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Evaluation of Postoperative Pain Following Sonic and Ultrasonic Root Canal Irrigation Activation Protocols in Patients with Non-vital Teeth Associated with Apical Periodontitis (Randomized Clinical Trial)

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ABSTRACT

Aim: Evaluate the degree of postoperative pain in patients with necrotic teeth with symptomatic apical periodontitis in mandibular first molar teeth at 6, 12, 24, 48 and 72 hrs time interval after using different irrigation activation techniques in single-visit endodontic treatment. ***Material and Methods:*** Seventy-eight patients diagnosed with necrotic mandibular first molar with symptomatic apical periodontitis were randomly allocated into 1 of 3 separate groups (n=26); Navitip group (control), EndoUltra group, or Eddy group. After a single visit root canal treatment and a specific method of agitation, depending on each group, the patients were given a questionnaire on which the patient would mark the degree of pain in a scale from 0 to 10 at 6, 12, 24, 48, 72 hours and 7 days post-obturation. Data were statistically analyzed with a significance level of P≤0.05. ***Results:*** EndoUltra ultrasonic agitation and Eddy sonic agitation as a final irrigation protocol showed significantly lower pain values than the control group, but there was no significant difference in pain values between the experimental groups. ***Conclusion:*** There was significantly less pain associated with EndoUltra ultrasonic and Eddy sonic agitation compared to Navitip irrigation.

1. INTRODUCTION

The success of endodontic treatment relies primarily on thorough root canal disinfection, followed by adequate seal of portals of entry and exit. Cleaning and shaping are performed with endodontic instruments and irrigation solutions to achieve maximum reduction of microorganisms and tissue remnants from the root canal space. [1]Root canal irrigation is a key part of successful root canal treatment (RCT). It has several important functions that may vary according to the irrigant used. Irrigation is also the only way to impact those areas of the root canal wall not touched by mechanical preparation. Different irrigation agitation techniques have been proposed to improve the efficacy of irrigation solutions within the root canal system. These techniques include the agitation of irrigation solutions with gutta-percha cones, lasers, brushes, and sonic and ultrasonic devices. [2] Sonic activation has shown to be an effective method to disinfect the root canals. Most actual systems have smooth plastic tips of different sizes activated at sonic frequency by a hand piece such as EDDY is a sonic energy irrigation-activation device that is powered at a high frequency, up to 6000 Hz, the instrument is reported to provide two physical effects, the cavitation and acoustic streaming as well as the cleaning efficiency. [3]Ultrasonic-activated irrigation is one of the possibilities to agitate a sodium hypochlorite solution in the root canal. It has been shown that dentin debris, pulp tissue, and biofilm can be removed from the root canal wall by the shear stress produced by acoustic streaming of the irrigant. [4]

2. METHODS

Sample size calculation: The sample was divided into 3 groups. Based on previous study [5], 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.[6]

Sample selection

After approval of the local ethics committee, 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. The exclusion criteria comprised medically compromised patients, pregnant or lactating females, psychologically disturbed patients, patients allergic to any medication used in this study, patients with swelling or acute periapical abscess, patients who administered anti-inflammatory analgesics or antibiotics 12 hours preoperatively. The exclusion criteria also comprised teeth with wide or open apex, vital pulp

tissues, association with swelling or fistula tract, no possible restorability, abnormal anatomy or calcified canals, previous root canal treatment, or periodontally affected with grade 2 or 3 mobility.

Root canal preparation

The tooth was isolated using rubber dam (Sanctuary Powder Free Latex Dental Dam, Malaysia) then patency of the canals was done using stainless steel hand K-file (MANI-MANI, INC. Industrial Park, Utsunomiya, Tochigi, Japan) sizes 15. Working length was measured using electronic apex locator (Root ZX, J. Morita USA, Irvine, USA) and was then confirmed with intraoral periapical radiograph (Kodak intraoral Periapical films, Kodak, USA) to be 0.5-1 mm shorter than radiographic apex using paralleling technique.

Root canals were mechanically prepared by crown down technique using ProTaper Next (DENTSPLY, Tulsa Dental, DENTSPLY Maillefer, TN, USA) nickel-titanium rotary instruments according to the manufacturer's instructions as follows:

- ProTaper Next rotary file set on electric motor (X-Smart, DENTSPLY, Tulsa Dental, DENTSPLY Maillefer, TN, USA) at a rotational speed of 300 rpm and 2 N cm torque using a gentle in and out brushing motion until the working length was passively reached.
- In the presence of NaOCl solution, 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.
- X2 (25/06) file was exactly used as described for X1 file, until the working length was passively reached. Afterwards, the canal was gauged with a size 25 K-file and, if the size 25 K-file was loose at length, canal shaping was continued with X3 (30/07) 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 ProTaper next file snugly fits the apical third of the canal at the working length.
- The canals were thoroughly irrigated with 2ml of freshly prepared 2.6% sodium hypochlorite (NaOCl) solution using plastic disposable syringe with side-vented needle (NaviTip; Ultradent, South Jordan, UT, USA) gauge 30 between every subsequent instrument. It was used passively into the canal, without forceful dispensing of the irrigant, placed 2mm short from the working length, which was verified by rubber stoppers. To achieve standardization, the volume of irrigating solution was fixed (2ml) after each file. A lubricant of 17% EDTA gel (EDTA, META, BIOMED, CO, LTD, Korea) was used with each file.

Final irrigation protocol

Navitip group (control group) Root canals were irrigated using 2 ml of 2.6% NaOCl with NaviTip double Sideport 31 G / 27 mm 1 mm shorter than the working length but without agitation.

EndoUltra group 2 ml of 2.6 % NaOCl was delivered into the canal using double side-port irrigation needle (Navitip Side port 31 G / 27 mm) which was used passively without forceful dispensing of the irrigant. Then irrigant was ultrasonically activated for 60 seconds with an ultrasonic device (Ultra X) at 40 kHz using #20/02 metal activator tip in an up-and-down motion where the tip was 1 mm short of the canal's working length.

Eddy group 2 ml of 2.6 % NaOCl was delivered into the canal using double side-port irrigation needle (Navitip Side port 31 G / 27 mm) which was used passively without forceful dispensing of the irrigant. Then irrigant was sonically activated for 60 seconds with a sonic device (EDDY) at 6000 Hz driven by air scaler 1 mm short of the canal's working length.

For all root canals in tested groups, 2 ml of 17% EDTA solution was then introduced into each canal for 1 minute to remove smear layer, followed by 10 ml of distilled water were used as a final flush of the canals to prevent erosion of the dentinal tubules.

Root canal obturation

After completion of the biomechanical instrumentation of the root canals, each root canals were completely dried using ProTaper Next absorbent paper points corresponding to the same size of the master file (X3). 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) and ADSEAL (ADSEAL, META BIOMED CO., LTD, Chungbuk) resin root canal sealer were used for obturation.

Cone fitness radiograph was taken to ensure proper length and preparation of the root canals. The ADSEAL sealer base and the catalyst were mixed till forming a mix with homogenous consistency. The mixed sealer was introduced into the canal through the master cone coated with sealer to the full working length. 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. No apical extrusion of gutta-percha beyond the apex was observed in any of the cases included. The access cavity was sealed using Resin-modified glass ionomer. All canals were shaped, cleaned, and obturated in a single visit. The details of each step were recorded in the patient's endodontic procedure form.

Post-operative instructions

Every patient was instructed to mark the VAS scale between (0-10) to determine Incidence and Intensity of pain pre-operatively and post-operatively after obturation at 6, 12, 24, 48, and 72 hours. 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. Pain level and was documented in the range of 0-10 numerically as no pain (0), mild pain (1-3), moderate pain (4-6) and severe pain (7-10).

The participants were instructed in case of presence of moderate (4-6 on VAS) or severe (7-10 on VAS) post-operative pain to take only one capsule of placebo which was given to him/her (powdered milk packed in opaque capsules). If the moderate or severe pain persist, patients were instructed to call the operator and were allowed to take 400mg Ibuprofen (Dailymed, USA). They were instructed to record the number of analgesic tablets taken. If there was still pain indicating a flare up (emergency), the patients were informed to contact the dentist and came to the clinic for an emergency intervention.

Each patient was given a chart to record postoperative swelling. If swelling was recorded, the patient, the patient would have been appointed for clinical examination to contact the operator to assess the severity in a swelling rating scale and determine if systemic antibiotics (Augmentin 625mg/8 hours/5 days) or drainage would have been needed.

After 7 days the patient delivered the assigned paper record.

Statistical analysis

The mean and standard deviation values were calculated for each group in each test. Data were explored for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests, data showed non-parametric (not-normal) distribution (scores).

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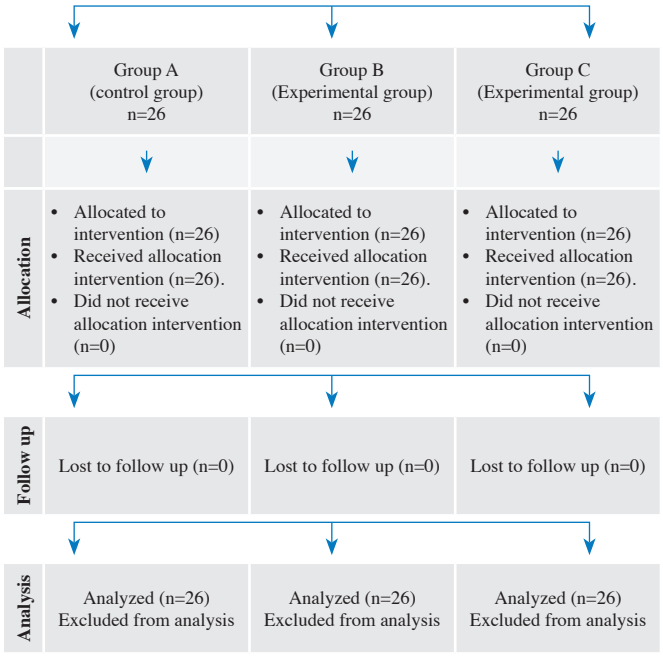
Friedman was used to compare between more than two groups in related samples. Wilcoxon was used to compare between two groups in related samples. Kruskal Wallis test was used to compare between more than two groups in non-related samples. Mann Whitney test was used to compare between two groups in non-related samples. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with IBM® SPSS® Statistics Version 20 for Windows.

3. RESULTS

In the present study, seventy-eight patients were included. The flow chart of the patients through the study is presented in the consort flow diagram in **(Figure 1)**.



EndoUltra ultrasonic group (Group B) and EDDY sonic group (Group C) showed significantly lower incidence and intensity of pain than the control group at 6,12 and 24 follow-up periods. **Figure 2** shows the incidence of pain at different time intervals for each group. **Table 1** shows the intensity of postoperative pain of the tested groups at different time intervals.**Tabel 2** shows incidence of analgesic intake of all groups .**Figure 3** shows intensity of instrumentation pain at different time intervals for each group. **Figure 4 shows** incidence of analgesics intake.

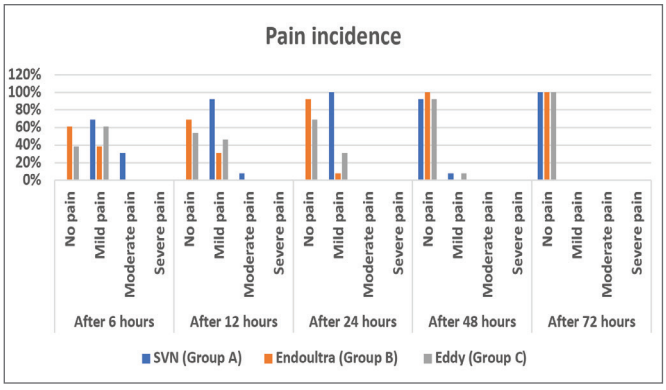


Figure (2) — Bar chart representing the incidence of pain at different time intervals for each group

Table (1):

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

Period	Pain intensity						P-value
	SVN (Group A)		Endoultra (Group B)		Eddy (Group C)		
	Mean	SD	Mean	SD	Mean	SD	
After 6hrs	2.62	1.19	0.46	0.66	0.77	0.73	**<0.001***
After 12hrs	1.85	1.07	0.38	0.65	0.62	0.77	**0.001***
After 24hrs	1.31	0.48	0.08	0.28	0.23	0.44	**<0.001***
After 48hrs	0.13	0.44	0.00	0.00	0.08	0.28	**0.210ns**
After 72hrs	0.00	0.00	0.00	0.00	0.00	0.00	**1ns**
p-value	**<0.001***		**<0.001***		**<0.001***		

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

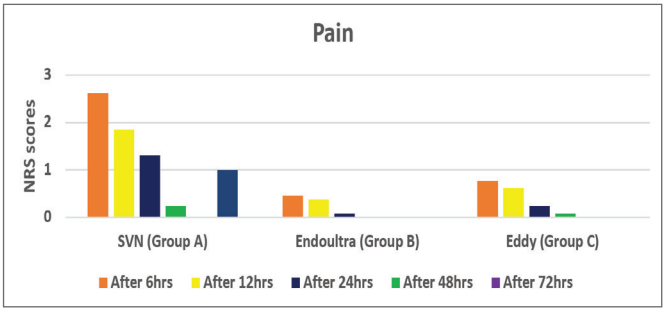


Figure (3) — Bar chart representing the intensity of instrumentation pain at different time intervals for each group

Table (2):

Incidence of analgesic intake of all groups

Variables		Analgesic intake						p-value
		SVN (Group A)		Endoultra (Group B)		Eddy (Group C)		
		n	%	n	%	N	%	
Incidence of analgesics intake	**No**	16	61.5%	24	92.3%	20	76.9%	**0.108ns**
	Yes	10	38.5%	2	7.7%	6	23.1%	

s: -significant (P<0.05)

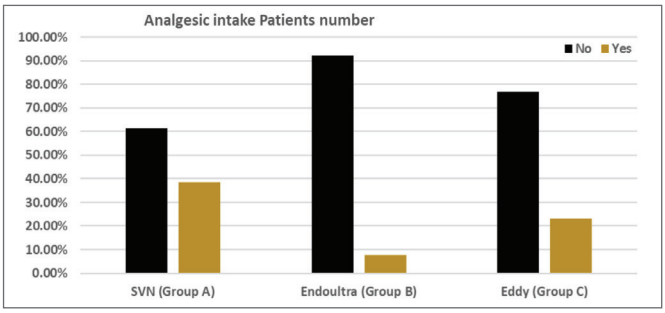


Figure (4) — Bar charts representing

4. DISCUSSION

The success of endodontic therapy depends on not merely on its efficacy and proper completion but also on minimal patient discomfort. Incidence of endodontic postoperative pain subsequent to endodontic treatment ranges from 1.4 to 16%. There are many factors contributing to postoperative pain and discomfort after root canal treatment including inadequate instrumentation, extrusion of irrigation solutions, and extrusion of apical debris. Evidence shows that apical extrusion of infected debris during chemomechanical instrumentation is the main etiologic factor for periapical inflammation and postoperative pain. [7]

The aim of the present study was to evaluate the degree of postoperative pain in patients with necrotic teeth with symptomatic apical periodontitis in mandibular first molar teeth using different irrigation activation techniques in single-visit endodontic treatment.

Mandibular first molars teeth were selected in the present study because post endodontic pain was previously reported in mandibular teeth due to their complex anatomy. [8,9] Postoperative pain was found to be significantly higher in the mandible compared to the maxilla because the mandible has a dense trabecular pattern, thus there is reduced blood flow and more localization of infection and inflammation, which might delay healing.[10]

Irrigation was performed using 30-gauge side vented needle inserted 2 mm short of working length to avoid production of high apical pressure increasing the risk for apical extrusion of debris which in turn increases the probability of postoperative pain.[11,12] The efficiency of irrigation solutions relate to the contact with all the root canal walls. However, because of the complex root canal anatomy, this effect may not be achieved using the conventionally accepted syringe needle. Many irrigation activation methods have been recommended for increasing the irrigation efficiency within the root canal system.

Passive ultrasonic irrigation (PUI) was introduced to increase canal cleanliness, better irrigant transfer to the canal system, soft tissue debridement, and removal of smear layer and bacteria. An ultrasonic tip is activated in the canal up to the WL and is moved passively in an up-and-down motion to ensure it does not bind with the root canal walls. [13]

EDDY is a sonic energy irrigation-activation device that utilizes a flexible 25, 0.04 polyamide tip. EDDY is powered at a high frequency, up to 6000 Hz, by an air scaler. With its 3D movement, the instrument is reported to provide two physical effects: the cavitation and acoustic streaming as well as the cleaning efficiency of PUI. [14]

In the present study, the Visual Analogue Scale (VAS) was used for measuring the pain intensity due to its simplicity, reliability, and adaptability to a broad range of populations and settings, easily understood by the patient and sensitive to changes in a patient's pain experience. [15,16]

In this study the pain intensity was recorded after 6 hrs , 12 hrs , 24 hrs , 48 hrs and 72 hrs from chemomechanical preparation. The 6 hours postoperative interval was chosen to provide sufficient time for anaesthetic effect disappear. [17] However, 12 and 24 hours were chosen as studies showed the most of the postoperative pain occurred on the first day after preparation. [18,19] While other study [20] found the most of the postoperative pain after preparation occurs between 24 and 48 hours intervals therefore in this study these time intervals were recorded.

Depris and irrigant extrusion during endodontic procedures is considered the main cause of postoperative pain. Unfortunately it is inevitable unless a negative apical pressure irrigation system is used. [21]

The primary outcome was the postoperative pain. The statistical analysis revealed that the incidence of the postoperative pain within EndoUltra group (group B) and Eddy group (group C) showed significantly lower than that of the control group (group A). These results may be attributed to passive ultrasonic device perform better microbial control in which the device enhances delivery irrigation to uninstrumented areas of root canal and help in removal of bacterial remnant by inducing acoustic streaming and cavitation of the irrigant. [22] This result is in agreement with study of **Yaylali** & **Demirci** that showed bacteria present in the root canal system responsible for postoperative pain.[23]

Furthermore the inability of conventional irrigation with Navitip double side needle to deliver the irrigant into more apical area in root canal lead to remenant of bacteria may be present that responsible to postoperative pain. [24]

This finding is supported by **Urban et al .2017** [25] and **Souza et al .2019** [26] who demonstrated that the use of PUI provides superior root canal cleanliness, better irrigant transfer to the canal system, soft tissue debridement and better antimicrobial property compared to syringe irrigation, this due to two main factors; firstly high power ultrasound produces a disagglomeration of bacteria biofilms in the root canal by the action of the acoustic current.

Khalap et al .2016[27] reported that the ultrasonic energy possesses the ability to create several nodes and antinodes throughout the length of file generating acoustic waves with the chemical action of the irrigant called as microstreaming and secondary acoustic streaming with frequency ranging from 40,000 to 45,000 Hz and along with the formation of cavitation effect. **Layton et al. 2015**[28] stated that PUI generates high shear stress in apical third of the root canal resulting in enhanced reduction of strictly adherent bacterial biofilm as compared to syringe irrigation.

The mean scores of postoperative pain intensity in this study were higher in control group (SVN) than intervention groups (EndoUltra and Eddy) at 6,12 and 24 follow-up periods. This may be attributed to passive pressure experted by the needles leads to greater hydrodynamic pressure leading to postoperative pain. This in accordance with systematic review puplished by **Konstantinidi et al. 2017** [29], they reported that the Ultrasonic / Sonic methods using negative pressure prevents the apical extrusion of the irrigant compared with methods using positive pressure (Manual dynamic agitation or needle). Furthermore, **Topcuoglu et al. 2018** [30] who stated that passive pressure of conventional irrigation extrudes great weight of depris apically.

The significance in postoperative pain results between the Sonic (EDDY) intervention group and control group (SVN) may be attributed to that fact that the use of Sonic agitation method promotes the removal of the biofilm layer in the root canal walls and increases the effectiveness of the irrigation solution. [31] This finding was supported by **Gümüs et al. 2021** [32] and **Yılmaz et al. 2019** [33] who attributed this to the fact that the use of sonic activated method results in less apical extrusion compared to the conventional endodontic syringe and therefore less postoperative pain.

Moreover, similar findings were observed in a systematic review conducted by **Pak and White et al. 2011**[34] in which pain incidence in the first 24 hours was 40%. Then declining sharply over the first 2 days after chemomechanical preparation.

In the present study the secondary outcome was to assess the incidence of analgesics intake. The frequency of analgesics taken by patients decreased by the time in each tested group. The incidence of post-instrumentation analgesic intake was higher in control group in compared to intervention groups with statistically no significant difference between the control and intervention groups. This may be due to the use of machine-assisted agitation making apical negative pressure prevent apical extrusion of irrigation [35].

The null hypothesis is accepted since postoperative pain incidence and intensity were not different between experimental groups (EndoUltra and Eddy) at 6,12,24 hrs.

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