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The Influence of Three Root Canal Irrigation Methods on Post- Operative Pain "Randomized Clinical Trial"

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ABSTRACT

Aim: This clinical study was designated to evaluate the influence of three root canal irrigation activation methods on post-operative pain using the Visual Analogue Scale VAS.

Material and Methods: 78 patients having symptomatic irreversible pulpitis in mandibular first molar with no periapical involvement. ProTaper Next rotary files were used for root canal preparation, the cases were then divided randomly into three equal groups based on the final irrigation agitation technique, with each group having 26 cases. (n=26). **Group A:** received irrigation with 2.6% sodium hypochlorite with NaviTip (31- gauge 27 mm) with double side port irrigator tip (SVN) without any agitation; **Group B**: received irrigation with 2.6% sodium hypochlorite with final mechanical agitation of irrigation with ultrasonic device activation (Endo ultra) (PUI) **Group C:** received irrigation with 2.6% sodium hypochlorite with final mechanical agitation of irrigation with sonic device activation (EDDY). Using a Visual Analogue Scale (VAS), postoperative pain was evaluated at intervals of 6,12,24,72 hours and 7 days.

Results: Overall results of study showed ,At the first (6,12,24 hours) there was a significant difference between the groups in pain incidence and intensity where group A showed more pain scores than group B and group C. At (48, 72 hours and 7 days) there were no significant difference between the groups where pain scores declined among the groups till it reaches nearly score (0) at 7 day.

Conclusion: group A **(SVN)** showed highest postoperative pain in the first 24 hours in comparison with the other groups, where the pain level decreased gradually in all groups after 24 hours.

1. INTRODUCTION

Post-operative pain can occur after root canal treatment and its control is one of the prime objectives of endodontic therapy. Various factors, including the instruments and methods utilized in cleaning and shaping, can influence the severity of post-operative pain. Postoperative pain is characterized as a feeling of discomfort following endodontic treatment and is experienced by 25%–40% of patients, regardless of pulp and per radicular condition. Pain affects 40% of people in the first 24 hours, then drops to 11% after 7 days. During root canal preparation, dental debris, pulp tissue, bacteria, and irrigants can be transported to the per radicular tissues, causing postoperative complications including as flare-ups [1].

In RCT, the use of a syringe and needle for manual irrigation is still generally acceptable. This approach, however, cannot reach areas that are unreachable such as apical fins and isthmus. In order to improve the efficacy of irrigation solutions within the root canal system, various irrigation agitation techniques have been implemented. Agitation using sonic and ultrasonic instruments is one of these approaches [2].

The ultrasonic tip extends up to the working length inside the canal and moves passively, increasing the efficacy of disinfection in the canals by agitating the irrigation solution. Acoustic streaming and cavitation effects are produced as a result of this activation, which have been reported to clear more debris from the canal [3].

Sonic activation has also been demonstrated to be a good way to disinfect root canals. Smooth plastic tips of various sizes are activated at sonic frequency by a hand piece operated at a high frequency up to 6000 Hz like most actual systems, such as EDDY. Sonic activation is said to improve cleaning efficiency by increasing cavitation and acoustic streaming [4].

2. MATERIALS AND METHODS

This study's trial design was a parallel randomized controlled trial. It was approved by the Research Ethics Committee of Faculty of Oral and Dental Medicine, Future University in Egypt FUE.REC (18)/10-2019.

2.1 Sample size determination

The sample was divided into 3 groups. A total sample size of 60 (20 per group) was sufficient to detect an effect size of 0.2, a power of 80%, and a significance level of 5%. The number was increased to a sample size of 66 to allow for non-parametric distribution of the outcome variable. Further increase of 25% to allow for least frequently used (LFU), so a total sample size of 78 (26 per group) was needed to compensate for possible losses during follow up. Sample size was calculated using G* Power program.

2.2 Patient selection

The study included 78 patients with symptomatic irreversible pulpitis in the mandibular first molar who met the inclusion criteria mentioned later. To get the target sample size, patients were recruited from the endodontic outpatient clinic at Future University's Faculty of Oral and Dental Medicine.

2.3 Eligibility criteria:

A- Inclusion criteria:

Patients in good health with no systemic disease: (American Society of Anesthesiologists/ (ASA Class I or II) [5].

Age range is between 20 to 40 years.

Patients having symptomatic irreversible pulpitis in mandibular first molar (vital pulp) with no periapical involvement.

Patients who can understand Visual Analogue Scale (VAS).

Positive patient's acceptance for participating in the study was required. Patients able to sign informed consent.

B- Exclusion criteria:

Medically compromised patients. Pregnant or lactating females.

Need for prophylactic antibiotic. Psychologically disturbed patients.

Patients with a history of allergy to any medication used in the study were excluded.

Patients who had taken pre-operative drugs as anti-inflammatory analgesic or antibiotics in the 12 hours preceding the injection.

Patients with swelling or acute peri-apical abscess. Teeth that have:

- Wide or open apex.
- Non vital pulp tissues.
- Association with swelling or fistulous tract.
- Acute or chronic periapical abscess.
- Periodontally affected with grade 2 or 3 mobility.
- No possible restorability.
- Pain on percussion.
- Abnormal anatomy and calcified canals.

2.4 Randomization

This sequence generation was done with each participant which was given a number from (1 to 78) using computer software (Microsoft Excel). Seventy-eight numbers were generated and distributed randomly in a table on an Excel sheet, and in front of each number a letter (C) for control and (I1 and I2) for intervention was typed. The random sequence was kept with the assistant supervisor.

2.5 Treatment procedure

After diagnosing the case as symptomatic irreversible pulpitis and confirming that the patient conforms to all eligibility criteria, the patient was enrolled in the study. The treatment of all cases were completed in two visits. Where in the first visit, The preoperative pain level was assessed by giving each participant a pain scale chart (VAS), tooth was anaesthetized by inferior alveolar nerve block using 1.8 – 3.6 ml (1-2 carpoules) 4% mepivacaine. A sterile round bur size # 4 was used to gain access, and Endo-Z Bur was used to complete the procedure. The rubber dam was used to isolate the teeth. An electronic apex locator was used to determine working length, which was subsequently validated with an intraoral periapical radiograph that would have been 0.5-1 mm shorter than the radiographic apex. ProTaper Next rotary instruments were used to mechanically prepare root canals utilizing the crown down approach.

2.6 Final Irrigation Protocol

Irrigation of the root canals was performed with 2ml of freshly prepared 2.6% sodium hypochlorite (NaOCl) solution where

Group A: **(SVN)** were irrigated using 2 ml of 2.6% NaOCl with NaviTip double Side port 31 G / 27 mm 1 mm shorter than the working length but without agitation.

Group B : **(PUI)** 2 ml of 2.6 % NaOCl was delivered into the canal using double side-port irrigation needle , Then irrigant was ultrasonically activated for 60 seconds with an Ultrasonic device (EndoUltra) at 40 kHz using a #20/02 metal activator tip in an up-and- down motion where the tip 1 mm short of the canal's working length

Group C: **(EDDY)** 2ml of 2.6 % NaOCl was delivered into the canal using double side- port irrigation needle, Then irrigant was sonically activated for 60 seconds with sonic device EDDY tips by VDW, which operates at a high frequency of up to 6000 Hz, driven by an air scaler 1 mm short of the canal's working length, with a flexible 25, 0.04 polyamide tip. For all groups 2 ml of 17% EDTA solution was then introduced into each canal for 1 minute, followed by 10 ml of distilled water were used as a final flush.

After completion of the biomechanical instrumentation of the root canals, the coronal access cavity was then temporarily restored to guarantee proper sealing and no oral fluid leaking inside the root canal.

Pain was assessed and recorded by the patient through using a VAS sheet that was handed to them previously, at 6, 12, 24, 48, and 72 hours and 7 days post operatively. In case of moderate or severe pain, patients were allowed to take Ibuprofen (400mg). They were also instructed to keep track of how many analgesic tablets they took.

Second visit (after 1 week): the vas sheet was collected from patient and Pain was assessed by the participant on the VAS sheet before the beginning of obturation. The root canals were obturated using the modified single cone technique by proper selection of gutta percha master cone corresponding to the same size as the master apical file (X3).Radiographic assessment with two different horizontal angulation of the root canal obturation was done.

2.7 Statistical analysis:

- In each test, the mean and standard deviation values were calculated for each group. Using the Kolmogorov-Smirnov and Shapiro-Wilk tests, the data was shown to have a parametric (normal) distribution.
- Friedman test was used to test the difference between more than two groups in related samples while Wilcoxon test was used to test the difference between two groups in related samples. Mann–Whitney U test was used to compare the difference between two groups in non-related samples for Pain evaluation.
- The significance level was set at P≤0.05. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

3. RESULT

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3. 1. Demographic Data

1. Gender

Regarding the gender distribution, 12 males (46.2%) and 14 females (53.8%) participated in group A (SVN), 13 males (50%) and 13 females (50%) participated in group B (EndoUltra) and 14 males (53.8 %) and 12 females (46.2%) were presented in group C (EDDY). There was no statistically significant difference between tested groups (P value = 0.859) (table 1).

2. Age

The mean age value and standard deviation (SD) for group A was 39.31±8.07 with the age ranged between (18-50) years, while, for group B, it was 39.65±7.26 with the age ranged between (18-49) years and for group C it was 37.04±5.61 with the age ranged between (18-50) years There was no statistically significant difference regarding age between tested groups (P value =0.353) (table 1).

3. 2. Pain Intensity and incidence at different time intervals of all groups

- At the first day (6-12-24 hours) there was a significant difference between the groups in pain incidence and intensity where group A (SVN) showed more pain scores than group B and group C ($p<0.05$).
- At (48-72 hours and 7 days) there were no significant difference between the groups where pain scores declined among the groups till it reaches nearly score (0) at 7 day ($p>0.05$). As shown in (table 1,2)

Table 1:

Incidence of pre & post-instrumentation pain at different pain categories of the all groups after 6 hrs, 12 hrs, 24 hrs, 48 hrs, 72 hrs and 7 days.

Pain incidence								
Variables		Group A (SVN)		Group B (EndoUltra)		Group C (EDDY)		P-value
		n	%	n	%	n	%	
Pre- operative	No pain	0	0%	0	0%	0	0%	0.401ns
	Mild pain	14	53.8%	13	50%	14	53.8%	
	Moderate pain	12	46.2%	13	50%	12	46.2%	
	Severe pain	0	0%	0	0%	0	0%	
After 6 hours	No pain	0	0%	0	0%	0	0%	<0.001*
	Mild pain	0	0%	19	73.1%	13	50%	
	Moderate pain	24	92.3%	7	26.9%	13	50%	
	Severe pain	2	7.7%	0	0%	0	0%	
After 12 hours	No pain	0	0%	0	0%	0	0%	<0.001*
	Mild pain	13	50%	26	100%	25	96.2%	
	Moderate pain	13	50%	0	0%	1	3.8%	
	Severe pain	0	0%	0	0%	0	0%	
After 24 hours	No pain	0	0%	0	0%	0	0%	0.005*
	Mild pain	21	80.8%	26	100%	26	100%	
	Moderate pain	5	19.2%	0	0%	0	0%	
	Severe pain	0	0%	0	0%	0	0%	
After 48 hours	No pain	0	0%	1	3.8%	0	0%	0.368ns
	Mild pain	26	100%	25	96.2%	26	100%	
	Moderate pain	0	0%	0	0%	0	0%	
	Severe pain	0	0%	0	0%	0	0%	
After 72 hours	No pain	5	19.2%	12	46.2%	11	42.3%	0.094ns
	Mild pain	21	80.8%	14	53.8%	15	57.7%	
	Moderate pain	0	0%	0	0%	0	0%	
	Severe pain	0	0%	0	0%	0	0%	
After 7 days	No pain	14	53.8%	21	80.8%	19	73.1%	0.099ns
	Mild pain	12	46.2%	5	19.2%	7	26.9%	
	Moderate pain	0	0%	0	0%	0	0%	
	Severe pain	0	0%	0	0%	0	0%	

Table 2:

Intensity of pre & post-instrumentation pain of the tested groups after 6 hrs, 12 hrs, 24 hrs, 48 hrs, 72 hrs and 7 days.

Period	Pain intensity						
	Group A		Group B		Group C		P-value
	Mean	SD	Mean	SD	Mean	SD	
Preoperative	**7.38**	0.75	**7.42**	**0.70**	**7.43**	**0.81**	**0.943ns**
After 6hrs	5.24	0.90	3.12	0.70	3.59	0.71	**<0.001***
After 12hrs	3.59	0.80	2.53	0.51	2.82	0.53	**<0.001***
After 24hrs	2.59	0.71	1.71	0.47	2.06	0.66	**0.001***
After 48hrs	1.76	0.66	1.24	0.56	1.35	0.49	**0.050ns**
After 72hrs	0.88	0.49	0.53	0.51	0.59	0.51	**0.118ns**
After 7 days	0.53	0.51	0.24	0.44	0.29	0.47	**0.171ns**
p-value	**<0.001***		**<0.001***		**<0.001***		

3. 3. Number and Incidence of analgesic intake:

There was statistically significant difference between the three tested groups regarding the incidence of analgesic intake (P<0.001). where the amounts of analgesics taken by the patients were higher at the first 48 hours among all groups, where patients at group A (SVN) recorded the highest amount of analgesics at the first 24 hours, while at (48-72 hours and 7 days) there were no significant difference between the groups where the number of analgesics intake decrease. (Table 3)

Table 3:

Total number and Incidence of intake of analgesics of the three tested groups.

Variables		Analgesic						p-value
		Group A		Group B		Group C		
		N	%	N	%	N	%	
Incidence of Analgesic intake	**Yes**	11	42.3%	2	7.7%	6	23.1%	**<0.001***
	No	15	57.7%	24	92.3%	20	76.9%	
Total no of tablet	**Mean SD**	3.35	0.80	0.46	0.71	1.12	0.98	

4. DISCUSSION

Managing and preventing the post-operative pain after endodontic procedure are one of the most important objectives of clinicians [6].

The amount of apically extruded detritus and irrigants could be affected by the irrigation agitation method. Any irrigation technique that lowers the possibility of extrusion would aid in reducing postoperative pain and discomfort [7, 8].

The goal of this study was to assess the impact of different irrigation activation techniques on PP in symptomatic irreversible pulpitis in mandibular molar teeth. During the RCT, all groups were treated with the same protocol but with the difference between groups being the final irrigation agitation technique. This ensured standardization and minimized the presence of variances.

In the present study, root canal treatment was completed in two visits where in the first visit, complete biomechanical preparation of the root canals were done because this procedure has the least incidence of post-operative pain and obturation was done one week later, thus ensure that the assessment of incidence and intensity of pain is in relation to the irrigation methods used without any interference of additional factors related to obturation.

The participants of tested groups were selected in age range from 20 to 40 years old, this age range was chosen as Visconti et al. [9] and Allegretti et al [10] reported that the younger patients showed higher pain levels during endodontic treatment. Furthermore, Watkins et al. [11] found that with increasing age, the expected and experienced pain levels declined dramatically. The mandibular first molars were chosen as they are much more likely to induce postoperative pain according to prior research [12].

The fact that radiologic and electrical root canal measurements do not always coincide is well recognised[13]. The WL was estimated with an electronic apex locator device and radiologically validated in this investigation to assure appropriate length measurement. To avoid over instrumentation, extrusion of canal content and biological debris into the periapical tissues. it is critical to keep all endodontic treatments within the canal. Since it might result in PP.

Sodium hypochlorite (NaOCl) is the most employed irrigating solution after each instrument used due to its potent antimicrobial and tissue dissolving effects. In the present study, sodium hypochlorite in 2.6% concentration was used to simulate the clinical condition in which the reduction of intracanal microorganisms is not any greater when 5.25% NaOCl is used [14].

Irrigation was done with 2 ml of freshly prepared 2.6% sodium hypochlorite (NaOCl) solution for 1 minute dispensed through a 30 gauge side vent irrigating needle, where needle penetration depth was done 1 mm shorter than the final working length as that length is considered as a proper depth to ensure adequate exchange of irrigant with decreased apical pressure and effective debris removal which in turn decrease the possibility of postoperative pain[15].

By agitating an irrigation solution, ultrasonic irrigation (Endoultra) was invented to improve the effectiveness of canal disinfection. An ultrasonic tip is activated in the canal up to 1 mm from the WL and moved in a passive up-and-down motion. [16].

Cleaning efficiency was also achieved utilising EDDY tips, which is a sonic irrigation- activation device that uses a flexible polyamide tip with size #25 and taper 4%, with 3D mobility at 1 mm from the WL. The cavitation and sonic streaming effects are provided by this instrument [17].

In this study the pain intensity was recorded preoperatively, after 6 hours, 12 hours, 24 hours, 48 hours, 72 hours and after 7 days after chemo-mechanical preparation.as in previous study Damyanov et al. [18] found that most of the postoperative pain after chemo- mechanical preparation occurs between 24 and 48hours interval, therefore in this study pain was also recorded at these intervals. While Singh et al [19] found that some patients may experience pain till 7 days after chemo-mechanical preparation, therefore pain was also recorded at 72 hours and 7 days after chemo-mechanical preparation, so in this study the pain was recorded at their intervals.

Multiple factors have a significant impact on PP. various scales and methods have been attempted to assess PP because evaluating so many different variables is considered a huge challenge [20] . The VAS scale was employed to assess postoperative pain in the current study [21]. When compared to other scales, this scale is straightforward to understand and gives simple, reliable, and valid results by enabling a greater range of responses.[22]. In this study the scale was described in full details to the patient to reduce errors that could occure by the patient during recording the PP intensity.

There are studies which concluded that variables such as age, sex, and preoperative pain could play a significant role in PP [23, 24.] however, in this study it showed no significant differences among the age/sex variables and preoperative pain scores between the groups

According to the results in this study showed the mean scores of post-pain intensity in this study were higher in control group (SVN) than in intervention groups Ultrasonic (EndoUltra) & Sonic (EDDY) at 6,12 and 24

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follow-up periods, while at 48,72 hours and 7 days post-instrumentation at which there was statistically non-significant in pain between tested groups.

This result can be explained by the fact that the (SVN) group extruded more irrigation solution and debris into the periapical tissue than the other two groups. This finding was correlated with, Rodrguez-Figueroa et al. [25] where he compared irrigant extrusion using PUI, the EndoActivator, or NI and found that utilizing PUI or the EndoActivator tip to within 1 mm of the WL appears to be quite safe and reduces post-operative discomfort.

On the other hand, some research have used various irrigation methods to assess the amount of apically extruded material. As in Karataş et al.[26] investigated the effects of several irrigation methods (NI, SA, and PUI) on apical debris extrusion and found that there was no significant difference in debris extrusion between the different irrigation strategies (NI, EA, and PUI). While Azim et al [27] reported no significant differences in debris extrusion between the NI and EA procedures.

5. CONCLUSIONS

Within the limitations of this study, it could be concluded that:

- Machine-assisted irrigation agitation devices are considered a reliable method as a final step irrigation protocol with successful management of post-operative pain.
- The incidence and intensity of post-operative pain decreased with time regardless the final irrigation protocol used.

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