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Evaluation of Postoperative 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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KEYWORDS

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ABSTRACT

Objectives: This clinical study was conducted to evaluate and compare the post-operative pain after the using of two different irrigation tips: end-vented NaviTip tip and double sideport NaviTip irrigator tip immediate postoperatively and 4, 12, 24,48,72 hours and 7 days utilizing a numerical rating scale (NRS).

Methods: 38 patients with vital lower posterior teeth without periapical radiolucency underwent one-visit root canal treatment, Root canals were prepared using NiTi ProTaper Universal rotary system then randomized into two equal gropus according to the needle used for irrigation group(A) NaviTip® 29-gauge 27 mm with End vented Tip and Group (B) NaviTip® 31-gauge 27 mm with Side vented Irrigator Tip. The needles of irrigation were penetrated 2 mm shorter than the working length. The trial design of this study is a Parallel randomized controlled trial. All demographic data, clinical and radiographic findings and modified VAS scores obtained from patients were statistically analyzed.

Results: showed that there was no statistically difference between the two groups regarding the demographic data, prevalence of pre-operative pain, after 4 hours, 12 hours, 24 hours, 48 hours and 7 days. There is no statistical significance difference between End vented NaviTip and Side vented NaviTip, while in both groups there was a statistically significant decrease in pain intensity preoperatively compared with all other time periods.

INTRODUCTION

The success of endodontic treatment depends primarily on the eradication of micro-organisms from the root-canal system and prevention of their reinfection. The presence of necrotic or vital tissue remnants within the root canal space may provide a source of nutrition for the surviving bacteria. (1) As of date, sodium hypochlorite (NaOCl) has been able to meet most of these criteria. The problem with needle irrigation is the need for close proximity of the irrigation needle to the apex to improve the irrigation efficacy, as it has been shown that the irrigating solution is delivered only 1- 2 mm deeper than the tip of the needle. (2) The use of safe end side vented needle close to the apex during ir-

rigation decreases the risk of extrusion of irrigant beyond the apex compared to the end vented needle. ⁽³⁾ Postoperative pain is a common finding in endodontic treatment, with incidence ranging from 3% to 58% in single and multiple visit treatment. ⁽⁴⁾

METHODOLOGY

The trial design of this study is a Parallel randomized controlled trial. In the randomized controlled trial (RCT), Approval for the Ethics Committee of Faculty of Oral and Dental Medicine, Cairo University, Egypt.

Sample size determination

Sample Size was calculated using PS program, with standard deviation 15. We needed to study 17 experimental subjects and 17 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis is 0.05. With the dropout rate of 10%, the total sample size becomes 38.

Patient selection

Thirty eight volunteer patients fitting the inclusion criteria described later were included in the study. The study participants were recruited from the pool of patients in the Department of Endodontics, Cairo University, Egypt.

Eligibility criteria

Inclusion criteria

- 1. Healthy persons between the age group of 18 and 65 years.
- 2. Posterior teeth that were diagnosed with irreversible pulpitis and confirmed using periapical radiographs.

Exclusion criteria

1. Patients using pre-operative drugsthat can alter pain perception as anti-inflammatory, analgesic, or antibiotics in the last 24 hours.

- 2. Pregnant patients or allergic patients to used materials.
- 3. Teeth with necrotic pulp, periapical radiolucency, swelling, or sinus tract.
- 4. Teeth requiring Re-treatment.
- 5. Teeth with grade 2 or 3 mobility.

Treatment procedure

Prior to the treatment, a careful medical and dental history was taken. Preoperative data for each patient were recorded in the predesigned patient's chart which includes age, sex, tooth number and intensity of pain prior to the treatment. The severity of pain was measured using the NRS . According to this scale, the level of pain was documented in the range of 0–10 numerically and verbally as no pain (0), mild pain (1–3), moderate pain (4–6) and severe pain (7–10). The treatment and the study design were explained to the qualifying patients and informed consent was obtained from the voluntary patients who were willing to participate in the study.

Randomization

Random sequence was generated using the random function in Microsoft Excel software. Allocation concealment was phone based. The random sequence tables were kept with the assistant supervisor. The operator called the assistant supervisor for confirmation of eligibility and to assign the patient to a group according to the random sequence.

Endodontic protocol

All the treatment was carried out by a single operator. Each patient was given a pain scale chart (Numerical Rating Scale) in order to record his/her pain level before any endodontic treatment. Each Patient was anaesthetized using 3% Mepivacaine HCl (ALEX CO., Egypt). Access to pulp chamber was performed using a small round bur and completed using Endo-Z bur. The tooth was properly isolated with rubber dam.



Working length was determined using an electronic apex locator then confirmed with intraoral periapical radiograph, to be 0.5-1 mm, shorter than radiographic apex. Mechanical preparation of rootcanals was done by crown-down technique using ProTaper Universal rotary instruments according to the manufacturer instructions. F3

Patients were randomly divided into 2 groups according to the needle type used during irrigation:

Group A: NaviTip® 29-gauge 27 mm with End vented NaviTipTip.

Group B: NaviTip® 31-gauge 27 mm with Side vented NaviTip.

For both groups, 2 ml of 2.5% NaOCl was expressed over 30 seconds after every use of each rotary instrument. As a final flush 3 ml of 17% EDTA was used for 1 minute to remove the smear layer followed by 10 ml of distilled water.

The canals obturated using modified single cone technique by ProTaper gutta percha cones. The patients was instructed to mark pain level at the pain chart. After the treatment, all patients received 1 capsule of placebo and prescribed tablets of

200 mg ibuprofen with the instructions to take the placebo within the 0-4 hour time interval after the treatment if needed, then only one tablet of analgesic every 8 hours in the event of pain after calling the doctor for consultation and to record the number of tablets needed.

RESULTS

A. Demographic Data:

The mean age of patients in Group (A) was 32.7 ± 7.8 years and range (18-45) while in Group (B) was 31.2 ± 7.7 years and range (22-55). There was no significant difference between mean age values between both groups (p=0.547).

Gender distribution in Group (A) involved 11 males and 8 females while in Group (B) involved 7 males

and 12 females. There was no significant difference between both groups for gender (p=0.194).

In Group (A) 47.4% of the patients received endodontic treatment for the mandibular premolars and 52.9% for the mandibular molars while in Group (B) 42.1% of the patients received endodontic treatment for the mandibular premolars and 57.9 for the mandibular molars. There was no significant difference between both groups for the treated tooth type at (p=0.744).

B- Pain intensity (NRS scores):

Results showed that there was no statistically difference between the two groups regarding prevalence of pre-operative pain, after 4 hours, 12 hours, 24 hours, 48 hours and 7 days. As shown in table 1 and figure 1

Table (1) Median and range of NRS score at different time points in the tested groups by Mann Whitney and overtime in each group by Friedman test

Groups different times	Group (Irrigation with End vented NaviTip)			Group B (Irrigation with Side vented NaviTip)			P value 1
	Median	Min.	Max.	Median	Min.	Max	P
Preoperative pain	8	0	10	7	3	10	0.756
Immediate postoperative	3	0	7	2	0	7	0.343
4 Hours	3	0	10	3	0	8	0.687
12 Hours	3	0	10	3	0	8	0.687
24 Hours	3	0	5	3	0	6	0.892
48 Hours	2	0	7	1	0	6	0.601
72 Hours	0	0	9	1	0	4	0.899
7 Days	0	0	4	0	0	4	0.784
P value 2	<0.001			<0.001			

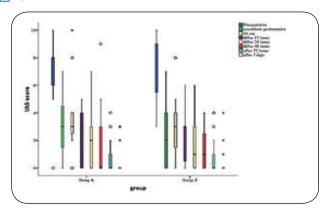


Fig. (1) Box plot showing the median NRS score in the tested groups at different time points. two groups (Group A: Irrigation with End vented NaviTip. Group B: Irrigation with Side vented NaviTip).

C. Drug intake:

1) Patients take Placebo:

In group (A) 68.4% of the patients received placebo, While in Group (B) 68.4% of the patients received placebo, there was no significant difference the two groups (p=1.000).

2) Patients received the medication (200mg Ibuprofen):

In group (A) 84.2% of the patients received the medication (200mg Ibuprofen), while in Group (B) 61.1% of the patients received the medication (200mg Ibuprofen), There was no significant difference between the two groups (p=0.114).

DISCUSSION

The purpose of this randomized controlled clinical study was to compare the difference in postoperative pain after using irrigation using Endvented NaviTip with Sidevented NaviTip needle. Mild discomfort after root canal treatment is a common experience for patients ⁽⁴⁾. It is very difficult to differentiate which factor causes pain and it is difficult to determine whether single or multiple factor elicit pain.

In the present study only mandibular premolars and molars were selected. Martin-Gonzalez et al. and Yesilsoy et al. ^(5,6) In the present study, 2.5% of NaOCl was used as intracanal irrgant; this concentration of NaOCl is in accordance with **Gomes-Filho et al** ⁽⁷⁾ who reported a good biocompatibility **Banos et al** ⁽⁸⁾ reported that NRS is a reliable method to assess pain in clinical settings when compared to the verbal rating scale. In this study, NRS was used for the evaluation of pain, because it is visually and verbally quantified for a better understanding by the patients.

In this study Side vented NaviTip and End vented NaviTip showed an observable drop in pain level was recorded immediately postoperative ,4 hours, 12 hours, 24 hours ,48 hours ,72 hours and 7 days post-operatively until disappeared. This is in accordance with previous studies that demonstrated that the incidence of post-obturation pain decreased over time; it was greatest during the first 48 hours, with a steady reduction in the following 7 days (9-11) .

Results showed no significance difference between End vented NaviTip and Side vented NaviTip in postoperative pain , This was in contrary to **Ramamoorthi et al**. (12) who showed Endo Activator resulted in significantly less postoperative pain than conventional syringe with 27 gauge open end needle. This may be attributed to activation of the irrigants done by Endo Activator, and the treatment was performed in 2 visits. Moreover Mtwo rotary files were used while in the present study universal ProTaper rotary file were used in the mechanical preparation.

Our results also was in contrary to **Al-zaka IM** (13) who showed That the Safety Irrigator showed significantly less post-operative pain than subsonic EndoActivator and conventional needle irrigation. This may attributed to The safety irrigator is an irrigation \ evacuation system that apically deliver the irrigant under positive pressure through a thin needle containing a lateral opening and evacuates the solution through a large needle at the root canal orifice. Also the type of teeth selected in this study was the anterior teeth while in present study the posterior teeth were selected.



As previous studies show, factors like age, sex, pulpal status, allergies and preoperative pain play a significant role in postoperative pain ⁽¹⁴⁾ .In this study, there were no significant differences for gender, age distribution and baseline pain score between the two groups, therefore the effects of these variables were considered to be minimized.

CONCLUSIONS

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

There is no statistical significance difference between End vented NaviTip and Side vented NaviTip, while in both groups there was a statistically significant decrease in pain intensity preoperatively compared with all other time periods.

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