





The Effect of Different Combinations of Calcium Hydroxide as Intra-Canal Medicament on Endodontic Pain: A Randomized Clinical Trial Study

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ABSTRACT

Introduction: After treating the tooth root canal, pain is one of the problems that many patients are facing. In order to reduce pain, and regarding the advice of treating necrotic teeth during several sessions, intra-canal medicaments can be used between sessions. The purpose of this study is to compare pain relieving effect of calcium hydroxide combined with three solutions of normal saline, chlorhexidine 2% and dexamethasone. Materials and methods: This triple blind randomized clinical trial was performed on 90 necrotic molars and premolars. The patients were classified in three medicaments' groups including mixture of calcium hydroxide and normal saline (G1), chlorhexidine 2% (G2) or dexamethasone (G3) that were placed in the canal during the first treatment session. The patients were provided with a Heft-Parker Visual Analog Scale form to record their pain in different intervals of 4, 24, 48, 72 and 96 h after cleaning and shaping the root canal. Data analysis was carried out using the Chi-Square, one-way ANOVA and Repeated Measure tests. Results: No significant difference was observed in the mean pain of the groups after 4 h (P>0.05). However, a significant difference was found between G1 and G3 in the mean pain from day 1 to 72 h after treatment. The mean pain was less in dexamethasone (G3) group (P<0.05), but the difference was not statistically significant at 96 h after treatment (P>0.05). No significant difference was found between "G2-G1" and "G2-G3" groups at different time intervals (P>0.05). Conclusion: The mixture of calcium hydroxide and dexamethasone compared to calcium hydroxide and normal saline in short and medium time had a significant effect on reducing pain after cleaning and shaping the root canal. It seems that the mixture of calcium hydroxide and dexamethasone can be considered as an effective medicament on reducing pain during root canal treatment sessions.

Keywords: Root Canal Therapy; Postoperative Pain; Dexamethasone; Calcium Hydroxide, Chlorhexidine

Introduction

Pain is common during an individual's life as an unpleasant sense. Dental treatments are often associated with pain [1-4]. Despite recent advances in pain management [5], in studies, pain has been reported with a prevalence of 2.53 to 58% [6, 7] indicating that post-endodontic pain continues to be highly prevalent.

Various factors have been identified for endodontic pain, including pre-treatment inflammatory conditions, or development of periapical root canal and degeneration of pre-

apex zone. The severity of pain is also related to genetics, patient's immune status, infection and rate of tissue degeneration, one of the predictive factors for pain after treatment is asymptomatic necrotic pulp with a periodontal lesion [8-15].

Considering the advice of treating during several sessions for teeth with non-vital pulp, intra-canal medicaments can be used for different purposes, such as reducing the amount of bacteria or inflammatory agents. In teeth with necrotic pulp, it is agreed that these teeth are more resistant to endodontic treatment and may require several sessions of endodontic treatment and as a result, for treating during several sessions, an antimicrobial dressing could be applied for approximately one week between sessions and inside the canal to maximize antimicrobial activity [16, 17].

Today, calcium hydroxide (CH) is considered as one of the most effective intra-canal medicaments in endodontic treatment because of its alkalinity and antimicrobial properties [18, 19]. However, meta-analyzes did not show a significant effect on pain relief [20]. Chlorhexidine is also one of the intra-canal irrigant that affects many gram positive and negative bacterial species [21, 22].

Another medicament used to reduce endodontic pain in different ways is corticosteroids family. The use of corticosteroids was criticized by Sinkford and Harris on 1964 [23] and Klotz on the following year [24]. They claimed that although the use of corticosteroids inhibits hyperemia or inflammation in vital teeth, it also has systemic complications, which was rejected by Abbot on 1992 [25]. Other recent studies did not report any specific side effects for this category [3, 26]. Although some recent studies claim that assumption of corticosteroids is effective for endodontic pain management [27, 28], however, due to the variety of intervention types or different methods of procedural unity, there is no evidence of the effect of corticosteroids on the reduction of endodontic pain [29, 30].

Therefore, the purpose of this study is to investigate the effect

of pain relief with medicaments of 1-calcium hydroxide and normal saline 0.9% (G1), 2-calcium hydroxide and chlorhexidine 2% (G2) and 3-calcium hydroxide and dexamethasone 8 mg/2 mL (G3) during treatment sessions in the root canal of necrotic molars and premolars.

Methods and materials

This study was a triple blind clinical trial approved by Aja University of Medical Sciences Ethics Committee, Tehran, Iran (IR.AJAUMS.REC.1397.005), as well as registered at the Iranian Center for Clinical Trials Registration www.irct.ir (IRCT20180521039766N1), on a total of 90 necrotic molars and premolars referred to the dentist.

The number of patients was obtained using software Med Calc. version 7.5 (Mariakerke Belgium); the test error was 5% and the test power was 80% [31]. According to Cochran formula, the sample size was estimated n=85 and by considering the division of patients into three groups, the total of 90 patients (30 patients in each group) were examined, otherwise putting patients in each group randomized and continued until it reached the aforementioned limit.

Table 1. Demographic information including the patients' gender, teeth type and age

N (%)	CH+Normal saline	CH+Chlorhexidine	CH+Dexamethasone	Total	P-value***					
Gender*										
Male	17 (56.7)	11 (36.7)	12 (40)	40 (44.4)	0.248					
Female	13 (43.3)	19 (63.3)	18 (60)	50 (55.6)						
Teeth type*										
Molar	25 (83.3)	26 (86.7)	23 (76.7%)	74 (72.2)	0.587					
Pre Molar	5 (16.7)	4 (13.3)	7 (23.3%)	16 (17.8)						
Total	30 (33.3)	30 (33.3)	30 (33.3)	90 (100)						
Age** Mean (SD)	27.90 (11.868)	25.90 (10.240)	29.47 (13.048)	27.76 (11.734)	0.504					

^{*} Amount (%), Chi- Square test; **Mean (SD), one- way ANOVA; *** The mean difference is significant at the 0.05 level

Table 2. The number of individuals with comparing the significance of the mean pain between the groups at different intervals

N (%)		None*	Mild*	Moderate*	Severe*	Tukey test	P-Value
4 h	G1	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)		
	G2	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	Not significant between groups	0.665
	G3	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)		
24 h	G1	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G1 and G3	
	G2	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G1: 34.67±51.443	0.019**
	G3	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G3: 7.87±24.126	
48 h	G1	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G1 and G3	
	G2	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G1: 29.50±40.905	0.035**
	G3	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G3: 6.17±30.981	
72 h	G1	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G1 and G3	
	G2	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G1: 16.63±39.406	0.028**
	G3	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	G3: 0.67±2.537	
96 h	G1	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)	Not significant between groups	0.161
	G2	14 (46.7)	13 (43.3)	2 (6.7)	1 (3.3)		

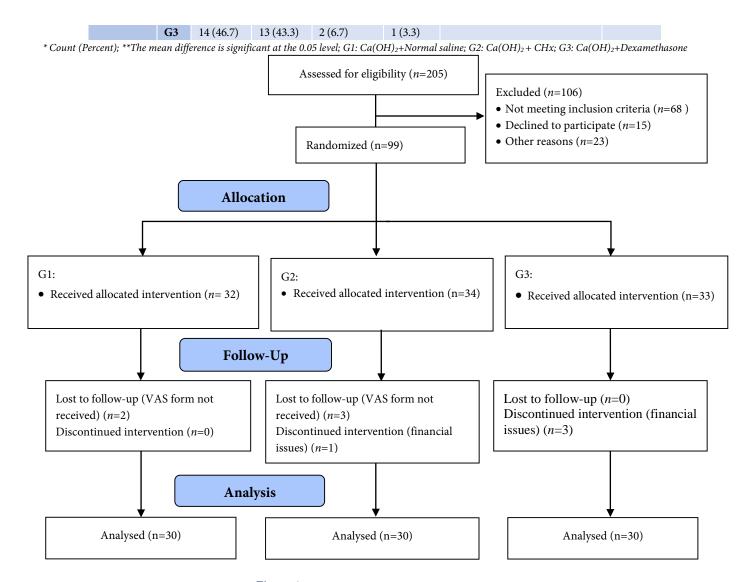


Figure 1. Flow-chart diagram of the study design

The study inclusion criteria included the absence of any systemic disease, necrotic molar or permanent premolar with closed apex, lack of any kind of resorption, non-use of antibiotics and pre-treatment analgesics; and the study exclusion criteria included no referral for continued treatment, patient's unwillingness to co-operate, not registering pain in the relevant form, pregnancy, non-restorable teeth, allergy to analgesics, suffering from a systemic disease and a history of chronic use of analgesics, drugs or alcohol.

In the first treatment session, after obtaining informed consent and performing vitality tests to confirm the necrotic condition, anesthesia was performed with lidocaine 2% plus epinephrine 1:80.000 (Daroopakhsh, Tehran, Iran) as an infiltration injection for maxillary teeth and block injection of inferior alveolar nerve for mandibular teeth. After ensuring

anesthesia, the teeth were isolated by rubber dam and after providing the access cavity, the length was determined using apex locator Root ZX (Morita Corporation, Japan), 1 mm less than the apex mark of the device, also re-checked by periapical radiography. Finally, cleaning and shaping were done by step back method and with handy K-files (Mani, Togichi, Japan).

The patients were categorized by an assistant according to random numbers Table. The dentist, patient and statistical analyst did not know the groups. Three different medicaments including CH (Golchai, Iran) with chlorhexidine 2% (Maquira, Brazil), dexamethasone 8 mg/2 mL (Caspian, Iran) or normal saline 0.9% (Samen, Iran) were prepared by an assistant with the same module and proportion for patients (0.12 g powder plus 0.14 mL liquid) on a glass slab and provided to the dentist. It was placed in the canal with lentulo (Thomas, France) for one week, and the tooth

was dressed with Cavisol (Golchai, Iran).

The patients were provided with a pain registration form based on the Heath-Parker VAS (Visual Analog Scale) to record

their pain at different intervals of 4, 24, 48, 72 and 96 h after

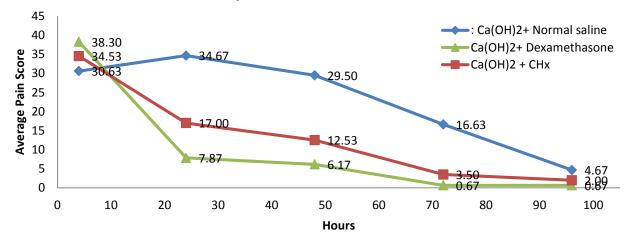


Figure 2. The mean (SD) of pain in treatment groups

cleaning and shaping of the root canal. In the second session, the patients referred in order to complete the root canal treatment.

The forms presented to the patients included a scale of 0 to 170 mm such that 0 mm was related to no pain, 1-54 mm was related to mild pain, 55-113 mm was related to moderate pain and 114-170 was related to severe pain. Meanwhile, the patients were asked to record the amount of their used analgesics by the fourth day.

The collected data were analyzed by SPSS software version 23 (SPSS Inc., Chicago, US). The Chi-Square test were used to assess the demographic variables of gender and type of teeth in the groups. The One-way ANOVA was used to examine the difference between the mean age and level of analgesics consumption in groups, as well as the comparison of mean pain at different time intervals.

Tukey's post hoc were used for pair wise group comparisons. In order to compare the effect of three medicaments, as well as the effect of time on the treatment, we used repeated measures analysis of variance. Data was presented in the form of time-dependent figures and tables of pain-demographic measurements. The significance level for the tests was considered 0.05.

Results

Totally 99 patients had the study inclusion criteria, 4 patients (4.0%) were excluded due to reasons such as economic issues and 5 patients (5.0%) due to failure to complete or give back pain registration form (Figure 1).

The remaining 90 patients were 40 men (44.4%) and 50 women (55.6%) with the mean age of 27.76 ± 11.734 (min 15 and max 65

years) in three different groups with 30 patients. Demographic variables of the patients are presented in Table 1. The Chi-Square test revealed that no significant difference was found between gender and tooth types in the groups (P>0.05). Also the One-way ANOVA also showed that no significant difference was found between the groups in terms of mean age (P>0.05). Also, no significant difference was found between the groups in terms of four-day mean of analgesics consumption (1.36 \pm 2.432) (P>0.05) (Table 1).

Numbers and percentages of those who have reported different pain rates at different time intervals have been reported in Table 2. Analysis of one-way ANOVA showed that in the first 4 h after the first session of treatment and 96 h after that, the mean pain reported was not significant between the groups (*P*>0.05). Tukey post hoc showed a significant difference in terms of mean pain at 24,48 and 72 h after the first session of treatment between the groups of CH and normal saline (G1) and CH and dexamethasone (G3) (*P*<0.05), and the mean pain was lower in dexamethasone group (Table 2). Figure 2 compares and shows the mean of the reported pain in the three treatment groups and in relation to time.

Repeated measures analysis of variance showed that the treatment between the groups as well as the effect of time and treatment was significant (P<0.05).

Discussion

This triple blind clinical trial reviewed pain relieving effect of three medicaments in the root canal of molars and premolars with necrotic pulp. It seems that a mixture of CH and dexamethasone was more effective than the other medicaments since the first 3 days. Although in the long run the amount of pain was still minimal with dexamethasone mixture and had the lowest mean pain, but after four days no significant difference was observed in the groups.

Although previous studies have already shown pain relieving effect of CH, some theoretical studies contradicted no effect of calcium hydroxide [32-34], and on the same hand a review study also concluded that CH had no significant effect on pain relief [20].

Some studies have also compared the effects of corticosteroids and calcium hydroxide [35-37]. In a systematic review study that investigated pain relieving effect of corticosteroids on post-operative pain, Iranmanesh *et al.* [29] stated due to the fact that studies that did not report the negative results of corticosteroids' effect on pain reliving were not published and also because of the difference in the study methods, it was not possible to conclude and accurately evaluate the effect of corticosteroids on pain relief. Accordingly, no specific dose of corticosteroids has been proposed. However, they stated that the intra-canal dose can be safe and effective [29].

Gama *et al.* [38] in their study on 138 asymptomatic teeth compared the effect of CH and chlorhexidine on post-operative pain and concluded that no significant difference was found between the groups at each of the intervals [38].

Therefore, in this study, the mixture of CH powder with solutions of normal saline, 2% chlorhexidine and dexamethasone to reduce pain after the root canal treatment were compared. The results showed that, except for the 4th h and 4th day after treatment, the group with CH mixed with dexamethasone significantly reduced pain compared to CH and normal saline group, although no significant difference was found at all intervals of the chlorhexidine group in terms of pain reliving in comparison with dexamethasone or normal saline groups.

In the study by Moskow *et al.* [39] which was conducted on 55 vital teeth, dexamethasone and saline were used as the final rinsing solution, as in the present study, they showed a significant difference between 24 and 48 h, and within 72 h no significant difference was observed between the groups [39], which is inconsistent with this study, which could be due to the durability or effect of the paste state of the mixture of CH and the medicaments in the present study in comparison with their study or it may be due to the difference in vitality state of the teeth in the studies.

The study by Ehrmann *et al.* [40] examined the effect of Ledrmix corticosteroid medicaments compared to calcium hydroxide paste or the absence of medicaments in the root canal of 223 non-vital teeth. They acknowledged that after 4 hours, a significant difference was observed between the groups in terms of pain before treatment and until the 4th day, pain reduction was

significant compared to the two other groups. The difference in the results of the fourth hour may be due to the difference in the type of corticosteroid and use of antimicrobials such as EDTA and NaOCl in the study for the canal rinsing, which can be considered as a confounding factor [40].

Rogers *et al.* [41], who compared pain relief of intra-canal forms of ketorolac, dexamethasone, ibuprofen and placebo on 48th maxillary teeth, reported no significant difference in the first 6 hours after treatment [41]. Iranmanesh *et al.* [29] also in their review concluded that the greatest effect of corticosteroids was at 35-48 hours after the treatment [29] which was consistent with the present study.

The present study is consistent with the study by Gama *et al.* [38] as well as Hepsenoglu *et al.* [42] which compared the relieving effect of CH and 2% chlorhexidine gel on 150 asymptomatic teeth that needed to be re-treated.

One of the limitations of this study is the difficulty of the study inclusion criteria in the referred population, and it is suggested that in future studies, different corticosteroids' doses should be studied with each other according to their post-treatment pain relief.

Conclusion:

Under the conditions of this study, and in patients with necrotic pulp, it seems that the combination of calcium hydroxide and dexamethasone can be considered as an effective medicament on reducing pain during the root canal treatment sessions.

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The current study was approved by Aja University of Medical Sciences Ethics Committee, Tehran, Iran (IR.AJAUMS.REC.1397.005), and registered at the Iranian Center for Clinical Trials Registration www.irct.ir (IRCT20180521039766N1).

Conflict of Interest: 'None declared'.

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