

Comparison of Inter-Appointment Pain Between Ledermix and no Intracanal Medicament in Acute Apical Periodontitis

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ABSTRACT

OBJECTIVE: To compare the mean difference in inter-appointment pain by using ledermix and no intracanal medicament in patients with acute apical periodontitis.

MATERIAL AND METHODS: This Randomized control trial was conducted at Operative dentistry department of Altamash Institute of Dental Medicine, Karachi during August 2009 to February 2010. Patients after selection were divided into two groups by even-odd method. Group 1: ledermix paste and Group 2: no intracanal medicament (control group). The follow-up visit was scheduled and the Mean inter-appointment pain was recorded after 48 hours on visual analogue scale.

RESULTS: In 222 patients mean inter appointment pain was 9.0 ± 0.71 in group 1 and 12.26 ± 0.90 in group 2. The mean difference between groups 3.26 ± 1.15 (95% CI of mean: 0.99 to 5.53).

CONCLUSION: Patients with ledermix paste experienced significantly less postoperative pain than with no intracanal medicament ($p=0.005$) at 48 hours.

KEYWORDS: Interappointment Pain, Ledermix Paste, Acute Apical Periodontitis.

INTRODUCTION

The basic objective of endodontic or root canal treatment (RCT) is infection removal and to eliminate or decrease pain through chemo-mechanical cleaning & obturating the root canal system. Some patients; however may feel uncomfortable or mild pain during or after procedure, if RCT is performed according to recommended principles then it should be considered as usual occurrence^{1,2}. There are certain indicators such as pain before start of the treatment, number of treatment visits, necrosis with apical periodontitis and anatomical location of tooth that lead to mild degree of pain. Apart from this; immediate postoperative pain associated with endodontic treatment in a tooth which was symptom less before treatment may affect the long term success rate.¹

The incidence of inter-appointment pain increases in teeth with necrotic pulp as the numbers of microorganisms are more in these root canal system³. Byproducts and degradation products of both microorganisms and pulpal tissue if left un-removed; even for a few millimeters in infected root canals; can lead to inter-appointment pain. Therefore, treatment demands removal of bacteria from the root canal system, and the obturation of the canal system to prevent re-infection. In addition, proper coronal seal and restoration of the tooth are the prerequisite to prevent recontamination of the root canal system^{4,5}.

The contributory factors of postoperative pain include chemical, mechanical, and/or microbial insult to the pulp or periradicular tissues. When infection involves the periradicular tissues it becomes more difficult to

remove or cure it by conventional methods. Development of acute inflammation beyond root apex causes severe pain and discomfort to the patient and may lead to interappointment pain.^{1,6}

Endodontic literature is full with different treatment modalities to relieve pain during RCT, including pre-medication, occlusal relief; non surgical & surgical drainage; intracanal dressing etc⁷. Pain control strategies include both non-pharmacological and pharmacological treatment that can be employed. But removal of necrotic tissues along with microorganisms is the basic requirement apart from other strategies. Products of inflammation and increased intra pulpal pressure stimulate nociceptors at nerve terminals that lead to severe pain with or without swelling. Therefore, much attention should be given to proper debridement to eliminate chances of interappointment pain with adjunct of canal medication.⁸ Intracanal medications are being used since long to augment chemo-mechanical procedure.⁹ One school of thought is that chemo-mechanical approach alone is not sufficient to decrease interappointment or post operative pain and recommends the interappointment canal medication.¹⁰ Other studies, however, have contradicted this approach and reported no significant differences when canals were medicated.¹¹

In 1930 Hermann introduced Calcium Hydroxide as a pulp capping agent and since then it is mostly used as an intracanal dressing material during endodontic therapy but with the invent of newer materials like Ledermix, the dominance of calcium hydroxide is questioned again.⁹

According to a study, carried out at The University of

Melbourne, symptomatic teeth with acute apical periodontitis, they found that in acute apical periodontitis, rapid decrease in pain occurred in those teeth which were dressed with Ledermix.¹²

According to Ehrmann et al., the patients with Ledermix intracanal medicament experienced significantly less 9.5 ± 14.6 postoperative pain than with no intracanal medicament 16.3 ± 20.8 at 48 hours.¹² Same group of researchers also studied the frequency of interappointment pain using three modalities (Ledermix, Calcium Hydroxide and no medicament). They found pain incidence of 6.9% with Ledermix, 12.3% with Calcium Hydroxide and 16.7% with no intracanal dressing at 4 hours.¹³

In recent years, several intracanal medicaments are introduced to prevent interappointment pain during root canal treatment. So far no local study of this kind has been conducted. Hence, this study aims to compare the mean difference in inter-appointment pain by using ledermix and no intracanal medicament in patients with acute apical periodontitis.

MATERIALS AND METHODS

This randomized control trial was conducted at out Patient Department of Operative Dentistry at Altamash Institute of Dental Medicine, Karachi from August 2009 to February 2010. The sample size was calculated by using statistical software (SPSS version 14) whereas the sampling technique was non-probability: purposive sampling. The inclusion criteria were single rooted teeth with acute apical periodontitis (history of pain in teeth on chewing between 40–60 mm of Visual Analog Scale within 48 hours before the first visit) and age group 14-60. While the exclusion criteria were root resorption as conventional root canal treatment that cannot be performed, malposed teeth in which access opening and instrumentation would be compromised, immature root apices because treatment option require some additional steps like apexification or apexogenesis, patients having severe periodontitis with grade 3 mobility because of poor prognosis and conditions in which conventional root canal treatment is contraindicated e.g. longitudinal tooth fractures. The patients who fulfilled all the inclusive criteria were selected for this study from the outpatient department of Altamash institute of dental medicine, Karachi. Confounding variables as well as bias was controlled by strictly following the exclusion criteria. Total 222 patients after selection were equally divided into two groups by even-odd method. Group 1: ledermix paste and Group 2: no intracanal medicament (control group). This study was conducted after approval of ethical review committee of the institution. All endodontic treatment procedures were performed by the principle investigator. The procedural risks and bene-

fits of treatment were explained to each patient and a written consent (annexure) was taken before the endodontic treatment procedure.

Tooth was anaesthetized with local anesthetic solutions (1:100,000 lidocaine) and then rubber dam was placed to isolate it. Access preparation was achieved by using high speed hand piece with a number (02) round bur and number (02) tapered fissure bur. Coronal half of canals was prepared by no.4, 3, 2 Gates-Glidden burs in crown down manner.

After pulpectomy, working length (WL) was determined with a periapical radiograph using ISO K-file #15. Optimal length is 1 to 2mm short of the apex.

According to the size of the image of the tooth on the preoperative radiograph, a file was inserted into each root canal so that it would reach approximately within 2mm of the radiographic apex. A reference point was chosen that was stable and easily visualized during preparation. After the radiograph had been exposed the file was removed. On working length radiograph, the difference between the end of the instrument and the root apex was measured and the file was adjusted to obtain the correct working length.

The step-back technique was used with K type hand files for the preparation. Apical canal patency was maintained. After preparation with each file, the canal was recapitulated with ISO size 10 K-file. Master apical files (MAF) was ranged from #35 to #55 depending on both the root anatomy and initial diameter of root canal.

After each file root canals were irrigated with 2.5% sodium hypochlorite (NaOCl) & 17% EDTA. Absorbent paper points were used to dry the canal after the preparation of the root canal.

After canal preparation and drying, following medicament was placed into the canal by lentulo spiral in groups randomly allocated by using Drawing Lots (lottery method):

Group 1: Ledermix Paste

Group 2: No Intracanal Medicament (Control Group)

To avoid recontamination of the canal, the access cavity was loosely packed with a sterile cotton pellet and sealed with Glass Ionomer cement.

The patients were instructed to record the intensity of pain at home, on a Visual Analogue Scale (VAS) from 0 – 100 mm, during 48 hours, whenever he/she experienced pain. The follow-up visit was scheduled after 48 hours and the mean inter-appointment pain was calculated and entered in the proforma (annexure) followed by obturation of the canals with gutta percha (GP).

The data was entered and analyzed in SPSS version 14. Mean, SD, 95% confidence interval, median (IQR) were estimated for age and mean VAS score, while frequency and percentage were computed for gender

of both groups. Unpaired t-test was used to compare mean of inter appointment pain between the two groups. A p-value of ≤ 0.05 will be considered as significant. Confounding variables like age and gender were controlled by stratification to observe the effect on inter-appointment pain.

RESULTS

Out of 225 patients 3 did not returned, therefore excluded from this study. A total of 222 patients with acute apical periodontitis were included in this study for root canal treatment. Patients were equally divided into two groups. In group 1, patients were treated with ledermix intracanal medicament and group 2 serve as control (no intracanal medicament). Most of the patients were 21 to 50 years of age as shown in Figure 01. The average age of the patients was 35.32 ± 11.04 years (95%CI: 33.86 to 36.79). Similarly overall average inter-appointment pain score was 10.63 ± 8.69 (95%ci: 9.48 to 11.78).

Out of 222 patients, 142(64%) were females and 80 (36%) were males as presented in table 2. Significant difference was not observed between groups for gender ($p=0.57$). Mean inter appointment pain was 9.0 ± 0.71 in group 1 and 12.26 ± 0.90 in group 2. The mean difference between groups was 3.26 ± 1.15 (95%CI of mean: 0.99 to 5.53). Patients with ledermix intracanal medicament experienced significantly less postoperative pain, than with no intracanal medicament ($p=0.005$) at 48 hours (Table I).

Comparisons of mean difference of inter-appointment pain between groups with respect to male and female are presented in Table II. In female significant differ-

FIGURE I: AGE DISTRIBUTION OF THE PATIENTS (n=222)

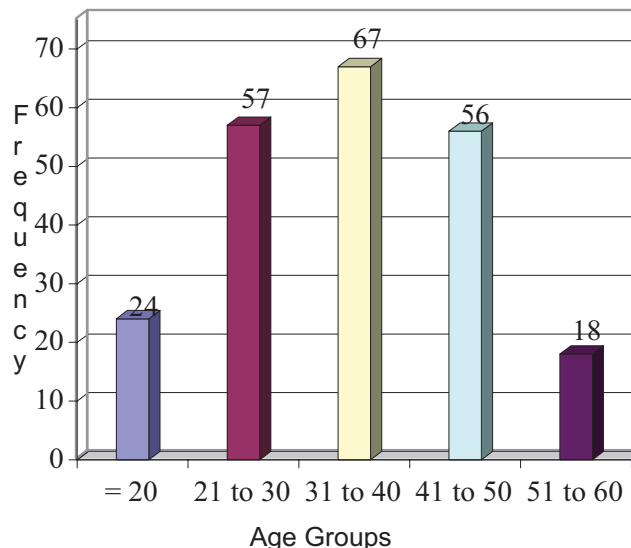


TABLE I: COMPARISON OF THE MEAN DIFFERENCE IN INTER-APPOINTMENT PAIN BETWEEN GROUPS

| Groups | Mean Pain Score | |
|-----------------|------------------|----------------|
| | Mean \pm SE | 95%CI |
| Group 1 (n=111) | 9 ± 0.71 | 7.59 to 10.41 |
| Group 2 (n=111) | 12.26 ± 0.90 | 10.47 to 14.05 |
| Mean Difference | 3.26 ± 1.15 | 0.99 to 5.53 |
| P-Value | 0.005 | |

TABLE II: DIFFERENCE IN INTER-APPOINTMENT PAIN WITH RESPECT TO GENDER

| Groups | FEMALES | | MALES | |
|-----------------|------------------|-----------------|------------------|---------------|
| | Mean \pm SE | 95%CI | Mean \pm SE | 95%CI |
| Group 1 (n=111) | 9.64 ± 0.89 | 7.86 to 11.42 | 7.95 ± 1.17 | 5.60 to 10.21 |
| Group 2 (n=111) | 12.00 ± 1.06 | 9.88 to 14.12 | 12.76 ± 1.68 | 9.35 to 16.18 |
| Mean Difference | 2.36 ± 1.39 | -0.399 to 0.512 | 4.81 ± 2.05 | 0.72 to 8.91 |
| P-Value | 0.093 | | 0.022 | |

TABLE III: COMPARISON OF MEAN DIFFERENCE IN INTER-APPOINTMENT PAIN BETWEEN AGE GROUPS

| Groups | Age ≤ 36 years | | Age >36 years | |
|-----------------|---------------------|---------------|------------------|----------------|
| | Mean \pm SE | 95%CI | Mean \pm SE | 95%CI |
| Group 1 (n=56) | 8.88 ± 1.04 | 6.80 to 10.95 | 8.88 ± 1.04 | 7.16 to 11.09 |
| Group 2 (n=58) | 11.29 ± 1.24 | 8.81 to 13.77 | 11.29 ± 1.24 | 10.68 to 15.96 |
| Mean Difference | 2.42 ± 1.62 | -7.82 to 5.61 | 4.19 ± 1.63 | 0.95 to 7.43 |
| P-Value | 0.138 | | 0.012 | |

ence was not observed between groups (difference, 2.36 ± 1.39 ; $p=0.093$) while male patients with ledermix intracanal medicament experienced significantly less postoperative pain than with no intracanal medicament ($p=0.022$) at 48 hours

Comparisons of mean difference of inter-appointment pain between age groups are presented in **Table III**. Significant difference was not observed between groups in those patients whose age was below 36 years (median groups), where as for above 36 years age group, difference was significantly lower in patients with ledermix intracanal medicament than control ($p=0.012$ - Table III).

DISCUSSION

The most significant finding of this study was the reduction in number of inter-appointment pain, when Ledermix was used as an inter-appointment medicament when compared to control group (with no intracanal medicament). Hence, supporting the clinical impression and subjective evidence regarding the effectiveness of Ledermix paste in decreasing the pain severity, often associated with instrumentation of canals.

Endodontic literature contains lots of studies regarding the efficacy of Ledermix in comparison with other intracanal medicaments. Ehrmann EH et al. found that the mean flare-up scores of the intracanal medicament Ledermix (corticosteroid/antibiotic mixtures) were significantly lower than the flare-up (pain and/or swelling) score of the control groups which were medicated with other materials.¹² Mohammadi Z et al. are also of the opinion that ledermix is better intracanal dressing material as compare to CaOH as later is resisted by refractory bacteria.¹⁴ Same author in his review article concluded that Ledermix is more effective medicament as it contains potent anti-inflammatory & anti-resorptive properties.⁹ One of the active ingredients of Ledermix paste is triamcinolone. Abbott et al. in their in-vitro study evaluated the rapidity and prompt action of triamcinolone. They concluded that the rate of release of triamcinolone is maximum during the first 3-8 hours but it reduced after 8 hours. One may infer from this that ledermix is effective in initial acute expression of painful symptoms.¹⁵

Some researchers believe that intracanal medication is not effective against microbiological film & further investigation is required regarding its efficacy.¹⁶ Trope is of the opinion that there is no significant difference when different medicaments like; Ledermix, Calcium Hydroxide and Formocresol are used. Trope meticulous adherence to exclusion criteria could perhaps be the reason that he had such a low flare-up rate of only 2.53 % (12 in 474 cases).¹⁷

On the other hand, Genet et al¹⁸ observed a flare-up

rate of 27 % in all cases treated. These investigators also found a direct correlation between the incidence of pre and postoperative pain occurrence. Seltzer also criticized the use of corticosteroids in endodontic therapy by stating that the disadvantage of using corticosteroids derives from the effects on inflammatory cells. According to him inflammatory cells hamper the process of phagocytosis and protein syntheses, which may result in delayed healing.¹⁹ But Abbott disproved these findings and went on to say that even if corticosteroids cause some adverse effects, they are of minor degree; therefore insignificant.²⁰

We observed no significant difference between groups for gender. Comparisons of mean difference of inter appointment pain between groups with respect to male and female are presented in table 2 and 3. In female significant difference was not observed between groups (difference, 2.36 ± 1.39 ; $p=0.093$) while in male, patients with ledermix intracanal medicament experienced significantly low postoperative pain than with no intracanal medicament ($p=0.022$) at 48 hours. Our results match with the findings of Pickenpaugh who also observed that there was no direct relationship between the interappointment pain and gender of the patient.²¹ On the contrary to our findings, some studies have shown that females are more prone to develop interappointment pain as compared to males. Such studies, like Fox and Morse, found females to be more prone to develop interappointment pain.^{22,23}

Comparisons of mean difference of inter appointment pain between groups with respect to age groups are presented in table 3. Significant difference was not observed between groups in those patients whose age was below 36 years of age (median groups) while for above 36 years of age, difference was significantly low in patients with with ledermix intracanal medicament than control ($p=0.012$).

In a study, Balban found that with advancing age, the percentage of cases of acute exacerbation of interappointment pain decreased. The reason he gave was that, in old age the pulp canal size decreases significantly. Thus there would be a decreased volume of debris; reduced flow of blood to the alveolus and thus reduced inflammatory response to infection. So Balban concluded that, with growing age, the chances of developing acute exacerbation decreases.²⁴ A prospective randomized trial, conducted by Morse et al., concluded that no direct or indirect relationship could be established between incidence of interappointment pain and age of the patient.²⁵

On the contrary, there are some studies that negate the idea given above. Some researchers concluded that patients above 50 years of age are more prone to develop interappointment flare-up. The reason given

was that, the cementum deposition increases with age. So, coronal transportation of radiographic apex is one possibility. This would lead to increased possibility of developing error in determining the working length. Consequently, apical extrusion of the debris would occur. Thus, patients in old age have more chances of developing interappointment flare-up than younger patients^{24, 26, 27}. But this could not be verified in this study as the maximum age of the patients included in the study was 50 years.

CONCLUSION

While assessing inter-appointment pain in both the groups, statistically significant difference was observed at 48 hours after the initial treatment in favour of Ledermix paste. Therefore, Ledermix may be a good choice as an intracanal medicament in order to reduce the interappointment pain of the patients.

FOOT NOTE:

The visual analog scale (VAS) is a tool widely used to measure pain. A patient is asked to indicate his/her perceived pain intensity (most commonly) along a 100 mm horizontal line, and this rating is then measured from the left edge (5VAS score). The VAS score correlates well with acute pain levels.

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