

THE EFFECT OF DIFFERENT POWER MODES OF A SONIC ACTIVATION DEVICE ON POSTOPERATIVE PAIN AFTER SINGLE VISIT ENDODONTIC TREATMENT OF ACUTE IRREVERSIBLE PULPITIS: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

Aim: This study aimed to investigate the effect of low, moderate and high power sonic energy levels on post-operative pain intensity and frequency of analgesic intake in acute pulpitis cases after single-visit root canal treatment.

Materials and methods: 80 patients were randomly allocated into 1 control and 3 experimental groups according to the irrigant activation protocol with 20 patients per group as follows : negative control: without activation (side-vented needle only) , power mode “low”, power mode “medium”, and power mode “high”. Canals were cleaned and shaped. 5 milliliters of 2.5% NaOCl were delivered by means of a side vented needle gauge 30 in the control group. For the experimental groups sonic activation was performed using a polyamide tip (6000 Hz; EDDY, VDW GmbH) connected to an air scaler (SONICflex, KaVo Dental GmbH, Biberach, Germany), 3 × 20 s, and the 5 ml of NaOCl were distributed into 4 milliliters for continuous irrigation during activation followed by 1 ml as a final rinse. Post-operative pain intensity was recorded after 6 hrs, 24 and 48 hrs using the VRS pain scale. Frequency of analgesic intake was also recorded. Statistical analysis was performed using Kruskal-wallis test followed by Mann-Whitney test.

Results: Non-significant differences were found among the control and experimental groups regarding the pain intensity and incidence ($P > 0.05$). Analgesic intake frequency was also comparable among all groups. Both parameters were significantly higher after 6 hrs as compared to the values after 24 and 48 hrs, ($P < 0.05$).

Conclusion: Irrigant activation using the 3 sonic power modes did not adversely affect post-operative pain levels in patients with acute irreversible pulpitis. Pain levels were significantly higher after 6 hrs than after 24 and 48 hrs.

KEYWORDS: Irrigant activation, post-operative pain, endosonic

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INTRODUCTION

Root canal irrigation is a mandatory step in the cleaning and shaping process, it complements the instrumentation procedure in reducing bacterial loads, debris and smear layer^(1,2). Nevertheless, the complexity of the root canal system anatomy hinders the complete elimination of tissue remnants and microorganisms. Sodium hypochlorite is the most commonly employed irrigating solution for its antibacterial and tissue solvent properties. Its action is affected to a major extent by its intra-canal penetration depth which is a function of the needle diameter as compared to the canal diameter⁽³⁾. This discrepancy has been compensated for by different irrigant activation techniques. Sonic activation is one of these methods which proved beneficial in enhancing irrigant penetration and action, thereby enhancing antimicrobial effectiveness and cleaning potential. These devices operate at lower frequencies than their ultrasonic counterparts. EDDY (VDW GmbH, Munich, Germany), is a sonic energy-based activation device with a flexible, non-cutting tip that is connected to an air scaler handpiece, operating at a frequency of 5000Hz to 6000 Hz. The soft polyamide tips activate the irrigating solution without compromising the dentinal wall integrity. Recent *in vitro* studies have shown that this device, compared with needle irrigation, improved the dentin debris removal from artificial canal irregularities^(4,5). It has three operational power settings: low, medium and high. The majority of studies on the disinfection effectiveness of EDDY irrigant activation used the device at the highest power mode⁽⁴⁾. This factor was found to exert a pronounced effect on irrigant streaming and cleaning effectiveness of sonic activation devices by increasing the tip oscillation amplitude. Nevertheless, some practitioners preferred to apply it at lower power modes to as a means of minimization of irrigant spraying, or to reduce the likelihood of irrigant extrusion.

The major concern about irrigant activation vs. extrusion would be related to the extent of post-operative pain levels. Therefore, it would be prudent to select a power setting that provides efficient irrigant activation-mediated cleaning and microbial reduction, besides a minimal pain-inducing effect on peri-apical tissues. There is insufficient data on the effect of power settings of EDDY sonic irrigant activation on postoperative pain after single-visit endodontic treatment in cases with symptomatic irreversible pulpitis. Therefore the aim of this study was to assess whether or not different power settings have a similar impact on the post-operative pain levels and frequency of analgesic intake or not. The null hypothesis is that no significant difference would be found among the tested groups.

MATERIALS AND METHODS

Sample size

A sample size of 80 (20 per group) was implemented to detect an effect size of 0.2, a power of 80%, and a significance level of 5%.

Patients' selection

Criteria of patients recruitment were defined and the research was accepted by the ethical committee at the Faculty of Dentistry, Ain Shams University. The approval number was FDASU-Rec IR 072309. The selected patients fulfilled the following criteria:

Female patients

Medically-free

The age range was from 25-45 years

They had symptomatic irreversible pulpitis in lower molars with mature roots.

Teeth were non-calcified root canals, free from root caries, internal or external root resorption.

Meanwhile the following conditions were excluded:

Pregnant females,

Patients with parafunctional habits

Previously root canal treated teeth, periodontally compromised teeth, evidence of external resorption, or root fracture

Patients having a mandibular first molar with a periapical lesion

Allergy cases to local anesthetics

Patients who had antibiotics or analgesics seven days pre-operatively

Diagnostic clues were based on pain extent, time span, frequency, and triggering and soothing factors. Symptomatic irreversible pulpitis was defined by a sustained exaggerated response that lasted more 10 seconds.

All patients were aware verbally and in written forms about the expected treatment outcomes and the possible risks (if any) and an informed consent was signed by each one of them. A randomisation software (<http://www.random.org/>) was implemented for patients allocation by a non-involved member in the study. The patients recruitment process and groups allocations were illustrated in the CONSORT flow diagram (Fig.1). The inflamed, the adjoining and the contralateral teeth were electrically tested. Each candidate was given a verbal rating scale (VRS) to register the pain level pre-operatively. The paralleling technique was used for radiographic diagnosis.

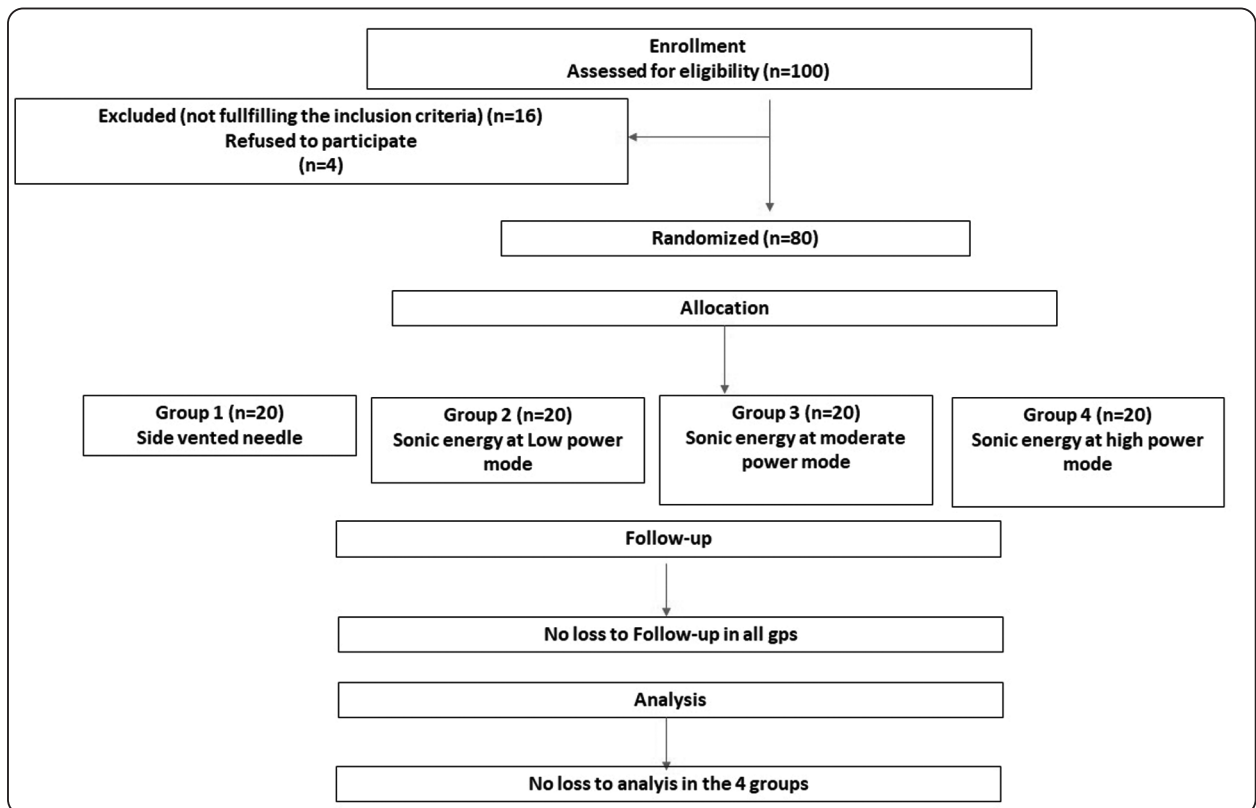


Fig. (1) Consort flow diagram

MANAGEMENT PROTOCOL

A single visit endodontic treatment was attempted. Teeth were anaesthetized by an inferior alveolar nerve block using 4% Mepivacaine HCl containing 1:100,000 epinephrine). Access cavities were opened under rubber dam isolation. Electronic working length determination was carried out using an apex locator (Root ZX, J. Morita, Tokyo, Japan) and radiographically confirmed. Canals were cleaned and shaped using E-Flex Gold rotary files as per the manufacturer instructions, (Eighteeth, Changzhou, China), apical enlargement was finished at 35 for small canals and 50 for large canals.

Irrigation regimens

Canals were irrigated using 5 milliliters of 2.5% NaOCl by means of a side vented needle gauge 30 inserted to the working length. Sonic activation was then performed using a polyamide tip (6000 Hz; EDDY, VDW GmbH) connected to an air scaler (SONICflex, KaVo Dental GmbH, Biberach, Germany), 3×20 s, with 5 ml of NaOCl, distributed into 4 milliliters for continuous irrigation during activation followed by 1 ml as a final rinse. The groupings were carried out as follows:

1. Negative control (n = 20): without activation
2. Power mode "low" (n = 20), amplitude range $120 \pm 15 \mu\text{m}$
3. Power mode "medium" (n = 20), $160 \pm 15 \mu\text{m}$
4. Power mode high (n = 20), $240 \pm 15 \mu\text{m}$

The sterile single-use EDDY irrigation tips, were inserted to full working length, while inserting the side vented needle at the cervical one third of the canal for continuous irrigation during activation. They were changed for independent irrigant activation per root. Sterile paper points were then used to dry the canals. Canals were obturated using the lateral condensation technique. Cases were imaged post-operatively. In case of unbearable pain, patients were advised to take 400 mg Ibuprofen analgesic.

Pain scoring

The VRS was used to assess the pain level after 6 hrs, 24 hrs and 48 hrs post-operatively (5). Patients were informed of the necessity of contacting the operator in case of development of severe pain or swelling to determine whether drainage or antibiotics will be needed. Moreover, how many ibuprofen tablets taken by the patient at every follow-up interval was included in the patient's file. The scale was graded as follows:

- 0: no pain,
- 1 to 3: mild (recognizable, not upsetting) ,
- 4 to 6: moderate (upsetting, but bearable) ,
- 7 to 10: severe (considerable discomfort, unbearable).

Statistical analysis

Nominal data were presented as frequency percentages, statistical analysis was carried out using Kruskal-Wallis test followed by Mann-Whitney test. Significance level was set at 0.05.

RESULTS

One hundred patients were examined, out of which 80 were included in the study. The information and data were gathered from the participants through phone calls, therefore no patients loss was recorded. Significantly higher incidence and intensity of post-operative pain was noted after 6 hrs than after 24 and 48 hrs, ($P < 0.05$). The pain intensity was the highest after 6 hrs then decreased over time in the 4 groups. Non-significant differences were noted among the different groups after 24 and 48 hrs ($P > 0.05$), (Fig.2). Significantly higher frequency of analgesic intake was observed in the 6-hour interval among the 4 groups as compared to the 24 and 48 hrs intervals ($P < 0.05$). Non-significant differences were found among patients who had analgesics once or twice in the 4 groups, ($P > 0.05$), (Fig.3).

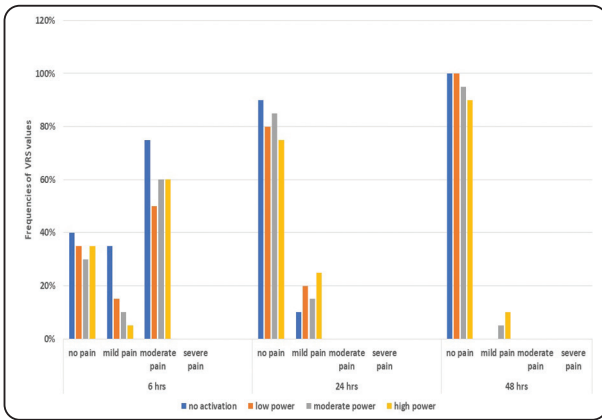


Fig. (2) Bar chart representing the frequencies of VRS values

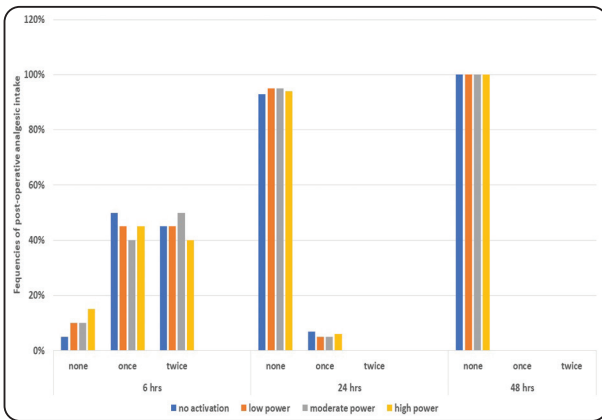


Fig. (3) Bar chart illustrating the frequencies of post-operative analgesic intake

DISCUSSION

Apical extrusion of irrigating solutions into periapical tissues is one of the main causes of post-operative pain. The extent of extrusion is directly linked to the irrigation methodology and activation techniques. Some practioners claimed that the lower power mode of sonic energy would reduce the likelihood of irrigant extrusion, which in turn would reduce post-operative pain levels when it comes to irrigation contribution . Therefore, this study aimed to assess whether sodium hypochlorite irrigant activation using different power modes of sonic energy would influence post-operative pain levels or not, after 6 hrs, 24 hrs and 48 hrs as compared to needle irrigation.

Acute pulpitis cases only were included given that pre-operative pain is one of the main predictors of postoperative pain. Female patients only were selected to standardize the gender factor. Age range was also unified to minimize the confounding variables. Multi-rooted teeth were considerably more prone for postoperative pain as a result of the complex anatomy (6). Necrotic or infected cases were excluded given that microbial contamination may remarkably affect postoperative pain levels. Moreover, apical resorption would predispose to higher likelihood of irrigants extrusion (7). Endodontic treatment was performed in a single visit to minimize the risk of intra-canal contamination in between visits and to eliminate the variable of intra-canal medications. Root canal length was determined using a combination of electronic and radiographic methods to ensure accuracy and to make sure that instrumentation and irrigation were confined to the canals. Sodium hypochlorite at 2.5% concentration was the used as the gold standard irrigant for its high anti-bacterial and tissue solvent properties. This concentration would ensure disinfecting and cleaning actions with lower cytotoxicity risk than the full concentration solution (5%) (8). Side-vented 30-gauge needles were used within 2 mms from the working length as to avoid any risk of extrusion with open-end needles. EDDY sonic tips were also activated within two millimeters from the working length (9).

The verbal rating scale (VRS) was implemented as the evaluation tool as it is a comprehensible way of delivering and collecting the information from the patients regardless of their education level(5). Nevertheless, variabilites in patients anxiety levels, imposed tissue trauma with anesthesia delivery and rubber dam placement might have differently contributed to the post-operative pain levels (10).

The null hypothesis was rejected given that there was a significant difference in post-operative pain incidence and intensity as well as frequency of analgesic intake after 6 hrs when compared to 24 and 48 hrs. Pain levels were higher after 6 hrs as

compared to 24 and 48 hrs, that would be related to the triggering of the inflammatory process peri-apically during the endodontic treatment. The polymorphonuclear leukocytes permeate the traumatized site within 6 hours, besides the outpouring of inflammatory mediators⁽¹¹⁾. 48 hours later, the proliferation stage begins with a lowering in the PMNs counts, and the macrophages penetrate the wound location⁽¹¹⁾. Similarly, Pak and White,⁽¹²⁾ documented a 40% pain incidence during the first 24 hours that was abruptly reduced after cleaning and shaping throughout the first two days.

The three power modes were comparable to the needle irrigation in the non-significant levels of post-operative pain. Irrigants and debris extrusion were the main factors predisposing to postoperative pain. Concept wise, some studies reported that sonic irrigant activation reduces post-operative pain levels by virtue of its anti-biofilm effects, besides its lower extent of irrigant extrusion^(4,13). Ramamoorthi also added that sonic activation optimizes the irrigant action with minimum required intra-canal volume⁽⁹⁾. Sonic and apical negative pressure irrigation systems were found to extrude less than syringes with side-vented needle or passive ultrasonic irrigation with continuous flow^(1,13-15). Sonic energy was shown to apply negative pressure in order to irrigate and eliminate debris from the apex without forcing the irrigant into the periapical tissues, such that each time the activator system is inserted into the canal, the irrigating solutions are apically exchanged rather than apically extruded⁽¹⁶⁾. When comparing needle irrigation to sonic irrigation dynamics, the needle has a simple flushing action, and to enhance its efficacy, it should be inserted in closer proximity to the apex which would provoke peri-apical irrigants extrusion due to the positive pressure produced during delivery^(2,17), which is also hard to control clinically⁽¹⁷⁾. In case of Sonic devices, the tip vibration in combination with its up and down movement in short vertical strokes, creates a hydrodynamic phenomenon⁽¹⁰⁾. By analogy, EndoActivator as a sonic device extruded irrigating solutions comparably to EndoVAC, and

both of them were significantly lower than PIPS and Max I Probe⁽¹⁸⁾. Karatas et al⁽¹⁹⁾ compared the effects of needle irrigation, sonic activation and passive ultrasonic irrigation and found no differences in extent of apical extrusion of debris. Yost et al⁽²⁰⁾ found out that the side-vented needle and EndoActivator groups exhibited similar NaOCl extrusion values. Similarly, Azim et al⁽²¹⁾ compared the volumes of apically extruded irrigants in an artificial model simulating clinical conditions and concluded that the needle irrigation and EndoActivator methods extruded similar volumes of irrigant. Boutsoukias et al⁽¹⁷⁾ found that the EndoActivator and PUI methods extruded less than manual dynamic agitation. When directly assessing the post-operative pain levels, the PUI, sonic and manual dynamic agitation did not differ in terms of pain scores at hours 8 and 48 in irreversible pulpitis cases^(22,23).

CONCLUSION

Within the limitations of the present study, it could be concluded that irrigant activation using the 3 power modes of EDDY sonic energy did not elevate post-operative pain or frequency of analgesic intake in single-visit root canal treatment of acute pulpitis cases. Pain levels and frequency of analgesic intake were significantly higher after 6 hrs when compared to 24 and 48 hrs as a part of the healing process.

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