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Post-operative Pain after Different Root Canal Irrigant Activation Methods in Patients with Acute Apical Periodontitis (Randomized Clinical Trial)

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Abstract

AIM: The objective of the study was to evaluate the degree of post-operative pain in patients with acute apical periodontitis after applying ultrasonic irrigation or manual dynamic agitation.

METHODS: Seventy-eight patients having mandibular first molar with symptomatic apical periodontitis were randomly allocated into three groups (n = 26); manual dynamic agitation (MDA) group, Ultra X group, and NaviTip group (control). After a single-visit root canal treatment and a specific method of activation, depending on each group, the patients were given a questionnaire on which they would mark the degree of pain in a scale from 0 to 10 after 6, 12, 24, 48, 72 h, and 7 d post-operative. Data were statistically analyzed with a significance level of $p \leq 0.05$.

RESULTS: Final irrigation protocol including ultrasonic activation and NaviTip (control) groups showed significantly lower values of pain than the MDA group. There was a reduction in pain values by time in all groups.

CONCLUSION: There was less pain associated with passive ultrasonic activation and side vented needle (NaviTip) irrigation compared to manual dynamic agitation.

Introduction

Post-operative pain after root canal obturation is an unpleasant sensation that occurs in 3%–58% of patients. Post-operative pain may be associated with various components, including microbial, inflammation, and/or immune-related factors as well as psychological elements. Studies have assessed the association between different irrigation solutions and related irrigation techniques on post-operative pain in patients undergoing root canal treatment [1]. Determination of the degree of post-operative pain after different activation is of prime importance to choose the least painful and the most efficient technique in cleaning of root canals, and thus this study was conducted.

Instruments used to shape the root canal do not touch the entire canal walls. There are always parts of the canal, especially in the apical one third and the isthmus region, that are left untouched by the tools used in mechanical preparation of the canal. Irrigation plays a major role in cleaning and disinfecting the root canals, thus improving the root canal treatment success rate. Removal of biofilm, debris, microorganisms, and necrotic tissues from the root canal system is performed manually as well as frequent canal irrigation. Canal shaping is mainly performed to allow the irrigant to reach inaccessible areas inside the canals for disinfection and to facilitate the insertion of obturating material to fill the canal system and achieve a hermetic seal [2].

The irrigant solution might be more efficient when it comes in direct contact with the surface of canal wall especially apical third of root canals that are difficult to be touched during mechanical preparation. Delivering the irrigant using the traditional syringe and needle irrigation technique results in an ineffective disinfection in particular areas such as isthmus and apical regions. Adequate activation following proper instrumentation improves the irrigant penetration to reach the untouched part. Acoustic microstreaming and irrigant agitation can be utilized by the use of ultrasonic allowing irrigant penetration into the areas untouched by the files which can eventually lead to the reduction of post-operative pain [3].

Moving a well-fitting gutta percha cone in a vertical motion inside a previously instrumented root

canal facilitates the exchange and displacement of the irrigant. This technique is called manual dynamic agitation (MDA), and despite being the most economic activation method [4].

This study will discuss whether the use of ultrasonic activated irrigation compared to manual dynamic activated irrigation as final irrigation protocol will affect post-operative pain in patients with mandibular first molar teeth with acute apical periodontitis. The null hypothesis of this research is that there was no difference in post-operative pain between the different activation methods.

Methods

Sample size calculation

Based on a previous study [5], the outcome variable was post-operative pain assessed by visual analog Scale. Using power 80% and 5% significance level, we needed to study a total sample size of 60 in which divided into three groups (20 per group). This number is to be extended to a total of 66 to adjust for using a nonparametric test. There was a further 25% increase to allow for least frequently used. The total sample size is increased again to 78 (26 in each group) to compensate for losses during follow-up. The sample size was calculated by PS (Power and sample size) G* program [6].

Sample selection

After approval of the local ethics committee (FUE.REC code (13)/5-2020), 78 patients from the outpatient clinic of endodontics at the Faculty of Oral and Dental Medicine, Future University, were diagnosis with necrotic mandibular first molars with symptomatic apical periodontitis. Patients with systemic diseases, pregnant or lactating female patients, psychologically disturbed patients, patients allergic to any sort of medications used in this study, teeth associated with swelling or acute periapical abscess, patients who administered anti-inflammatory analgesics or antibiotics 12 h preoperatively, immature teeth, impossible restorability, abnormal anatomy or calcified canals, previous root canal treatment, or with grade two or three mobility were all part of the exclusion criteria.

Access cavity preparation

A 2-stage access cavity preparation was performed. The first stage involved removal of all caries and/or coronal restorations completely with sterile bur without exposure of the pulp chamber. In the second stage, the access cavity was performed with high speed handpiece using sterile round carbide bur size 3 (Dentsply, Tulsa Dental, Dentsply Maillefer, TN, USA) and flaring was done with Endo Z bur (Dentsply).

Root canal preparation

Using rubber dam (Dental Dam, Sanctuary Dental, UK), the tooth was isolated followed by patency of the canals using size 15 stainless steel hand K-file (Mani, Mani inc, Industrial Park, Utsunomiya, Tochigi, Japan). Electronic apex locator (Root ZX, J. Morita USA, Irvine, CA, USA) was used to measure working length and was then confirmed with digital intraoral periapical radiograph (Soredex, Digora Toto sensor, Finland) by paralleling technique to be within 0.5–1 mm short from radiographic apex.

Crown down technique was performed in instrumentation of root canal using ProTaper Next (PTN) (Dentsply Maillefer, Ballaigues, Switzerland) NiTi rotary files according to the manufacturer's instructions as follows:

- PTN rotary file set on electric motor (X-Smart, Dentsply, Maillefer, USA) at speed of 300 rpm and torque of 2 N cm using a gentle in and out brushing motion until the working length was passively reached.
- X1 (17/04) file was used in one or more passes, alternatively with small-sized hand files, if necessary, until the working length was reached, in the presence of NaOCl solution.
- X2 (25/06) file was precisely used as X1 file, then instrumentation was continued till X3 (30/07) as a master apical file.
- Preparation of all canals was completed when a hand K-file whose ISO size corresponding to the tip size of the used PTN file snugly fits the apical third of the canal at the working length.

The canals were thoroughly irrigated with 2 ml of freshly prepared 2.6% sodium hypochlorite (NaOCl) solution using plastic disposable syringe (S-S disposable syringe, SUNG SHIM medical Co, Korea) with side-vented needle gauge 30 (Ultradent, South Jordan, UT, USA) between every subsequent instrument. It was used passively into the canal, without forceful dispensing of the irrigant, placed 2 mm short from the working length, which was verified by rubber stoppers. To achieve standardization, the volume of irrigating solution was fixed (2 ml) after each file.

Final irrigation protocol

MDA group

Delivery of 2 ml of 2.6% sodium hypochlorite into the canal was utilized using double side vented needle (NaviTip Sideport 31G/27 mm) passively. Intermittent manual activation for 1 min in up-and-down motion using master gutta percha cone was performed.

Ultra X group

Delivery of 2 ml of 2.6% sodium hypochlorite into the canal was utilized using double side vented needle (NaviTip Sideport 31G/27 mm) passively. Then the irrigant solution was ultrasonically activated for 1 minute using Ultra X (Eighteeth, Changzhou sifary technology, China) at 40 kHz power with X-blue (bendable) metal ultrasonic tip (Length: 18 mm, Size: 20/2%) in an up-and-down motion where the tip was 1 mm shorter than working length.

NaviTip group (control group)

2 ml of 2.6% sodium hypochlorite with double side vented needle (NaviTip Sideport 31G/27 mm) was passively introduced in the root canal 1 mm shorter than the working length but without activation.

For all root canals in the tested groups, 2 ml of 17% EDTA solution was then introduced into each canal for 60 s for the removal of the smear layer, then final

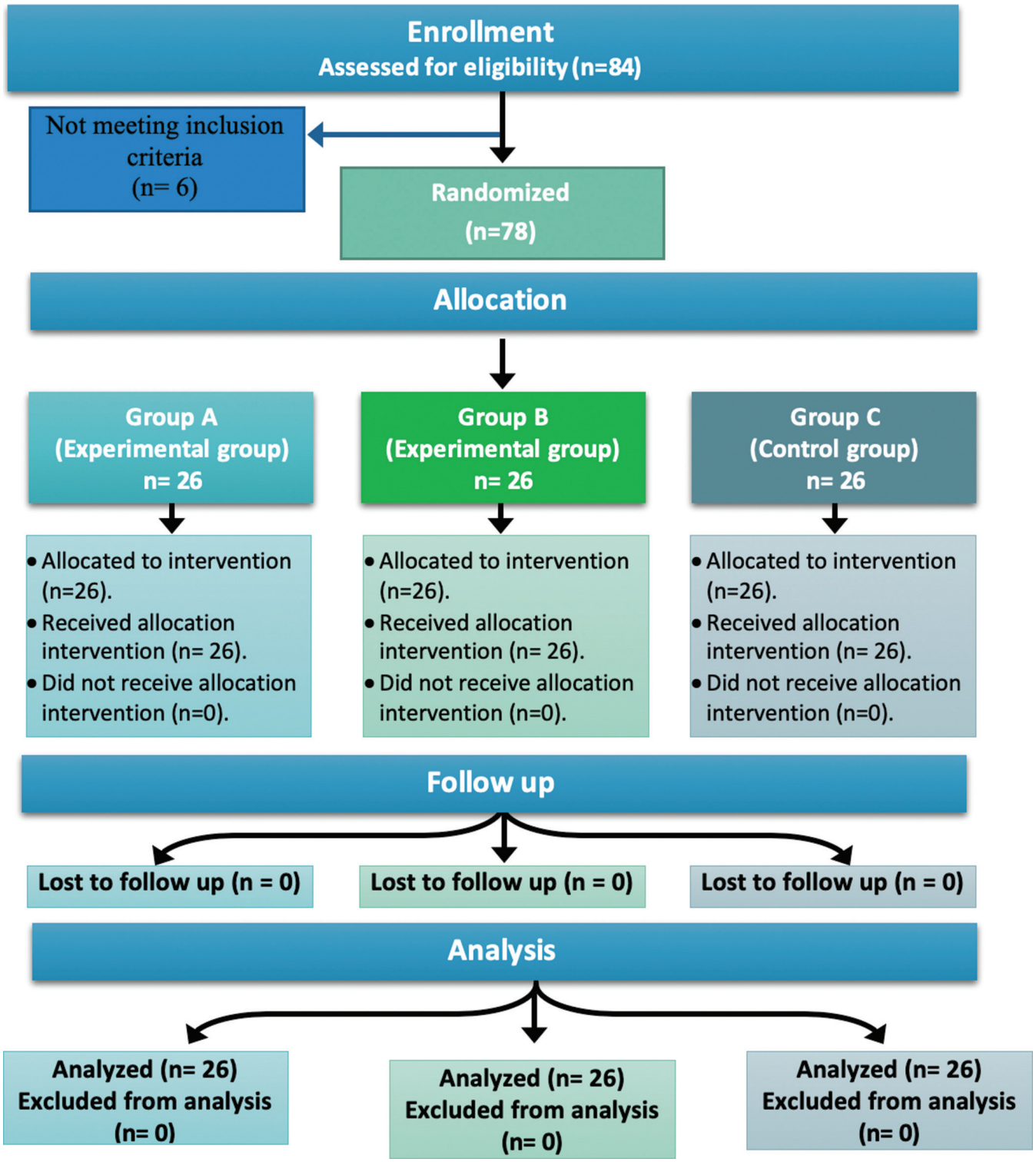

Figure 1: Consort flow diagram

flush using 10 ml of distilled water to prevent erosion of the dentinal tubules.

Root canal obturation

Following the instrumentation of all canals, each root canal was completely dried using ProTaper Next absorbent paper points (Meta Biomed co. LTD) corresponding to the master file (X3) size. Using modified single cone technique, the root canals were obturated by gutta percha cones corresponding to the master apical file (X3) size and along with the use of ADSEAL (ADSEAL, Meta Biomed co. LTD) resin-based root canal sealer. Radiographic X-ray was taken to confirm the proper fitness of the cone to the full working length. The mixed sealer was introduced into the canal coated on the master cone. A spreader of # 25 was selected and auxiliary cones of # 25 were placed. Obturation was considered completed when the spreader no longer penetrates beyond the cervical line. Excess gutta percha was sealed off using heated condenser tip.

Post-operative radiographs were taken to ensure proper obturation. The access cavity was sealed using resin-modified glass-ionomer. The root canal treatment procedure was all performed in a single visit. The details of each step were recorded and stored in the endodontic procedure form of each patient.

Post-operative instructions

Each patient was instructed to mark the VAS scale between (0 and 10) to determine incidence and intensity of pain preoperatively as well as after obturation at 6, 12, 24, 48, 72 h, and 7 d. VAS scale was explained in different ways to the patient to facilitate the understanding and recording of the pain intensity. It expressed pain numerically and verbally in Arabic. Numerical description was presented as a scale beginning from zero (0) representing no pain to ten (10) representing maximum possible pain. Documentation of pain levels was as follows: In the range of 0 to 10 numerically, no pain (zero), mild (1–3), moderate (4–6), and severe (7–10). After 7 d, the patient delivered the assigned paper record.

Statistical analysis

For each group in each test, the mean and standard deviation values were calculated. Using Kolmogorov–Smirnov and Shapiro–Wilk tests, data were explored for normality and showed parametric (normal) distribution. Wilcoxon test was used to test the difference between two groups in related samples, while Friedman test was used to test the difference between more than two groups in related samples. And to compare the difference between two groups in non-related samples Mann–Whitney U test was used. The significance level was set at $p \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

Results

The Ultra X and NaviTip groups showed significantly lower incidence of pain than the MDA group at 6, 12, and 24 h follow-up periods. Figures 2 and 3 show the incidence of pain and pain on biting, respectively, for each group at different time intervals. Tables 1 and 2 show the intensity of pre-operative and post-operative pain and pain on biting, respectively, of the tested groups at different time intervals. Analgesics intake frequency decreased by time in all tested group. Highest mean value was recorded at 6 h in all groups. There was no pain after 72 h and 7 d for all tested groups.

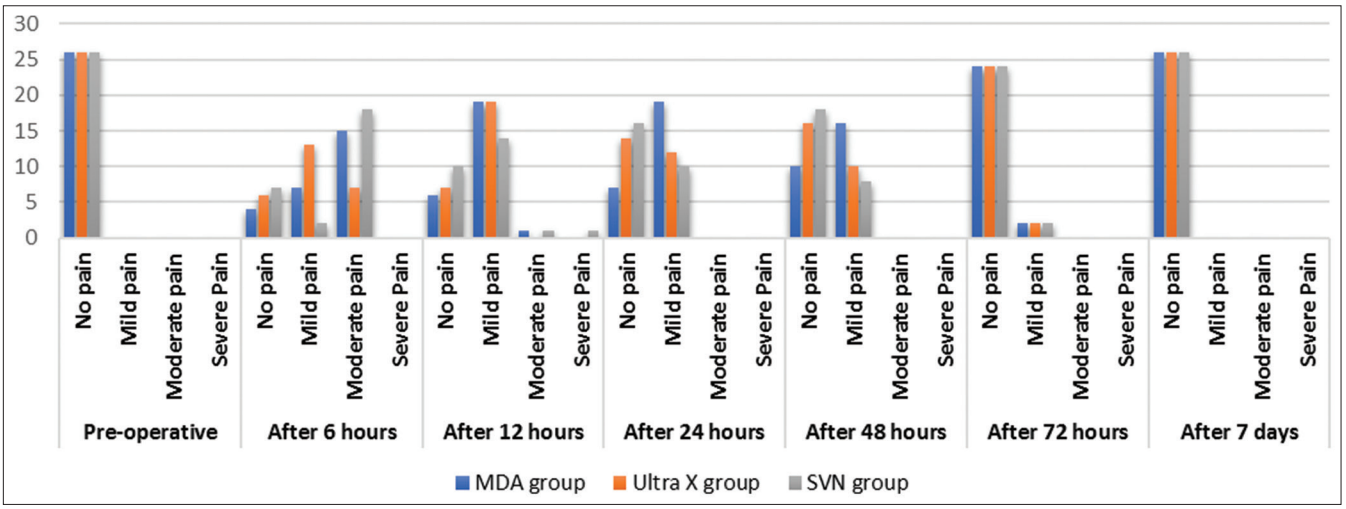

Figure 2: Bar chart representing the incidence of pain at different time intervals for each group

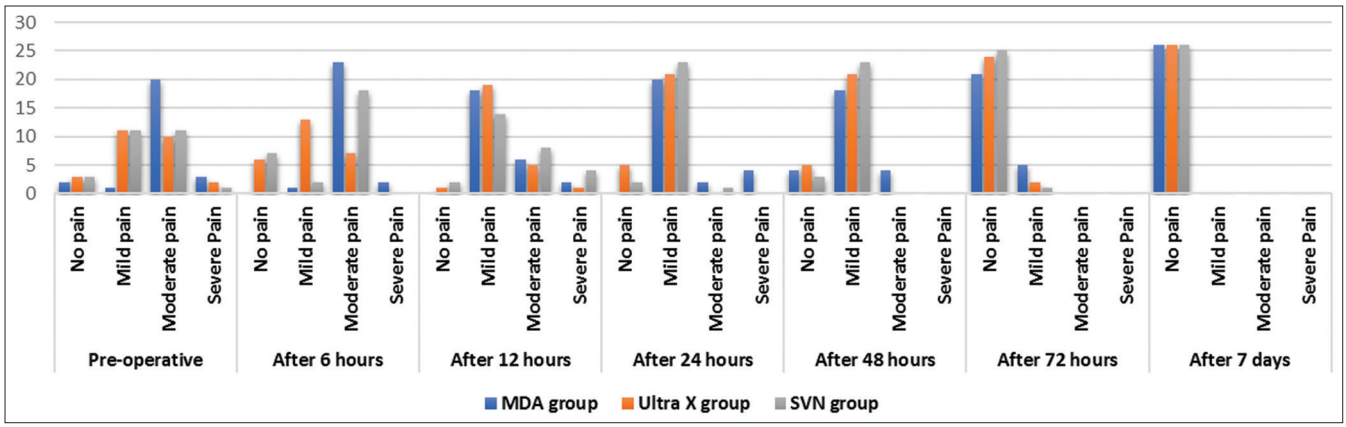

Figure 3: Bar chart representing the incidence of pain on biting at different time intervals for each group

Table 1: Intensity of pre- and post-operative pain of the tested groups after 6, 12, 24, 48, 72 h, and 7 d

Period	Pain intensity						
	NavTip		Ultra X		MDA		p-value
	Mean	SD	Mean	SD	Mean	SD	
Pre-operative	8.701	0.611	8.546	0.706	10.70	0.701	0.669^{ns}
After 6 h	5.558	0.341	3.211	0.461	9.231	0.691	< 0.001*
After 12 h	3.402	0.512	2.521	0.320	7.100	0.210	< 0.001*
After 24 h	2.620	0.310	2.001	0.650	7.026	0.500	< 0.001*
After 48 h	1.002	0.250	0.840	0.610	2.280	0.420	0.529^{ns}
After 72 h	0.860	0.310	0.700	0.451	1.021	0.380	0.408^{ns}
After 7 d	0.000	0.000	0.000	0.000	0.000	0.000	1^{ns}
p-value	<0.001*		<0.001*		<0.001*		

*Significant (p < 0.05) ns: Non-significant (p > 0.05).

Table 2: Intensity of pre and postoperative pain on biting of all groups after 6, 12, 24, 48, 72 h, and 7 d

Period	Pain on biting intensity						
	NaviTip		Ultra X		MDA		p-value
	Mean	SD	Mean	SD	Mean	SD	
Pre-operative	4.38	2.01	4.25	1.75	4.50	1.89	0.210^{ns}
After 6 h	4.05	1.68	3.21	1.45	3.80	1.35	< 0.001*
After 12 h	3.20	1.60	3.15	1.18	2.95	1.10	0.0015*
After 24 h	3.10	1.45	3.01	0.87	1.17	0.65	0.0032*
After 48 h	2.63	1.09	0.77	0.48	1.05	0.43	0.650^{ns}
After 72 h	0.16	0.14	0.01	0.01	0.02	0.15	0.245^{ns}
After 7 d	0.00	0.00	0.00	0.00	0.00	0.00	1^{ns}
p-value	<0.001*		<0.001*		<0.001*		

*significant (p < 0.05) ns; non-significant (p > 0.05)

Discussion

The main target of root canal treatment by means of chemo-mechanical preparation, including cleaning, shaping, and disinfection, is to eventually be able to hermetically seal the canals in an attempt to end up with a pleasant outcome for the patient [7]. Over the years, many cleaning techniques have been proposed aiming to aid in reduction of post-operative pain occurrence and intensity. Various methods have been used to scale post-operative pain [8]. Visual analog scale was used ranging from zero to ten for the measurement of the severity of post-operative pain. The main reasons this scale was chosen are validity, ease of use, simplicity, and reliability. Furthermore, it has been used in the previous studies that evaluated post-operative pain following endodontic treatment [9].

In the current study, intensity of pain was recorded preoperatively, after 6, 12, 24, 48, 72 h, and after 7 d from root canal obturation. The intensity of pain was measured preoperatively for each patient to record a reference point for the post-operative pain following endodontic treatment. Post-operative pain record after 6 h provided enough time for the disappearance of anesthetic effect. Meanwhile, the previous studies showed that most of the post-operative pain took place on the 1st day after chemo-mechanical preparation, hence, 12, 24, and 48 h were chosen [10]. Nagendrababu *et al.* [11] found that the peak of post-operative pain after root canal treatment takes effect between 24 and 48 h intervals. Singh *et al.* [12] stated that in some cases, post-operative pain may persist up to 7 d after root canal treatment; therefore, pain values were also taken at 72 h and 7 d following root canal obturation.

Teeth with acute apical periodontitis were chosen as the main inclusion criteria since flare ups are more likely to occur in such cases compared to vital pulp cases, and this kind of pain is among the most terrifying pains to patients due to its severity and intensity [13]. Two cartridges of anesthetic solution were used equivalent to 3.6 mL, in agreement with Gazal *et al.* [14] who stated that 1.8 mL (single cartridge) of local anesthetic for inferior alveolar nerve block injections is only effective in 30%–80% of the patients. Lip numbness was checked after 10–15 min to ensure the success of injection technique.

Root canal treatment was completed in a single visit since previous studies have proved that the number of visits did not affect the incidence nor the intensity of postoperative pain [15]. Root ZX apex locator was used for the determination of the working length of the root canals because of its high accuracy [16]. Radiographic X-ray was taken to confirm working length since depending only on one of those techniques reduced accuracy and increased the possibility of over-instrumentation [17]. PTN rotary files were used in the root canal instrumentation. They are manufactured from M-Wire NiTi alloy to boost cyclic fatigue resistance and enhance flexibility. It gives the maximum safety during canal instrumentation, as well as it causes the least amount of apical extrusion of debris. [18], [19].

Between every subsequent file, 2.6% sodium hypochlorite was used as an irrigant due to its tissue

dissolving capabilities and strong antimicrobial effect [20]. To ensure standardization and to minimize variations, same protocol was executed in all groups except for the final flush. Irrigation was carried out using conventional syringe and side vented needle which showed a lowering effect on irrigant extrusion into the periapical area in comparison to regular needle [21].

The post-operative pain records after root canal obturation were significantly higher among patients in the MDA group than patients in the other groups at 6, 12, and 24 h time intervals. This was attributed to the compression of the irrigant into periapical tissues after multiple strokes using the master cone in a vertical motion in MDA group [22]. Irrigant and debris extrusion during endodontic treatment can be considered the main cause of post-operative pain. However, the quantity of extruded irrigant and debris previewed in some *ex vivo* studies are not yet confirmed to occur clinically nor to stimulate pain significantly or cause damage to the periapical area [23].

It was proven that MDA group showed more extrusion of irrigant and debris significantly than both ultrasonic activation and NaviTip. It is likely that swinging instruments causes a lateral flow against the canal walls, while inserting a well-fitting master cone to the full working length generates a flow in an apical direction which could cause post-operative pain [24]. Using ultrasonic activation in the final irrigation protocol showed the least pain intensity which can be attributed to the swaying ultrasonic tips which inhibit apical extrusion of debris or irrigant in comparison to the other techniques that cause positive pressure, including MDA and NaviTip [25].

In this study, only one ultrasonic device with a specific frequency was tested. Other limitations in this study include the types of irrigants used and the number of devices used for activation. Further randomized controlled trials are recommended with final step irrigation activation using different mechanical activation methods to investigate their effects with regard to pain after endodontic treatment. In addition, performing bacterial cultural analysis following root canal preparation of necrotic teeth with acute apical periodontitis after final irrigation step with different mechanical activation may give us great insights on the cleanliness of the canals which may affect post-operative pain.

Conclusion

Within the limitations of this study, it can be concluded that mechanical agitation is considered to be a reliable technique as a final irrigation protocol with a moderate range of post-operative pain. MDA seemed to cause more pain than passive ultrasonic irrigation and side vented needle irrigation with NaviTip.

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