ORIGINAL ARTICLE

Comparison of the Effect of Ledermix Paste and No Intracanal Medicament on Interappointment Pain During Root Canal Therapy

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ABSTRACT

Objective: To compare the mean interappointment pain using Ledermix paste and no intracanal medicament in patients with acute apical periodontitis.

Study Design: Randomized controlled trial.

Place and Duration of Study: Operative Dentistry Department, Watim Dental College, Rawalpindi, from 1st March to 31st August 2018.

Materials and Methods: Sixty patients who were fulfilling the inclusion criteria were selected. Two groups were made Group 1 and Group 2. The patients were divided into these groups based on table of random numbers. Single blind technique was followed while dividing the patients. Group 1 patients had ledermix placed into the tooth and Group 2 patients had no intracanal medicament placed into the tooth. Patient pain score was recorded after 48 hrs using Visual Analogue Scale. SPSS version 23 was used to analyze the data.

Results: Mean inter-appointment pain was 3.23±1.43 for Ledermix (Group-1) and for no intracanal medicament (Group 2); the mean inter-appointment pain was 5.87±1.30. A statistically significant difference was recorded with a *p*-value of 0.005.

Conclusion: Patients in which Ledermix was placed as an intracanal medicament experienced significantly less inter-appointment pain as compared to patients having no intracanal medicament (p=0.005) at 48 hours. Hence, ledermix can be effectively used as an intracanal medicament to reduce inter-appointment pain for patients seeking endodontic treatment for acute periapical periodontitis in routine clinical settings.

Key Words: *Acute Apical Periodontitis, Intracanal Medicament, Inter-Appointment Pain, Ledermix, Root Canal Therapy.*

Introduction

Infection of the root canal can result in apical periodontitis.[1]The objective of root canal treatment is to reduce the bacterial load from the root canal. The prevalence of inter-appointment pain was reported to be 2.3%.[2] The occurrence of interappointment pain is influenced by various factors. These include age of patient, gender, type of tooth, condition of periapical tissues and preoperative severity of disease.[3] Microbial injury is the most common cause of inter-appointment pain.[4] Frequency of interappointment pain is greater in teeth with necrotic pulp having periapical lesionsas compared to teeth with vital pulps. Cleaning and shaping holds greater importance in comparison to the placement of intracanal medicaments in disinfecting the root canal system.[6] Obturation effectively entombs and seals the microorganisms remaining within the root canal system. Thus, placement of an intracanal medicament may not be required.[7,8]

Infection of root canal and surrounding tissues may occur from the microorganisms remaining in dentinal tubules after shaping and cleaning.[9] The placement of intracanal medicaments would enhance the disinfection of root canal.[10,11]Anti-inflammatory agents have been incorporated in these intracanal medicaments. The antibiotics have been shown to be effective in necrotic teeth and for the periradicular tissues. The local administration of

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antibiotics is a more effective method for reduction of pain during endondontic treatment.[12] The combination of antibiotics and corticosteroids in medicaments such as Ledermix are highly effective in acute apical periodontitis.

The objective of our study was to compare the mean inter-appointment pain using Ledermix paste and no intracanal medicament in patients with acute apical periodontitis.

Materials and Methods

Study was conducted after approval of Institutional ethic review committee. The study design was randomized controlled trial. Sampling technique was non-probability consecutive sampling. Inclusion criteria consisted of both male and female patients with age ranging from 18-50 years, with symptomatic mandibular posterior teeth with a diagnosis of acute apical periodontitis and those willing to undergo endodontic treatment. Exclusion criteria included patients with teeth that were malposed, with a fluctuant facial swelling, immature root apices, root fractures, mentally handicapped patients, terminally ill patients and non-cooperative patients. Study was conducted from March to August 2018 at operative department, Watim Dental College, Rawalpindi. Sixty patients who were fulfilling the inclusion criteria were invited by the principal investigator to participate in the study. Informed consent was taken from all the patients. The patients were divided into two groups based on table of random numbers. Single blind technique was followed while dividing the patients. The principal investigator performed all endodontic treatment. Local anaesthetic was used to anesthetize the tooth. Rubber dam was used to achieve the isolation. Access cavity was prepared with a round bur. Pulpectomy was done and working length confirmed by taking a periapical radiograph. Step back technique was used to prepare the canals till 35K file. During the treatment, the irrigation of the canals was done using Miton's technique in which 1% NaOCl was used alternating with 15% EDTA. Paper points were used to dry the canals. Lentulo-spiral was used to place the following medicaments into canals in the groups.

Group 1: Ledermix paste

Group 2: No intracanal medicament

Access cavity was sealed with sterile cotton and Cavit. Patient was recalled after 48 hours. Visual Analogue Scale was used to record the degree of pain on a scale of 0 to 10 with 0 indicating no pain and 10 indicating worst pain. Followup was ensured by keeping contact number and address of the patients.

SPSS version 23 was used to analyze the data. For both qualitative and quantitative variables, descriptive statistics were calculated. For age and pain scores (quantitative variables) mean±SD was calculated. For gender (qualitative variable) frequency and percentage was calculated. Comparison of the mean pain score in the two groups was done using Paired sample t-test. *p*-value< 0.05 was considered significant.

Results

A total of 60 patients with acute apical periodontitis were included in this study for root canal treatment. The patients were equally divided into two groups. In-group 1, patients were treated with ledermix as intracanal medicament and group 2 served as control (no intracanal medicament). Average age of the patients was 28.32±8.95 years. Similarly, overall average inter-appointment pain score was 4.55±1.89 as shown in Table I. Out of 60 patients, 35(58.3%) were females and 25(41.7%) were males.

Mean inter-appointment pain was 3.23±1.43 for Ledermix and for no intracanal medicament; the mean inter-appointment pain was 5.87±1.30 as presented in Table II. Mean difference was 2.64±1.93.

Average score for intracanal medicament i.e ledermix on visual analog scale for pain was 3 as shown in Table III whereas average score was 6 or 7 for patients in which no intracanal medicament was placed as shown in Table III.

According to Independent Sample *t*-Test- the null hypothesis is rejected implicating that ledermix is effective in reducing pain in patients with acute apical periodontitis.

Comparison of mean difference of inter-appointment pain between groups with respect to male and female was also calculated as shown in Table IV. For males in whom ledermix intracanal medicament was used, the mean inter-appointment pain was 3.00±1.55 and in whom no intracanal medicament was used, the mean pain score was 5.67±1.44. In males, significant difference was not observed between groups (difference 2.67±1.85).

For females, the mean inter-appointment pain for ledermix and no intracanal medicament was 3.35±1.56 and 6.07±1.16 respectively. In females' significant difference was not observed between groups (difference 2.72±1.95).

Independent Sample *t*-test for gender for both no intracanal medicament as well as for medication (i.e., Ledermix) are insignificant as p>0.05. For no intracanal medicament p=0.242 and for medication p=0.141. Both the p values are greater> than 0.05 showing that the variable tested here i.e., gender is not significant.

Table I: Descriptive Statistics of Age and Pain

Whole sample (n=60)	Mean ± (SD)
Age in years	28.32 ± 8.975
Pain on visual analogue score	4.55 ± 1.899

Table II: Inter-Appointment Pain according to Use of Intracanal Medicament

Intracanal medicament	Sample size (n)	Mean	Standard Deviation (SD)	P Value
No intracanal medicament	30	5.87	1.306	.001
Ledermix	30	3.23	1.431	

Table III: Average Score on VAS

	Average score on VAS
No intracanal medicament	6 or 7
Ledermix	3

Table IV: Pain on Visual Analogue Score for Patients Grouped on the Basis of Gender

Gender	Group	Mean Pain on VAS	Sample (n)	P value
Male	Group 1 Group 2	3.00±1.155 5.67±1.447	10 15	0.242
Female	Group 1 Group 2	3.35±1.565 6.07±1.163	15 15	0.141

Discussion

Placement of intracanal medicaments results in the reduction of microbial factors. It was concluded from the present study that pain associated with necrotic teeth having acute apical periodontitis in which Ledermix dressing was placed experienced less pain as compared to those patients in which no intracanal medicament was placed after first 48hrs.

Contrary to our findings on the use of intracanal medicaments, in which mean pain score for ledermix (3.23±1.43) on VAS was less in contrast to no intracanal medicament (5.87±1.30), number of clinical researchers have shown that inter-appointment pain is not relieved nor it can be prevented by the use of intracanal medicaments.[13] Patil et al, concluded in his study that inter-appointment dressing with calcium hydroxide does not relieve pain in all cases and therefore use of intracanal medicament is not always recommended.[14] The results of study conducted by Ehrmann et al., were similar to those with our study. In this study, patients in which Ledermix dressing was used as intracanal medicament experienced significantly less 9.5±14.6 post operative pain than those patients in which no intracanal medicament 16.3±20.8 was placed at 48 hours.[15] The frequency of interappointment pain was studied by same group of researchers. In this study three treatment modalities were used that included use of no intracanal medicament, calcium Hydroxide and Ledermix medicament. Pain incidence was found to be 6.9% with Ledermix while it was 12.3% with Calcium Hydroxide and it was 16.7% with no intracanal medicament at 4 hours.[16.17] Negm reported in his study that in 85% of the cases pain was completely relieved after 1 hour whereas more than 93% of the cases were pain free after 24 hours. [18] In majority of patients when Ledermix is placed in the root canal system reduction of pain occurs within an hour. The study conducted by Schneider supports this results in which it is stated that when a steroid antibiotic combination such as Ledermix is placed in the root canals, pain of the patient subsides before he even leaves the dental office. Many studies have confirmed that Ledermix is an effective intracanal medicament. It is perfect for use between the appointments and in root canal therapy. The intra canal use is not associated with any systemic side effects. It can be removed easily removed from the canal as it is water soluble.[19] In the current study no adverse effects were found with the use of Ledermix paste as well. Smith et al, has demonstrated that the periapical inflammation is significantly reduced by the preparation that contain corticosteroid following the canal preparation.[20] In contrast to this, Seltzer strongly criticized the use of corticosteroids. In his study he has stated that the major drawback of using corticosteroids is their effect on inflammatory cells. He also stated that repair process is adversely affected by the use corticosteroids.[21]Steroids are not

widely used due to their immunosuppressive effects in endodontics. To prevent the potential invasion of bacteria, antibiotics should be added to the steroids in topical formulations.[22]

Both the components used in Ledermix paste have the ability to diffuse through the cementum and dentinal tubules. In this way they reach the periapical tissue as well as the periodontium.[11] The demeclocycline component of the Ledermix paste has the ability to diffuses through the dentine over a period of time. During the first few days, the concentration of demeclocycline is very high. It is high enough to inhibit most of the known bacteria causing endodontic infection in the dentine. However its concentration decreases over time.[23]The diffusion of corticosteroid component of Ledermix paste (triamcinolone) is found to be much higher than the antibiotic component (demeclocycline). During the first 3-8 hours, the rate of diffusion of triamcinolone is highest with 30% of the triamcinolone released during the first 24 hrs.[6] It can be inferred from this that triamcinolone component of Ledermix is effective in initial acute phase whereas the antibiotic component of Ledermix i.e. demeclocycline provides antimicrobial substantivity.

We observed that there is no significant difference between groups for gender. Our results match with the findings of Absi et al. They also observed that there was no association between patient's gender and inter-appointment pain.[24] Contrary to our findings, study by Nair et al., observed that there is greater incidence of inter-appointment pain in females as compared to males. Levels of nor adrenaline and serotonin can be altered in females due to changes in female hormone levels during menstruation, use of oral contraceptives and hormone replacement therapy, therefore leading to decreased pain threshold in females.[25]

Limitations of the Study

Our study was not multi-centered and was not double blinded. Therefore, exceptional level of accuracy could not be achieved. More longitudinal studies need to be carried out or planned in order to evaluate the demerits and side effects of local application of the antibiotic as well as corticosteroid that might include development of bacterial resistant strains and suppression of immune cells.

Conclusion

Less inter-appointment pain was experienced by the patients in with ledermix was used as an intracanal medicament as compared to patients having no intracanal medicament (p=0.005) at 48 hours. Hence, ledermix can be effectively used as an intracanal medicament to reduce inter-appointment pain for patients seeking endodontic treatment for acute periapical periodontitis in routine clinical settings.

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