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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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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 eitherNaviTip 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: The End-Vented NaviTip showed more pain than the Side-Vented NaviTip at 4, 12, 24-hrs. Pain intensity seems to decrease by time in both groups till it disappeared after one week dayswith no difference in drug intake post-operatively between both groups.

Introduction:-

The goal of endodontic treatment is to remove inflamed vital and necrotic pulp remnants from the pulp space and to prevent the occurrence of periradicular diseases, or promote healing of already existing pathosis[(1)]. Successful endodontic treatment can be achieved through proper chemo-mechanical preparation as mechanical instrumentation only is insufficient for complete cleaning and shaping of the root canal system due to the complex anatomy harboring tissue debris and microbes [(2)].

Sodium hypochlorite is the gold standard irrigant used for root canal disinfection in endodontic treatment due to its tissues dissolving ability,antibacterial effect, biofilm destruction and endotoxins inactivation[(3)]. The extrusion of sodium hypochlorite beyond the apex causes severe irritation to the periapical tissues causing pain, swelling and tissue damage [(4)].Other irrigants such as hydrogen peroxide may cause pain and emphysema if itreaches the periapical tissues [(4)].

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Post-operative pain is a common finding after endodontic treatment, its incidence ranges from 3% to 58% in single and multiple visit treatment. It may be due to microbial, mechanical, or chemical injury to the periapical tissues [5], such as irrigant extrusion beyond the apex.

The problem with needle irrigation is the need for close proximity of the irrigation needle to the apex to improve the irrigation efficacy. However, the closer the needle tip is positioned to the apical tissue, the greater is the chance of apical extrusion of the irrigant[6].Sodium hypochlorite extrusion beyond the apex causes severe irritation to the periapical tissues leading to pain, swelling and tissue damage [4].

However the use of safe-end side-vented needle close to the apex during irrigation decreases the risk of irrigant extrusion [7], and few studies investigated the effect of irrigation devices and methods on post-operative pain [8, 9], thus the aim of this study was to compare the degree of post-operative pain after the use of side-vented and end - vented needles.

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 anaesthetized using the inferior alveolar nerve block technique using 2% MepivacaineHClwith 1:20,000 Levonordefrin(MEPECAINE-L ALEX CO. for Pharmaceuticals and Chemical Industries, Egypt.). Intrapulpal anesthesia was given if there was still pain then the tooth was disinfected using chlorhexidinemouthwash.

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 ProTaperUniversal nickel-titanium rotary instruments (ProTaper Universal Dentsply, Tulsa dental, DensplyMaillefer, 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 2ml 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 GuttaPerchaDentsply, Tulsa dental, DensplyMaillefer, 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]. Secondary outcomes measured were theplacebo intake incidence, analgesic intake incidence and number of analgesic pills needed at each time point as recorded by the patient.

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.the End-vented needles showed an observable increase in pain levels at 4, 12, 24, 48-hrs while the Side-vented needles showed an observable increase in pain at 12, 24, 48-hrs. (Table 1 and Figure 1).

The End vented NaviTip needles showed higher pain level than the Side vented NaviTip needles at 4, 12, 24-hrs.There was statistically significant difference($p > 0.05$) at 4, 24-hrs between the two tested groups.
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)

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

	Group A (EVN)			**Group B (SVN)**			**Test value**	***p*-value 1**
	Median	Min.	Max.	Median	Min.	Max.		
Pre-operative	8	6	10	9	7	10	$Z = -0.177$	0.928
Immediatepost-operative	2	0	4	2	0	3	$Z = -0.388$	0.964
After 4 h	4	2	6	2	1	5	$Z = -3.811$	0.002*
After 12 h	6	2	9	5	2	7	$Z = -2.371$	0.054
After 24 h	5	0	8	3	2	7	$Z = -0.446$	0.040*
After 48 h	3	0	8	3	0	6	$Z = -0.384$	0.524
After 72 h	2	0	4	1	0	4	$Z = -0.503$	0.435
After 7 days	0	0	4	0	0	3	$Z = -0.299$	0.618
***p*-value 2**	<0.001			<0.001				

* *Indicates significance at* $p \leq 0.05$
p-value1 for comparison between both groups.
p-value2 for comparison over time in each group separately.

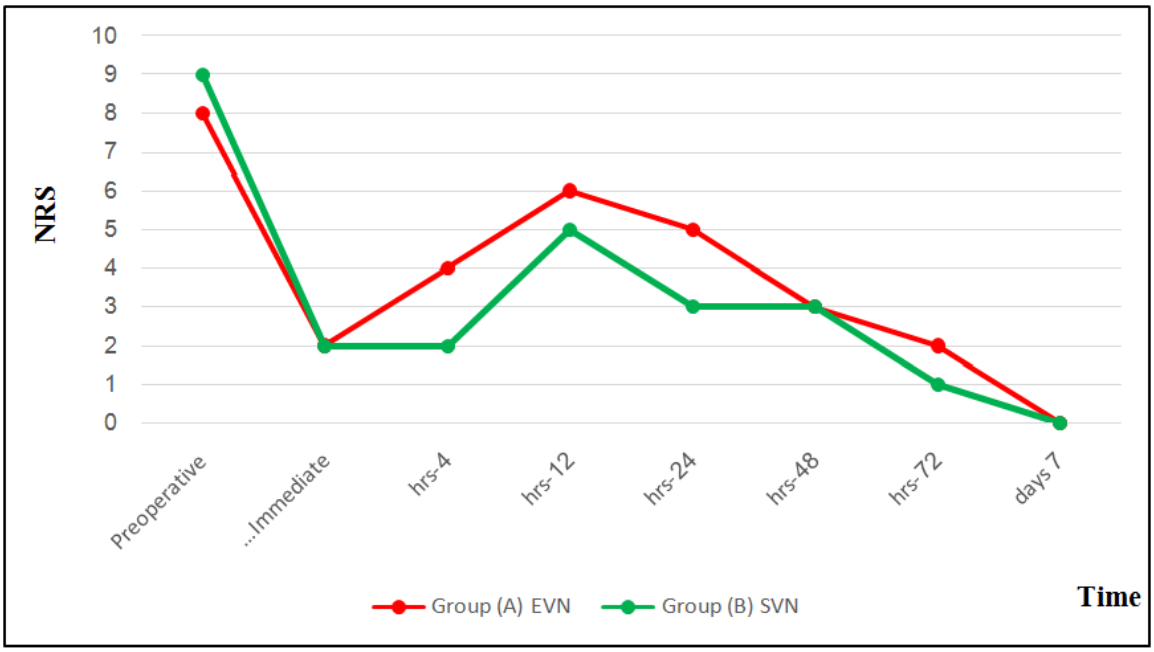

Figure 1:- Line chart showing the change in the NRS scores values over time for the two groups; (Group A: EVN and Group B: SVN).

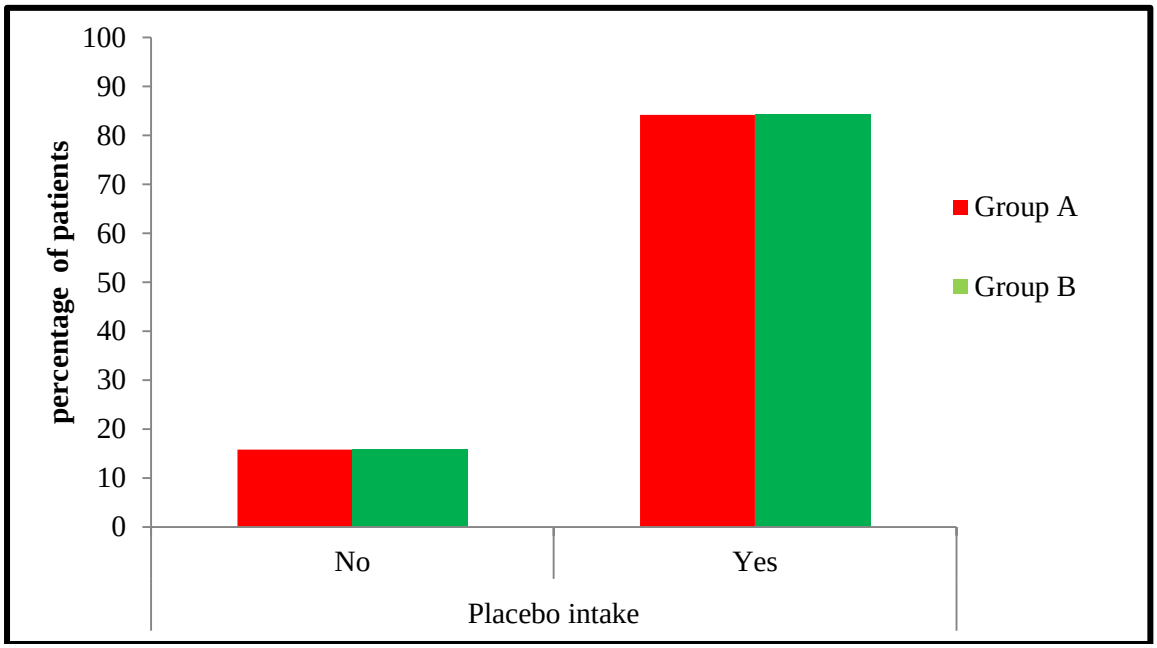

Figure 2:- Bar chart representing Placebo intake distribution and Ibuprofen intake distribution in the two tested groups; (Group A: EVN and Group B: SVN).

Discussion:-

Development of post-operative pain after root canal treatment is a common finding. Several risk factors such as gender and age, number of visits, type of intracanal medication used, presence of pre-operative pain, pulpal and periradicular diagnosis and apical extrusion of debris have been correlated with the occurrence of flare-ups [10].
Teeth with irreversible pulpitis were selected in this study to reduce the risk of exacerbation by residual micro-organisms found in teeth with necrotic pulp, teeth with apical periodontitis or re-treatment cases [10]. Moreover, mandibular posterior teeth were selected due to higher incidence of pain in comparison with maxillary anterior teeth because of the mandibular dense trabecular pattern, that reduces the blood flow and causes localization of infection and exudates leading to delayed healing patterns [11].

Root canal treatment was completed in a single-visit as ***Wong et al. (2015)***[12] reported that there was no statistically significant difference in post-obturation pain incidence after one day and seven days between single-visit or multi-visit endodontic treatments. In addition, single-visit treatment has more advantages such as reducing the risk of flare-up induced by leakage of the temporary seal between appointments, moreover it reduces patient's appointments per tooth, allows for immediate use of canal for retention of posts, helps to avoid multiple injections and rubber dam placement and reduces procedural costs [13].

Root canal preparation was performed by crown-down technique using ProTaper Universal rotary system, this was in agreement with***Nekoofar et al. (2015)***[14] who concluded that post-operative pain was significantly lower with ProTaper Universal rotary instruments compared with WaveOne reciprocating instruments and ***Arias et al. (2015)***[15] who found that more post-operative pain occurred after step-back manual instrumentation than after crown-down rotary instrumentation.

In this study, 2.6 % NaOCl was used as routine irrigant due to its broad antibacterial activity and organic material dissolution ability [16]. A low concentration of 2.6% NaOCl was used due to less toxicity and same antibacterial efficacy compared with higher concentration of 5.25 % NaOCl [17, 18].

Three milliliters of 17 % EDTA was used for smear layer removal as NaOCl lacks the ability to dissolve inorganic material [19] and 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 [20].

The needles were placed 2 mm short from working length during irrigationas ***Boutsioukis et al. (2010)***[6] suggested that 2-3 mm short of working length would ensure adequate irrigant exchange without causing high apical pressure.

Modified single cone technique was used for obturation in this study according to ***Alonso-Ezpeleta et al. (2012)***[21]who found that the incidence and intensity of pain after cold lateral condensation was lower than vertically condensed Thermafil and ***Peng et al. (2007)***[22] who found that warm guttaperchaobturation caused a higher rate of over-extension than cold lateral condensation after a meta-analysis of 10 clinical studies.

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. It is preferred by patients and clinicians over the Visual Analogue Scale (VAS) for its relative simplicity, ease of administration and scoring [23].

Assessment of post-operative pain was done immediately post-operative and after 4, 12, 24, 48 and 72-hrs and 7 days [8, 9] to record any difference in pain intensity between both groups as ***Tang et al. (2015)***[24]reported higher pain intensity with needle irrigation compared to ultrasonic irrigation even after 7 days. Pre-operative pain was measured as ***Alí et al. (2016)***[25] showed that the presence of pre-operative pain is the most influencing variable on post-operative painprevalence.

The side-vented and end-vented needles showed an observable drop in pain levels until pain disappeared, this was in accordance to ***Pak et al. (2011)***[26] who reported that post-treatment pain decreased substantially after 1-2 days of treatment and continued to drop to minimal levels after 7 days. The results of this study showed an observable increase in pain levels at 4, 12, 24, 48-hrs with the end-vented needles and at 12, 24, 48-hrs with the side-vented needles compared to the immediate post-operative pain levels. This was in contrast with the results of Al-***Zaka (2012)*** [9] that showed that the highest pain levels occurred at 4-hrs then decreased at 24 and 48-hrs, this may be due to assessment of pain only in single rooted teeth with asymptomatic irreversible pulpitis.

The end-vented needle showed higher pain level than side-vented needle at 4, 12, 24-hrs, but was only statistically significant at 4, 24-hrs, this can be explained by the findings of ***Altundasar et al. (2011)***[7] and ***Yeter et al. (2013)***[27] who reported higher apical extrusion by the end-vented needle than the side-vented needle with higher risk of inducing pain. However, this was in contrast with the results of ***Uzunoglu et al. (2015)***[28] who reported no difference in the apical extrusion between end-vented and side-vented needles, this may be due to using the needles at a greater distance from the apex.

Psychological factors such as pain anticipation may affect the patients' perception and reporting of post-operative pain incidence and intensity [29], therefore a single placebo capsule filled with starch was given to the patients if they felt pain after the treatment before allowing analgesic intake to avoid masking the pain. The results of the study showed no difference in placebo intake between both groups.

Ibuprofen was prescribed in case of continued pain after the intake of the placebo capsule as it is the standard medication for post-operative pain relief after root canal treatment[30]and was proven to provide similar pain relief compared to other analgesics [31, 32]. A low dose of 200 mg allows for a better measure of pain intensity and analgesic intake, as higher doses may obscure the outcome [33]. The results of the study showed no difference in ibuprofen intake between the two groups at all the time points.

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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