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Post-operative Pain after Using Calcium Hydroxide and Ledermix Intercanal Medication with 5.25% Sodium Hypochlorite Irrigation: A Randomized Controlled Trial

Alferra AAAS*

Department of Endodontics, October 6 University, Egypt

Abstract

Aim: The mean goal of this article is to evaluate the pain after using of intracanal medications; calcium hydroxide and Ledermix with 5.25% sodium hypochlorite irrigating solutions utilizing Visual Analogue Scale.

Material and methods: 44 patients dividing into two groups then into two visit treatment which the first visit access cavity was performed after anesthesia and cleaning and shaping by using perotaper universal with irrigation protocol and then canal dried then either calcium hydroxide or Ledermix is applied inside the canal and then closed by temporary filling then after 7 days in the second visit canal irrigation and dry then obturation performed by single cone which selecting responding to master apical file. Mark the Visual Analog Scale using to measure the pain by patient as follows; immediate after treatment in the first visit before, after 3 hours, after 24, 48 hours, 7 days and after obturation.

Results and Discussion: Before root canal treatment, after mechanical preparation, 1 day, 2 days, and 7 days of the first visit and immediately after obturation, shows no different in pain value between all groups. After 3 hours of first visit, Ledermix group shows markedly lower pain value in Visual Analog Scale (VAS) score than NaOCI 5.25% group.

Conclusion: With limitation of this study there were slightly different between both groups. There's no real data to prove that using of ledermix lead to relief the post endodontic pain and still matter of debate and need further study to prove it.

Keywords: Endodontics; Pain; Protaper; Ledermex

Introduction

Most of patients looking for oral health care due to presence of pain. A lot of causes lead oral pain but the mean cause of pain we can find it in our clinics is that related to the pulpal origin. The severity of pain differs according to different types of dental illness [1,2]. The pain can be slightly light, spontaneous, throbbing and severe pain.

After mechanical preparation of root canal, the Intracanal medication solve the problem of root canal treatment pain [3-5]. The dental practitioner looking for the antibacterial, sedating and anti-inflammatory properties that found in Intercanal medication [4,5]. the effect of Intracanal medication lead rapid solve of pulpal a periapical pain between the sessions of root canal treatment. Osteoclast activety can be decrease by some Intracanal medication which is a large field being study now a days, also encouraging the hard tissue formation in oral cavity [6,7].

Some studies on calcium hydroxide effect pain after applied as Intracanal medication between the sessions of root canal treatment shows the anti-bacterial properties of calcium hydroxide lead to decrease the pain between the sessions [8]. However, another study can show the using of calcium hydroxide can lead to increase the pain between the sessions of root canal treatment [9]. The other study also shows different result as they compare the calcium hydroxide between the steroids and formecresol as intracanal medication and there is no difference in pain level of flare up conditions [10]. Although, many researches on calcium hydroxide and Ledermex still need more investigations. The main goal of our study is focusing on pain during applying calcium hydroxide and Ledermex as Intercanal medication between the sessions of root canal treatment.

Now-a-days the usage of calcium hydroxide has been increased, as it has an antimicrobial effect leading to the reduction of intracanal bacteria between the appointments in cases of pulpal necrosis. Also, Calcium

Hydroxide is indicated in cases of pulpal lesions, pulpal infection as well as pulpal necrosis [10,11].

Aim of this study

The mean goal of this article is to evaluate the pain after using of intracanal medications; Calcium Hydroxide and Ledermex with 5.25% sodium hypochlorite irrigating solutions utilizing Visual Analogue Scale.

Materials and Methods

Following Cairo University Ethics Committee, Endodontic Department Ethics Committee and the patient will be asked to follow general instructions to sign a printed consent that explain the aim of the study and obligated the patient to fill the pain dairy 3 hours post-operative and, 24 hours, 48 hours and $7^{\rm th}$ day after root canal treatment accurately and honestly then return it to the operator in the due time. The patient will be instructed basically not to take any analgesic or inflammatory drugs and to report if they take any of them. The clinical trial will follow CONSORT statement 2010 (www.consort-statement.org)

Eligibility criteria

Inclusion criteria: Age: 25-45-year-old, medically free, Non-vital mandibular molars and No sex predilection.

*Corresponding author: Alferra AAAS, Department of Endodontics, October 6 University, 14 Riverside, hookstt, NH, Egypt, Tel: 6032649915; E-mail: dr.aziz_elfarra@hotmail.com

Received: July 05, 2018; Accepted: November 17, 2018; Published: November 21, 2018

Citation: Alferra AAAS (2018) Post-operative Pain after Using Calcium Hydroxide and Ledermix Intercanal Medication with 5.25% Sodium Hypochlorite Irrigation: A Randomized Controlled Trial. Oral health case Rep 4: 146. doi:10.4172/2471-8726.1000146

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Exclusion criteria: Pregnant females, History of allergy to Sodium Hypochlorite, Preoperative premedication 12 hours before procedure. Periodontal disease, acute abscess cases and Retreatment cases

Setting and location

From Endodontic females, History of allergy to Sodium Hypochlorite, Preoperative premedication 12 hours before procedure.

Patient will be selected from Endodontic clinic at cairo university, faculty of dentistry, endodontic department.

Dental units: Sirona, C8, Sirona Dental Systems GmbH. Periapical X-ray Machine: Planmeca Intra X-ray Unit, Planmeca, Finland.

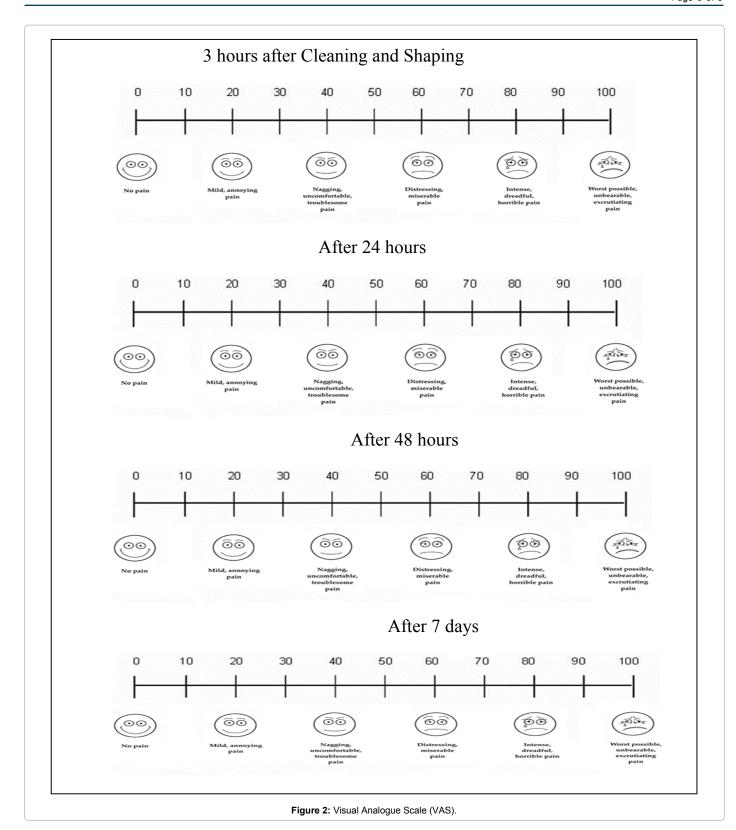
Intervention

All data include: the patient history of medical and dental illness, clinical and radiographic information collected and recorded (Figure 1).

At first visit

Tooth will be anaesthetized by local anesthesia with non-aspirating

| Name: (| Last) | | | | | (Firs | t) | | | | | | Date: | | | Tooth | : |
|---|---------------------------------------|---|---|--|---|---|---|----------------------------|---------------------|--------------------------|--------------------------|--------------------------|-----------------|--------|-----------|----------------------|--------------|
| Chief C | JECTIV omplain of Prese | t: | 55: | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | |
| Quality: Onset: Location | 1: | Dull Stim Ro Localiz | ed | Modera Throbb Intermi Diffuse | oing ittent | Severe Constar Spontar Referre | neous | Radiati | | | | | | | | | |
| Duration Initiated Relieved | by: | Second Cold Cold | s Heat Heat | Minute Sweet OTC-N | Sponta | Hours aneous Narc-N | Palpati feds | Constar on M | nt asticat | tion | Sup | ination | 1 | Keep | s awake | at night | |
| Extraor Facial sy | ECTIVI al: welling: swollen: | Yes | No No | | | Intraor Soft tis Swellin Sinus to Clinica | sues: | WNL Yes Yes Restn | No No Cario | (| Mild Closed Exposu | Mode re F | erate Fractu | | were, 1 | Location: | |
| | | | Heat EPT | | D-I- | Mah | Bite | Dis- | | | Periodontal Exam | | | | | | |
| # | Cold | Heat | EPI | Perc | Palp | Mob | Stick | color | МВ | В | DB | DL | L | ML | Recesan | Furcation | Blee Prob |
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| Radiogr Alveolar Lamina Roots: Pulp Car Pulp Car Crown: Sinus Tr | Bone: Dura: amber: nal: | Modings: WNL WNL WNL WNL WNL WNL Traces | Obscur Curvati Calcific Calcific Caries | re ation | Late Broken Resorpt Pulp Sto Bifurca Restora | one ted | cy A Widene Perfora Exposu Resorpt Crown | tion re | Dilac | eration option RCT | on i | Fracti Perfo Furca | ure ration | | Long | Sinus / Perfora | |
| A. (Asse Diagnos Etiology | 9 | | | | Rev Pul APP rior RCT | CPP | | A C | Necr PA akage | Co | nd Ost | | | | 0.000 | Pulpless orptn VI | RF |
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| | | Caries o | control | RCT | ReT | x 18 | eD A | Apico | Apex | ificat | ion/ge | nesis | Pe | m/K | esorption | n Repair | |
| Prognos | ntic: | Caries o | | RCT lengthen | | x I& otamp | | Apico section | Apex Extra | | | nesis | Pe | ri / K | esorptio | n Kepaur | |



syringe_using 1.8 ml Mepivacaine Hcl 2% - Levonordefrin 1:20000. Tooth will be disinfected and isolated with rubber dam. Tooth will be relived from occlusion by using articulating paper and diamond stone (Dia-bur, Mani).

The round bur and diamond stone are used for access cavity

preparation (Dia-bur, Mani). Working length will be determined by using electronic apex locator (Root ZX, J. Morita USA, Irvine, CA) and confirmed with intraoral periapical radiograph (Kodak intraoral Periapical films, KODAK). Mechanical preparation was performed by using Protaper Universal sequence until F2 file (Dentsply).

Root canals will be irrigated by using 5.25% sodium hypochlorite with a disposable plastic syringe (3 ml, 27G, Ameco, 10th of Ramadan city, Egypt); irrigation will be done between each file during mechanical preparation of root canals with 3ml for 1 minute. The canal was dried by Paper points (Dentsply). Between visits access cavity will be closed with a sterile dry cotton pellet and temporary filling (Cavit temporary filling, 3M ESPE, Germany) with using either calcium hydroxide intracanal medication (DENTSPLY Maillefer, TN) or Ledermix.

At second visit

After 7 days from the first visit, patient will be recalled for completion of root canal treatment. Rubber dam will be applied, and temporary filling will be removed with excavator. Root canals will be irrigated as the first visit. Dryness of the root canals will be done with paper points. Obturation is done by selecting of single cone of gutta percha F2 (Dentsply) and then the spreader and plugger chose to ensure fitting of F2 gutta percha and complete the obturation by warm gutta percha after using of system B. the resin sealer was used (Dentsply).

Outcomes

Post-operative pain evaluation will be done 3 hours after completing cleaning and shaping in the first visit then 24 hours, 48 hours and 7 days by using Visual Analogue Scale. After some instructions, patient will be instructed not to take any analgesic or anti-inflammatory drugs

| Group | Ledermix g | roup | Calcium h | p-value | | |
|---------------------------------------|------------|------|-----------|---------|---------|--|
| | The mean | SD | The mean | SD | , ruius | |
| Before root canal treatment | 0 | 0 | 0.95 | 4.36 | 0.295 | |
| After mechanical preparation | 20 | 0 | 19.05 | 4.36 | 0.295 | |
| After 3 hours | 0 | 0 | 19.05 | 4.36 | <0.001* | |
| After 1 day | 0 | 0 | 0 | 0 | 1.000 | |
| After 2 days | 0 | 0 | 0 | 0 | 1.000 | |
| After 7 days | 0 | 0 | 0 | 0 | 1.000 | |
| After obturation | 0 | 0 | 0 | 0 | 1.000 | |
| *Significant at p ≤ 0.05 [*] | | | | | | |

Table 1: The standard deviation (SD), the mean and probability value (p-value) between calcium hydroxide and Ledermix groups.

| Period | The mean difference | SD | <i>p</i> -value |
|-------------------------------------|---------------------|------|-----------------|
| After mechanical preparation | 18.10 | 8.73 | 0.001* |
| Before treatment – After 3 hours | 0 | 0 | 1.000 |
| Before treatment – After 1 day | 0 | 0 | 1.000 |
| Before treatment – After 2 days | 0 | 0 | 1.000 |
| Before treatment – After 7 days | 0 | 0 | 1.000 |
| Before treatment – After obturation | 0 | 0 | 1.000 |
| *Significant at p ≤ 0.05* | | | |

Table 2: Standard deviation (SD), the mean and probability value (p-value), result of Wilcoxon signed-rank test for difference period of time in Ledermix group.

| Period | Mean difference | SD | <i>p</i> -value |
|---|-----------------|------|-----------------|
| Before treatment – After cleaning and shaping | 18.10 | 8.73 | <0.001* |
| Before treatment – After 3 hours | 18.10 | 8.73 | <0.001* |
| Before treatment – After 1 day | -0.95 | 4.36 | 0.317 |
| Before treatment – After 2 days | -0.95 | 4.36 | 0.317 |
| Before treatment – After 7 days | -0.95 | 4.36 | 0.317 |
| Before treatment – After obturation | -0.95 | 4.36 | 0.317 |
| *Significant at p ≤ 0.05 [*] | | | |

Table 3: Mean, standard deviation (SD) values and results of Wilcoxon signed-rank test for the changes by time within calcium hydroxide group.

and to report if he took any of them and Patient will be asked to mark the Visual Analogue Scale between 0-100 to determine intensity of pain if occur in the specific time needed and the dentist will going to call him in these times to remind him to use the Visual Analogue Scale (Figure 2). Patient will have to come in the exact due date of 2nd visit for obturation.

Sample size: 44 patients will be selected from the output clinic of the endodontic department. Randomization: Sequence Generation: Computer sequence generated In the Center of Evidence Based Dentistry-Cairo University. Finally, data will be returned to evidence-based research center for decoding the given number for each irrigating solution to collect and tabulate the data for each concentration used followed by statistical analysis.

Results

Evaluation of Visual Analog Scale between calcium hydroxide group and Ledemix group

Before root canal treatment, after mechanical preparation, 1day, 2 days and 7 days after mechanical preparation and also after obturation there were no difference between two groups in Visual Analog Scale. After 3 hours, Ledermex group showed statistically significantly lower mean VAS score than NaOCl 5.25% group (Table 1).

Difference period of time in Visual Analog Scale for Ledermix group

There was no difference in Visual Analog Scale in all period except after mechanical preparation there was increase in Visual Analog Scale value (Table 2).

Difference period of time in Visual Analog Scale for calcium hydroxide group

There was no difference in Visual Analog Scale in all period except after mechanical preparation and after 3 hours after mechanical preparation there was increase in Visual Analog Scale value (Table 3).

Discussion

One of the methods in treatment of root canal infection by using Intracanal medication. Interacanal medication after mechanical preparation of root canals, pulp capping and traumatic exposure cases can be treated by using Ledermix (triamcinolone and dimethylchlorotetracycline in water soluble cream) [12]. post-operative root canal pain can be easy manage by using of Ledermix as Intracanal medication between the sessions of root canal and the pain will relief in few hours [10]. Numerous past studies show diminution or absence of interappointment pain when ledermix was used after debridement [13]. A lot of patients report the post-operative pain was relief after using of Ledermix as Intracanal medication in cases with acute apical periodontitis comparing with calcium hydroxide Intracanal medication in the same cases [12].

Many clinical endodontics cases can be managed by using of calcium hydroxide. The antibacterial properties of calcium hydroxide especially in almost all types of bacterial infection in root canal can be easy disinfected by using of calcium hydroxide as Intracanal medication. One of disadvantages of calcium hydroxide is the ability to dissolving in short period of time but in other hand this disadvantage makes this material to be effective in treatment of infections [14]. However, the antibacterial properties of calcium hydroxide still not clean and need further investigations [15].

The incidence of post-operative pain has been reported by many authors and each study has their own idea. Stletzer et al. shows 40% of the patients had post-operative pain after root canal preparations for 698 teeth [16]. Other O'Keefe report 16% of the patients had moderate to severe post-operative pain after root canal treatment [17]. Also, Clem found the 25% of post-operative pain after root canal preparations for 318 teeth [18].

The post-operative pain in this study was higher after mechanical preparations of root canal in calcium hydroxide and Ledermix groups. However, after 3 hour the incidence of post-operative pain was higher in calcium hydroxide group with statically significant different between both groups. After 24hours, 48 hours, 7 days there were no statistically significant difference between both group and both groups show no pain at all. The incidence of post-operative pain after treatment and after 3 hours its might be due to instrumentation of root canal lead to extruded of Intracanal bacteria apically [19].

Conclusion

With limitation of this study there were slightly different between both groups. There's no real data to prove that using of ledermix lead to relief the post endodontic pain and still matter of debate and need further study to prove it.

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