Original Research Article

Comparative evaluation of post-operative pain with different calcium hydroxide formulations when used as intracanal medicament in root canal treatment- In vivo study

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The purpose of this study was to compare to evaluate the post operative pain with different calcium hydroxide formulations when used as intracanal medicament in root canal which was evaluated by VAS scale.

Materials and Methods: The 150 subjects were randomly assigned to four groups and one control group depending upon the intracanal medicament: Group 1: Calcium hydroxide paste (Ivoclar) was used as intracanal medicament, Group 2: Calcium hydroxide paste with iodoform (Metapex) was used as intracanal medicament, Group 3: Calcium hydroxide points (Hygenic) was used as intracanal medicament, Group 4: Calcium hydroxide paste using chitosan (0.2%) as vehicle was used as intracanal medicament, Group 5: Control group containing dry sterile cotton. The incidence and intensity of preoperative pain and experienced post operative pain (on 6th, 12th, 24th and 48th hour) after first visit of treatment were assessed according to patient’s recordings in visual analogue scale.

Results: The medicament causing least operative pain are ranked according to superiority as Calcium hydroxide paste > Calcium hydroxide points > Calcium hydroxide with chitosan > calcium hydroxide with iodoform

Conclusion: At 6th postoperative hour, least post operative pain was recorded by the calcium hydroxide points and high post operative pain in calcium hydroxide with iodine (Metapex). At 12th, 24th, 48th postoperative hour least post operative pain was recorded by calcium hydroxide paste (Apexcal).

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1. Introduction

Endodontics has taken huge stride since its inception, to alleviate the pain. In fact one of the major criteria for success following endodontic treatment is related to the elimination or reduction of postoperative pain. Researchers have been trying to handle the post operative pain both systemically and locally. But understanding pain is not as simple as it seems. It is at first, a sensation derived from various stimuli and second, an emotional response to the stimulus (O’Keefe 1976).¹

Post operative pain may be associated with inflammation in the periradicular tissues caused by over instrumentation, or irritants egressing from root canal during treatment or the presence of microorganisms as a result of failure to properly disinfect the canals. It has been established beyond doubt that bacteria play a decisive role in the development of endodontic lesions.² Residual bacteria in the apical part of root canal have been held responsible for the failures. Consequently one of the major goals of successful endodontics is elimination of bacteria from root canal space and the removal of substrate they depend on.³

According to Schilder, cleaning refers to removal of all contents of root canal system before and during
shaping. However, complete total elimination of bacteria from root canal is difficult to accomplish and significant portions of the root canal walls remain untouched after mechanical instrumentation. Consequently, chemical irrigant and intracanal medicaments seem necessary for eradication of infected tissues and microorganisms in addition to mechanical debridement.  

Various medicaments used in endodontics range from phenolic compounds and its derivatives, chlorhexidine gluconate, calcium hydroxide, triple antibiotic paste, formocresol etc. The effect of high pH of calcium hydroxide alters the integrity of cytoplasmic membrane by means of chemical injury to organic component and transport of nutrient. In the bewildering array of materials used in the field of endodontics, calcium hydroxide has resisted the test of time. There is still a gap in the knowledge regarding the best medium to be mixed with calcium hydroxide. Of these, ever since its introduction by Hermann in the beginning of 20th century, calcium hydroxide has gripped endodontics in a wide array of uses.  

It is believed that hydroxyl ions from calcium hydroxide develop their mechanism of action in the cytoplasmic membrane, because enzymatic sites are located in it. Thus this medication presents two fundamental enzyme properties: the inhibition of bacterial enzymes leading to antimicrobial effect and activation of tissue enzymes such as alkaline phosphatase leading to mineralization effect.  

Various vehicles like water, saline, glycol, etc. have been tried to carry calcium hydroxide to achieve maximum efficiency but still search of better vehicle is going on. Vehicles can speed up or slow down the ionic dissociation, substances that aid the filling of pulpal cavity by means of their consistency, substances used as antimicrobial medium and media that enhance radioopacity.  

Metapex, is a silicone oil based calcium hydroxide paste containing 38% iodoform. Iodoform based calcium hydroxide paste, all over the years has been used exhaustively as it is antiseptic due to iodine release in nascent state when it comes in contact with secretions or endodontic infections. Iodine action gives them a high reactivity by precipitating proteins and oxidizing essential enzymes and it is used as disinfectant as well as antiseptic.  

Chitosan is a natural polysaccharide and has a property of biocompatibility, biodegradability, bioadhesion and biotoxicity to the human body. Chitosan has a broad spectrum of antibiotic properties and it has high chelating ability for various metal ions in acidic condition. Chitosan is obtained by deacetylation of chitin which is found in crab and shrimp shells (Kurita 1998) and has become ecologically interesting for various applications because of its abundance in nature and low production cost (Peter 1995). The chelating behaviour of chitosan indicates that this solution acted on the inorganic portion of the smear layer, favouring its removal. Its addition to calcium hydroxide, chitosan when used as an intracanal medicament has been shown to promote prolonged calcium ion release (Ballal et al 2009).  

Despite of its several advantages, removal of calcium hydroxide from the root canal can be time consuming and has been shown to interact with sealers, so an innovative solution to these drawbacks is the introduction of calcium hydroxide points as an intracanal medicament (Hegde M N et al 2006). The points are 28mm in length and a distinctive brown colour differentiates the calcium hydroxide points from the gutta percha points. They serve as an effective alternative to calcium hydroxide paste and are available in ISO sizes of 15 to 140. Calcium Hydroxide Points are made of 52 % calcium hydroxide, 42% gutta percha, sodium chloride and surfactant and colouring agents. When used as an intra canal medicament in endodontic therapy, moisture in the canal activates the calcium hydroxide and the pH in the canal rises to level of 12+ within minutes. The average treatment time is 1-4 weeks. Calcium hydroxide points maintain an outer dentin pH above 9.5 when compared to aqueous calcium hydroxide.  

Various studies on post operative pain evaluation comparing calcium hydroxide with other medicaments have been done but studies comparing post operative pain following medication with different vehicles of calcium hydroxide are not many. Thus this pioneer study is undertaken to evaluate the effectiveness of water based calcium hydroxide, iodoform based calcium hydroxide, calcium hydroxide with chitosan as vehicle and calcium hydroxide points when used as intracanal medicament in relieving post operative pain.  

2. Materials and Methods  
One hundred and fifty patients requiring root canal treatment on maxillary or mandibular anterior, mandibular first and second mandibular premolars were included in this prospective study. A detailed medical history, dental history & drug history (including drug intake and drug allergies) of all the patients were recorded. Before starting the procedure, an informed consent was obtained from all the patients. The age, gender and tooth number of patient was recorded.  

Patient selection was based on the following factors:  
1. Positive patient acceptance of proposed treatment procedure.  
2. Sufficient treatment time available to properly complete the procedure.  
3. Single rooted teeth were included in the study.  
4. Vital teeth  
5. Presence of sinus tract  
6. Teeth with irreversible pulpitis, with or without apical periodontitis  
7. Teeth with periapical resorption.  
8. No previous root canal intervention
9. Tooth mobility within 0 to 1 degree

2.1. Exclusion criteria

1. Patients with a positive history of antibiotic usage within the past month.
2. Pregnant patients.
3. Patients requiring antibiotic premedication for dental treatment (including infective endocarditis, prosthetic joint and immunocompromised disorders.
4. History of allergy
5. Failure to sign informed consent
6. Teeth with root caries
7. Calcified canals
8. Teeth with periapical radiolucency greater than 0.5 cm

2.2. Assessment of pain

The intensity of pain was measured by instructing patients to complete a visual analogue scale (VAS) using Verbal Descriptor Scale (VDS) as a guide. Before starting the treatment procedure, all the patients were instructed to place a mark on the horizontal scale to represent the intensity of postoperative pain experienced. The markings on the VAS were measured and the degree of pain was categorized as:

| Visual Analogue Scale (VAS) Score | Score |
|----------------------------------|-------|
| No pain                          | 0     |
| Mild pain                        | 0.1-3 |
| Moderate pain                    | 3.1-6.9|
| Severe pain                      | 7-10  |

The procedure of the study was explained to the patient in local language and a written consent form was obtained. After clinical examination and radiographic examination, patients were randomly assigned to five groups. Each group had sample size (n=30) depending upon intracanal medicament used as follows:

- **Group 1**: Calcium hydroxide paste (Ivoclar)
- **Group 2**: Calcium hydroxide paste with iodoform (Metapex)
- **Group 3**: Calcium hydroxide points (Hygenic)
- **Group 4**: Calcium hydroxide paste using chitosan (0.2%) as vehicle
- **Group 5**: Control group containing dry sterile cotton

After proper diagnosis, history taking and examination, the tooth requiring root canal treatment were anesthetised with 1.8ml, 2% lignocaine with 1:100,000 epinephrine. After rubber dam isolation, access cavity was prepared on each tooth and working length (WL) was determined with #15 k-file using an electronic apex locator. WL was confirmed with a digital X-ray (RVG 5100). All canals were prepared with Protaper NEXT file system (Dentsply) following crown down technique. Copious irrigation was done alternatively with 3% NaOCl and 15% EDTA with the last flush of normal saline. The 150 selected samples were randomly divided into four study groups depending upon the intracanal medicament used as follows:

3. Results

The results of our study show that application of calcium hydroxide propylene glycol based paste (Group 1) in root canal reduces the post operative pain after 12, 24 and 48 hour post operative better in comparison to other groups.

The post operative pain was minimum with (Group 3) calcium hydroxide points and maximum with (Group 5) control group at 6th post operative hour. After 12 hours post operative pain was minimum with (Group 1) followed by Group 3 and maximum with (Group 5) control group. After 24 hours post operative pain was minimum with (Group 1) followed by Group 3 and maximum with (Group 5) control group. After 48 hours post operative pain was minimum with (Group 1) followed by Group 3 and maximum with (Group 5) control group.

We found that the medicament causing least operative pain are ranked according to superiority as Calcium hydroxide paste > Calcium hydroxide points > Calcium hydroxide with chitosan > calcium hydroxide with iodoform. At 6th postoperative hour, significant difference was observed in the incidence of post operative pain between all four calcium hydroxide groups (Group 1, Group 2, Group 3, and Group 4) with control group (Group 5). Also statistically significant difference was seen between Group 2 with Group 1 (calcium hydroxide with iodoform with calcium hydroxide paste) & Group 2(calcium hydroxide with iodoform) with Group 3 (calcium hydroxide points). At 12th postoperative hour no statistically significant difference was found among all groups. At 24th postoperative hour, significant difference in post operative pain was found between (Group 1) calcium hydroxide paste and (Group 5) control, calcium hydroxide with iodoform (Group 2) and (Group 5) control group, (Group 3) calcium hydroxide points with (Group 5) control group, (Group 4) calcium hydroxide with chitosan and (Group 5) control group. In this study group 1 with time interval of 6 hour and 24 hour showed statistically significant results (Figure 6)

4. Discussion

The golden rule of successful root canal therapy is infection elimination and three dimensional obturation of the canal to preclude subsequent reinfection. However,
current techniques of debridement leave parts of root canal space completely untouched by the instruments.

Different media, such as normal saline, distilled water, chlorhexidine etc are used for mixing of calcium hydroxide, thereby affecting its dissociation into \( \text{Ca}^+ \) and \( \text{OH}^- \). However, there is still a gap in the knowledge regarding the best medium to be mixed with calcium hydroxide. Therefore, this study is carried out to determine which medium is more efficient when mixed with calcium hydroxide in terms of reduction of interappointment pain.

Apexcal is a viscous polyethylene glycol based paste which contains calcium hydroxide 29%, bismuth carbonate 22% and excipients (polyethylene glycol, glycerine, and water) 49%. It showed very homogenous and constant consistency overtime. Estrela et al described that liberation of calcium and hydroxide ions was faster and more significant when used as calcium hydroxide distilled water paste.

Metapex contains calcium hydroxide with iodoform in silicon oil. In 1928 Walkoff introduced iodoform as a root canal filling material in primary teeth. The superior antimicrobial effects of Metapex may be due to the combination with iodoform and to the viscous and oily vehicle, which may prolong the action of the medicament. Accordingly, a study showed that oily vehicles increase the antimicrobial effects of calcium hydroxide against E. faecalis and other bacteria.

The temporary calcium hydroxide points are new device for calcium hydroxide delivery for intracanal dressing which contain calcium hydroxide at concentration of 50-54% that can be easily inserted and removed from the pulp space when their role is accomplished with presence of few residues.

Chitin is a straight homopolymer consisting of (1,4)-linked N-acetyl-glucosamine units, which can be found in the exoskeleton of crustaceans such as crabs and shrimps. Chitosan is composed of copolymers of glucosamine and N-acetyl-glucosamine. Chitosan is generally regarded as biocompatible, non-toxic, and biodegradable and is inherently antibacterial in nature.

As per the available literature, various calcium hydroxide preparations have been tried so as to utilize its antibacterial potential. The reason that Apexcal showed minimum post operative pain might be that propylene glycol present keeps it to remain in paste form for a considerably longer period of time which indicates its good handling qualities. Other paste preparations dries up within a short period of time which is not desirable as it would be less convenient for use as intracanal medicament.

The results of our studies are in concurrence with Paul K et al 1997, Shetty S et al 2014 who found that paste of calcium hydroxide with propylene glycol exerts significant antibacterial action. According to Shetty S et al 2014 the high \( pH \) of calcium hydroxide paste with propylene glycol may be attributed to its high molecular weight (76.09) hygroscopic nature and viscosity thereby having sustained release of ions.

According to Chew Han Ho et al (2000) calcium hydroxide points maintained an outer dentine \( pH \) above 9.5 for approximately 2 days, whereas the aqueous calcium hydroxide paste did not reach this \( pH \). This illustrates the increased mobility of the hydroxyl ions released by the points compared with aqueous calcium hydroxide paste. The alkalisation of outer root dentin is important to achieve in situations where the aim is to reverse the acid environment necessary for root resorption by osteoclasts. According to Likoloas Economides et al 1999 the initial high \( pH \) value of calcium hydroxide points may be due to the increased amount of calcium hydroxide (50-52%) in its composition and ability of material to leach out in the moist environment of root canal.

The results found in our study are in accordance with Larsen and Bindslev who observed that the aqueous suspension exhibited the highest \( pH \) and calcium ion liberation. They also observed that the oil paste containing calcium hydroxide was largely lacking in both ion release and antimicrobial properties. Tchaou et al and Pabla et al reported least antimicrobial activity of Metapex against aerobic and anaerobic bacteria in comparison to zinc oxide, eugenol, KRI paste and MAISTO paste in their study.

The results of this study show variations between the hydroxyl ion release dynamics of different commercial calcium hydroxide pastes. The commercial products used in this study vary in composition, in terms of the solvents and thickeners, and in the loading of calcium hydroxide. It has been shown that lower the contact angle, the faster the medium will spread on tooth surface, and contact angle less than 90°indicates good wetting properties. A low viscosity is desirable to permit flow of medication into root canal and a high penetration concentration. Estrela et al (2002) demonstrated that the lower the viscosity, the higher the ionic dissociation of calcium hydroxide. Thus under the limitations of this study viscous calcium hydroxide paste – propylene glycol remains the material of choice as a vehicle over calcium hydroxide points, oil based paste (metapex), aqueous (chitosan) calcium hydroxide paste.

5. Conclusion

Thus from this study we come to conclusion

1. During the observation period, diffusion of ions had taken place and an alkaline \( pH \) was maintained by all the calcium hydroxide formulations.
2. At 6th postoperative hour, least post operative pain was recorded by the calcium hydroxide points and high post operative pain in calcium hydroxide with iodine (Metapex).
3. At 12th, 24th, 48th postoperative hour least post operative pain was recorded by calcium hydroxide paste (Apexcal).

6. Conclusion

Within the limitation of the present in vivo study, it can be concluded that:

1. Calcium hydroxide paste (propylene glycol/water based) is most effective in reducing pain from 6 hour to 48 hours.
2. Calcium hydroxide points significantly showed lowest pain scale which got later increased at 12 hour, 24 hour, and 48 hour.
3. Control group without any medicament showed maximum post operative pain as compared to other groups at 6 hours, 12 hours, 24 hours, and 48 hours.
4. A definite conclusion as to which intracanal material medicament should be preferred between calcium hydroxide paste, calcium hydroxide with iodoform, calcium hydroxide points and calcium hydroxide with chitosan, can be withdrawn after correlating the findings of the present study with other clinical studies. Therefore more studies are advocated to reach a definitive conclusion.

7. Source of Funding

None.

8. Conflict of Interest

None.

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