



RESEARCH ARTICLE

EVALUATION OF POST-OPERATIVE PAIN AFTER IRRIGATION USING END-VENTED NAVITIP TIPS VERSUS SIDE-VENTED NAVITIP TIPS IN TEETH WITH IRREVERSIBLE PULPITIS: A RANDOMIZED CLINICAL TRIAL

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Manuscript Info

Manuscript History

Received: 20 December 2019

Final Accepted: 22 January 2020

Published: February 2020

Key words:-

End-Vented Needle, Irrigation, Post-Operative Pain, Side-Vented Needle

Abstract

Objectives: The aim of this prospective randomized clinical trial was to compare the degree of post-operative pain and analgesic intake at 0, 4, 12, 24, 48, 72-hrs and 7 days after the use of two different irrigation needles.

Subjects and Methods: Thirty eight participants diagnosed with symptomatic or asymptomatic irreversible pulpitis in mandibular posterior teeth received single-visit root canal treatment and were divided randomly into two groups according to the type of needle used during irrigation either NaviTip 29-gauge, 27 mm with End-Vented needle (EVN) or NaviTip 31-gauge, 27 mm with Double Sideport Irrigator Tip (SVN). Post-operative pain was measured using Numeric Rating Scale (NRS) pre-operatively, immediate post-operatively and at 4, 12, 24, 48, 72-hrs and 7 days. Placebo and analgesic intake was recorded at the different time intervals.

Results: There was no difference between both groups in the NRS scores at all the post-operative time intervals. An observable increase in pain levels was recorded at 4-hrs followed by an observable drop in pain levels at 12, 24 and 48-hrs post-operatively until pain disappeared at 7 days with no difference in drug intake post-operatively between both groups.

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Introduction:-

Postoperative pain is one of the main challenges in endodontic treatment; it has been a major concern to the patients and clinicians.⁽¹⁾ Pain is a complex psycho physiologic phenomenon that may occur as a result of various causes such as microbial factors, mechanical, or chemical injury to periapical tissues.⁽²⁾ Mechanical reason may be over-instrumentation, chemical factors include the extrusion of medications, filling materials, or irrigants into the periapical tissues that may result in acute inflammation.⁽³⁾

Irrigation is essential for root canal chemical debridement because it allows for cleaning beyond what might be achieved via instrumentation alone.⁽⁴⁾ Sodium hypochlorite is the most commonly used irrigating solution owing to its antimicrobial effect and tissue dissolution properties.⁽⁵⁾ However the extrusion of irrigating solution beyond the apical constriction may result in postoperative pain.⁽⁶⁾ Sodium hypochlorite can cause severe tissue irritation and

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necrosis if extruded into the periapical tissues.^(7,8) Different irrigant delivery techniques are used to reduce this potential risk.⁽⁹⁾

Irrigation with syringe was advocated as an efficient method of irrigation.⁽⁹⁾ The main goals in needle design are to maximize effectiveness and safety; there are different types of irrigating needles on the market. Classic open-ended irrigating needles are the most widely used irrigant delivery method.⁽¹⁰⁾ Although this technique is simple, potential complications exist.⁽⁵⁾

Few studies measure the effect of irrigation methods on postoperative pain⁽¹¹⁾, hence the aim of this study is to compare the degree of postoperative pain at 0,4,12,24,48,72 hours and 7 days after the use of recently introduced side vented needles and end vented needles during the treatment of mandibular posterior teeth with irreversible pulpitis.

Subjects and Methods:-

The trial design of this study was a prospective randomized clinical trial, the patients were asked to follow the general instructions and to sign a printed informed consent after the explanation of the treatment procedures.

Patient Selection:

Patients were carefully diagnosed and checked for the eligibility criteria through careful medical history, dental history, extra-oral and intra-oral clinical examination, visual examination of the suspected tooth, percussion test and pulp testing, in addition to proper intra-oral radiographic assessment.

Thirty-eight participants diagnosed with symptomatic or asymptomatic irreversible pulpitis in mandibular posterior teeth were included in this study. Patients' age was in range of 18-60 yrs. Patients taking any medication that would affect pain perception, patients suffering from systemic diseases that could affect treatment, pregnant patients and patients allergic to any medication used in the study, in addition to patients with necrotic teeth, periapical radiolucency, swelling, sinus tract, grade two or three mobility or retreatment cases were all excluded from the study.

Recording of the chief complaint and history of presence or absence of pain in the patient's own words was done. If there was a history of pain, a determination of pain criteria: intensity, character, duration, frequency, provoking and relieving factors and localization was done. The patient was asked to mark the level of pain experienced pre-operatively in the pain diary and the analgesic intake.

Randomization:

Random sequence was generated by the Center of Evidence Based Dentistry, Faculty of Oral and Dental Medicine, Cairo University using the random function in Microsoft Excel software for 38 participants and each participant was assigned a letter C for control and I for intervention with 19 participants in each group. The sequence table was kept with the co-investigator. Each participant was given a number from 1-38 after he/she was confirmed eligible for the study after access cavity preparation. Based on the number the patient was then allocated into intervention or control group after contacting the co-investigator and asking him about which group the number stands for. Blinding was done for the patient, as he/she was not informed of the irrigation needle type and for the outcome assessor that collected the NRS and analgesic consumption data from the patients. The operator could not be blinded due to the nature of the study as the needles' vents must be exposed and could not be masked.

Endodontic Protocol:

Patients were anesthetized using the inferior alveolar nerve block technique using 2% Mepivacaine HCl with 1:20,000 Levonordefrin (MEPECAINE-L ALEX CO. for Pharmaceuticals and Chemical Industries, Egypt.).

Access cavity was prepared, teeth isolated using rubber dam, and working length was determined using electronic apex locator, which was confirmed radiographically at 0.5-1 mm shorter than the radiographic apex. Root canals were instrumented using ProTaper Universal nickel-titanium rotary instruments (ProTaper Universal Dentsply, Tulsa dental, Dentsply Maillefer, USA) in a crown down technique using 19% EDTA cream as lubricant with each file.

The patients were randomly divided into two equal groups according to the needle type used during irrigation; Group A, NaviTip® 29-gauge 27-mm (Ultradent Products Inc., South Jordan, UT, USA) with End-Vented Tip (EVN) and Group B, NaviTip® 31-gauge 27-mm (Ultradent Products Inc., South Jordan, UT, USA) with Double Sideport Irrigator Tip (SVN). Irrigation was done using freshly prepared 2.5% NaOCl to maintain chlorine stability and performed 2 mm short of the final working length. Eight milliliters of 2.5% NaOCl were used during access cavity preparation and initial coronal instrumentation then 2 ml of 2.5% NaOCl was expressed over 30 seconds after each rotary instrument use and 3 ml of 17% EDTA was used for 1 minute followed by 10 ml of distilled water as a final flush.

After completion of instrumentation and irrigation, Obturation was done using Protaper Universal gutta-percha cones (ProTaper Universal Gutta Percha Dentsply, Tulsa dental, Dentsply Maillefer, USA.) corresponding to the final finishing file and Resin based sealer (ADSEAL META BIOMED CO., LTD., Korea.), using the modified single cone technique. A radiograph was obtained to ensure proper master cone extension. Obturation was considered complete when the spreader can no longer penetrate beyond the cervical line. Excess gutta-percha was cut off using a heated plugger and teeth were then sealed using Cavit. All procedures were done in a single-visit and all steps were checked radiographically.

Post-operative pain evaluation:

After the treatment, all patients received post-operative instructions and an emergency kit containing one capsule of placebo packed with starch and a prescription for 200 mg ibuprofen. Patients were instructed to take the placebo within the 0-4-hrs time interval after the treatment if needed. If the pain was not relieved, the patients were instructed to call the doctor for consultation and the doctor would allow the use of the prescription as one or more tablets of analgesic every 8-hrs. Post-operative pain was measured at immediate post-operatively, 4, 12, 24, 48 and 72-hrs and 7 days after root canal treatment in addition to a pre-operative record using Numeric Rating Scale (NRS) scale, which is a 10-cm line with 11 marks and 10 intervals. Pain was categorized into four categorical scores: none, mild [1-3], moderate [4-6], severe [7-10].

Results:-

The side-vented and end-vented needles showed an observable drop in pain levels at all the time points compared to the pre-operative pain levels until pain disappeared. (Table 1 and Figure 1). There was no statistically significant difference ($p > 0.05$) in the pain levels between both groups at all the post-operative time points. There was no statistically significant difference ($p > 0.05$) between the two tested groups regarding placebo intake incidence, medication intake incidence, or Ibuprofen pills intake. (Figure 2 and Figure 3).

Table 1:- Median, minimum and maximum NRS scores at different time points in both groups; (Group A: SVN and Group B: EVN) by Mann Whitney test and over time in each group by Friedman Test.

	Group A			Group B			p-value 1
	Median	Min.	Max.	Median	Min.	Max.	
Pre-operative	0	0	6	0	0	7	0.629
Immediate Post-operative	0	0	0	0	0	0	1.000
4 Hours	1	0	10	0	0	10	0.676
12 Hours	0	0	10	0	0	10	0.562
24 Hours	0	0	10	0	0	8	0.474
48 Hours	0	0	8	0	0	8	0.673
72 Hours	0	0	1	0	0	2	0.970
7 Days	0	0	0	0	0	0	1.000
p-value 2	<0.001			<0.001			

* Indicates significance at $p \leq 0.05$

p-value 1 for comparison between both groups.

p-value 2 for comparison over time in each group separately.

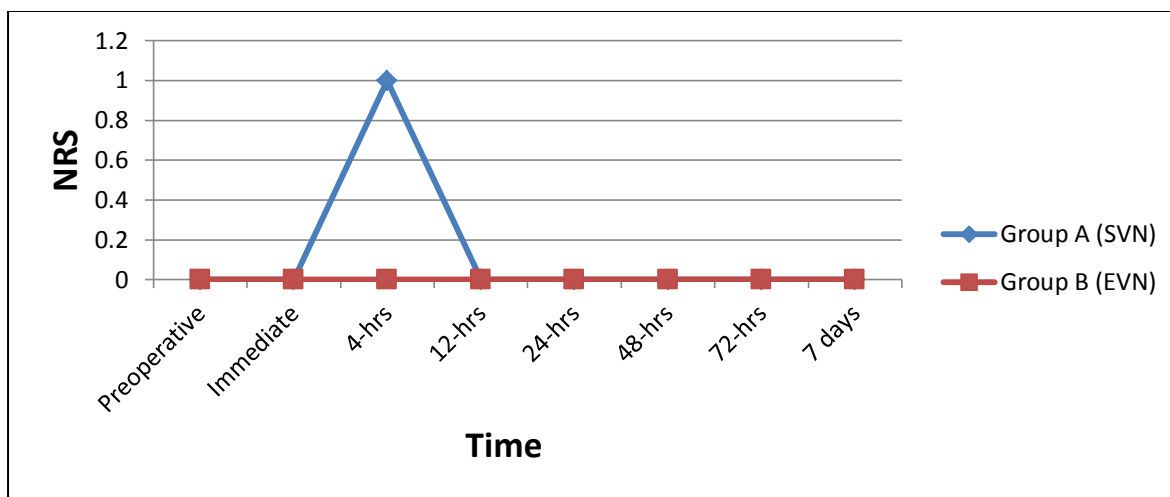


Figure 1:- Line chart showing the change in the NRS scores values over time for the two groups; (Group A: SVN and Group B: EVN).

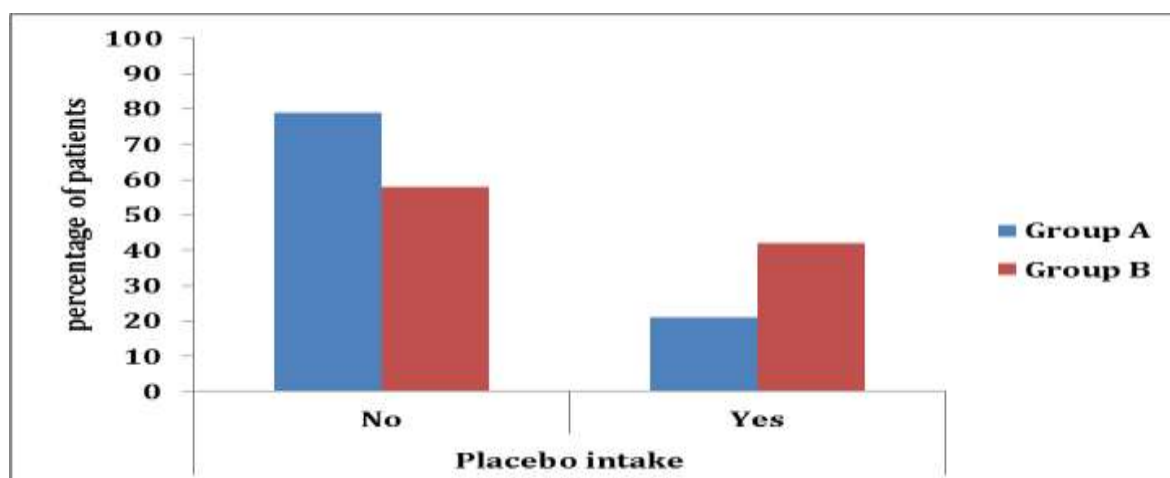


Figure 2:- Bar chart representing Placebo intake distribution in the two tested groups; (Group A: SVN and Group B: EVN)

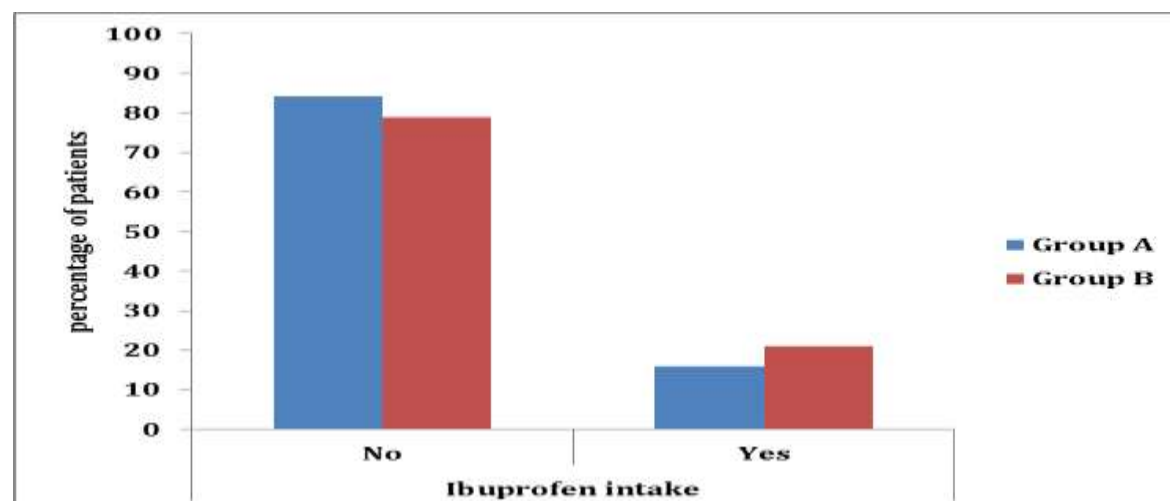


Figure 3:- Bar chart representing Ibuprofen intake distribution in the tested groups; (Group A: SVN and Group B: EVN).

Discussion:-

Postoperative pain after root canal treatment is a common finding and it is defined as pain of any degree that occurs after initiation of RCT. ^(12,13) The purpose of this randomized controlled clinical study was to compare the postoperative pain after single visit root canal treatment of mandibular teeth with irreversible pulpitis using End-vented NaviTip and Side-vented NaviTip needles for irrigation during RCT. According to a prospective study by Georgopoulou et al (1986) ⁽¹⁴⁾ pain-free patients do not exceed 57% of all endodontic cases. Some of the reasons for postoperative discomfort in irreversible pulpitis patients are the mechanical cause that occurs due to over instrumentation and chemical factors such as apical extrusion of irrigants, intracanal materials or filling materials. ⁽¹⁵⁾ The randomized controlled trial shows the highest level of evidence, which can reduce the bias most effectively through blinding and randomization. This can be done by randomly distributing the patients between the groups, thus balancing the patients' baseline characteristics that may influence the outcome in both groups, so that any difference in the outcome could be explained only by the treatment. ^(16,17) In the present study, every effort was made to reduce any factors affecting postoperative pain. Patients who take analgesics or antibiotics before the procedure, patients with systemic disease, pregnant females and patients with periodontal disease or acute periapical cases were excluded. Therefore, only medically free patients who had mandibular posterior teeth with irreversible pulpitis with no clinical or radio-graphic signs or symptoms of acute or chronic apical periodontitis were included in the study. ⁽¹⁸⁾ In this study mandibular posterior teeth were selected according to Arias et al (2013) ⁽¹⁹⁾ who reported that post-endodontic pain was significantly higher when the treated tooth was a molar and the probability of experiencing moderate or severe pain was higher in mandibular teeth. Patients can feel pain more frequently in the mandibular teeth (42%) in comparison with maxillary teeth (26%). This might be related to the mandibular dense trabecular pattern, which reduces the blood flow and causes localization of infection and exudates leading to delayed healing patterns. ⁽²⁰⁾ Root canal treatment was completed in a single-visit as Wong et al (2015) ⁽²¹⁾ found that there was no statistically significant difference in postoperative pain incidence between endodontic treatment that was done in single-visit or multi-visits. Prashanth et al (2011) ⁽²²⁾ also reported that postoperative pain after endodontic treatment was similar following both single and multiple visits. Moreover, single-visit treatment has more advantages such as reducing the risk of flare-up induced by multiple-visit endodontic treatment such as leakage, loss of temporary seal ⁽²³⁾, allows for immediate use of canal for post retention also the patient is not disturbed by multiple anesthetic injections and the rubber dam placement procedures, etc. ⁽²⁴⁾ Root canal preparation was performed by crown-down technique using Universal Protaper rotary file. Early flaring of the coronal part of the preparation may improve instrument control during preparation of the apical third of the canal. ⁽²⁵⁾ The rotary motion has been shown to direct debris upward toward the orifice, avoiding its compaction in root canal decreasing periapical extrusion of debris ⁽²⁶⁾, resulting in significantly lower pain compared with the reciprocating motion. ⁽²⁷⁾ Also Azar et al (2005) ⁽²⁸⁾ reported that ProTaper rotary instruments extruded less debris and irrigant than the step-back technique. A lubricant (Glyde File Prep) was used with each file. It was suggested that significantly less debris was produced due to the effect of Glyde File Prep combined with sodium hypochlorite. ⁽²⁹⁾ In this study, NaOCl was used as a routine intracanal irrigant, as it is the best available canal irrigant because of its antibacterial and organic tissue-dissolving properties. ⁽³⁰⁾ A low concentration of 2.6% NaOCl was used as high concentration of 5.25 % NaOCl is highly toxic and causes degradation of dentin matrix components which affects the mechanical properties of teeth. ⁽³¹⁾ In addition, both concentrations showed the same antibacterial efficacy. ⁽³²⁾ As a final flush three milliliters of 17 % EDTA was used for smear layer removal as NaOCl lacks the ability to dissolve inorganic material ⁽³³⁾, then 10 ml of distilled water were used immediately after EDTA to avoid the prolonged effect of the chelating agent on the micro-hardness of root dentin and adhesion to resin-based sealers. ⁽³⁴⁾ Obturation was done using modified single cone technique using ProTaper Universal gutta percha points. According to previous studies lateral compaction technique resulted in significantly more pain compared to modified single-cone obturation technique. ⁽³⁵⁾ The Numeric Rating System (NRS) was used to evaluate the pain intensity as it provides a descriptive numerical value to the patient and for statistical analysis. ⁽³⁶⁾ It is preferred by patients and clinicians over the Visual Analogue Scale (VAS) for its relative simplicity ease of administration and scoring. It's also characterized by high reliability and validity. ⁽³⁷⁾ Assessment of pain intensity was carried preoperatively, immediate postoperatively, after 4 hours, 12 hours, 24 hours, 48 hours, 72 hours and after 7 days. Pain was recorded preoperatively as Ali et al. (2016) ⁽³⁸⁾ showed that presence of preoperative pain is a significant predictor for postoperative pain after endodontic treatment. The 4 hours after instrumentation was enough time to allow the anesthetic effect to completely disappear. ⁽³⁹⁾ However, 12 and 24 hours were chosen as Genet et al (1986) ⁽⁴⁰⁾ showed that most of the post-operative pain occurred on the first day after initiating endodontic treatment then subsequently the pain decreased. A 24 hours and 48 hours post instrumentation intervals were chosen because Damyanov et al (2012) ⁽⁴¹⁾ found that most of the postoperative pain after endodontic treatment occurs between 24 and 48 hours. A 7 days post-instrumentation intervals as Tang et al (2015) ⁽⁴²⁾ reported higher pain intensity with needle irrigation compared to ultrasonic irrigation even after 7 days. In

the present study group A: Side-vented NaviTip group showed an observable drop in pain levels immediately postoperative, 12 hours, 24 hours, 48 hours, 72 hours and 7 days post-operatively until it disappeared completely. While there was a constant decrease in pain levels over time in group B: End-vented NaviTip group. This was in accordance with previous studies that demonstrated that the incidence of post-operative pain decreased over time; it was greatest during the first 48 hours and it continued to drop in the following 7 days. ^(43,44) The results of this study showed an observable increase in pain levels at 4-hrs in group A: End-vented NaviTip group compared to the immediate post-operative pain levels, this may be contributed to the loss of local anesthetic effect. ⁽³⁹⁾ This was in accordance with the results of Gondim et al (2010) ⁽¹⁰⁾ and Al-Zaka (2012) ⁽¹¹⁾ that showed that the highest pain levels occurred at 4-hrs then decreased at 24 and 48-hrs post-operatively. There was no statistically significant difference in the pain levels between the end-vented needle and the side-vented needle groups at all the post-operative time intervals. This can be explained by the findings of Uzunoglu et al (2015) ⁽⁴⁵⁾ who reported no difference in the apical extrusion between the end-vented and side-vented needles. However, these results were in contrary to Altundasar et al (2011) ⁽⁴⁶⁾ and Yeter et al (2013) ⁽⁶⁾ who reported higher apical extrusion by the end-vented needle than the side-vented needle of the safety irrigator but this result may also be due to the safety irrigator's mode of action which provides irrigant by positive pressure and evacuates it by negative pressure. Placebos are pharmacologically inert substances that have no therapeutic effect. They act by alleviating anxiety to decrease patient's psychological fear which may affect patients reporting post-operative pain incidence and intensity. ⁽⁴⁷⁾ In this study, after the treatment, all patients for both groups received post-operative instructions and one capsule of placebo (Nido milk packed in capsule). Therefore the effect of this variable was considered to be minimized. Pochapski et al (2009) ⁽⁴⁸⁾ showed no difference between dexamethasone and placebo at 24 and 48 hours post-operatively. Results of this study show no significance difference in placebo intake between the two groups. Each clinician should evaluate the benefits and risk of prescribing analgesics after root canal treatment. In our study, ibuprofen 200 mg NSAIDS was prescribed as it's the standard analgesic anti-inflammatory drug to relief pain after endodontic treatment. ⁽⁴⁹⁾ Patients were informed to take ibuprofen 200 mg only if they developed pain after taking the placebo drug during the 7 days follow-up period. Minimal dose of ibuprofen was prescribed because higher dose may obscure the outcome especially with very low pain levels created by our endodontic treatment protocol in general. ⁽⁵⁰⁾ Results showed no significance difference in ibuprofen intake between both groups, therefore the effects of this variable was considered to be minimized.

Conclusion:-

Within the limitations of this study, it could be concluded that the Side-Vented and End-Vented NaviTip needles caused more or less similar post-operative pain in patients with irreversible pulpitis in mandibular posterior teeth after single-visit endodontic treatment and it could be recommended to use the Side-Vented or End-Vented NaviTip needles for irrigation with the described irrigation protocol.

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