week recall session. Clinical success was determined by clinical examination of the studied teeth and recording subjective data. Radiographic success was determined by assessing postoperative radiographic images.

Outcome Measures

The primary outcome of the study was clinical/radiographic success. Clinical failure was determined by signs/symptoms of inflammation/infection (ie, swelling, abscess, sinus tract, and pain that could not be controlled by medication). Nonsteroidal anti-inflammatory drugs