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Original Article

Evaluation Of Postoperative Pain After Using Sonic Vibringe Irrigation System Versus Conventional syringe irrigation In Single Rooted Teeth With Symptomatic Irreversible Pulpitis: A Randomized Clinical Controlled Trial

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Abstract

Aim: The aim of this study was to clinically compare the postoperative pain after Vibringe sonic irrigation system and conventional needle irrigation during root canal treatment in single-rooted teeth. **Method**s: A total of 18 patients with symptomatic irreversible pulpitis in need of nonsurgical endodontic retreatment were randomly divided into 2 groups (n = 9) . Patients were carefully diagnosed and checked for the eligibility criteria . Irrigation in (group A) was delivered and sonically activated by Vibringe and Irrigation in (group B) was done using conventional needle. The presence of postoperative pain was assessed 6, 12, 24, and 48 hours after treatment according to the NRS where; 0; No pain, 1-3; mild pain, 4-6; moderate pain, 7-10; severe pain "severe pain, analgesic had no effect in relieving the pain". Data were analyzed using the Mann-Whitney U,Friedman's test, and Fisher's Exact tests . **Results:** Postoperative pain was non significantly different in the Vibringe group in comparison with the conventional needle group (P >.05) on all time intervals " 6 -12-24 and 48 hours" (P-value = 0.753) . Pain scores from base line to 6 hours post-operatively showed statistically significant decrease in both Vibringe and Conventional needle irrigation group (P-value <0.001). **Conclusions:** The sonically activated Vibringe irrigation system and conventional needle irrigation are equally safe with low incidence of post-operative at 6, 12 , 24 and 48 hours intervals.

.Keywords: Sonic ,Irrigation , Postoperative Pain , Vibringe

1. Introduction

Postoperative pain is defined as the sensation of discomfort after endodontic intervention. According to the 2011 systematic review of Pak and White(Pak and White 2011), the prevalence of pain in the first 24 hours is 40%, falling to 11% after 7 days.

Chemomechanical debridement is an important phase of root canal treatment (RCT). However, a study using micro-computed tomography have shown that most of the areas of the main root canal wall remain untouched by the instruments(Metzger et al. 2010).

To enhance the effectiveness of cleaning and disinfecting all areas of the root canal, several irrigants are commonly used as initial and final rinses to overcome the shortcomings of using a single irrigant, such as sodium hypochlorite (NaOCl), ethylene-diaminetetraacetic acid or chlorhexidine(Kandaswamy et al. 2010). In addition to these various irrigants,

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numerous irrigation devices and needle tips have been developed with the aim of improving the delivery of irrigant throughout the root canal using sonic or ultrasonic energy and negative apical pressure(Jiang et al. 2010).

The Vibringe is the first endodontic sonic irrigation system that enables delivery and activation of the irrigation solution in the root canal, in only one step (Dumani et al. 2016). The activation of the disinfectant by acoustic streaming enriches and completes the irrigation procedure and improves the success rate of endodontic treatments. It has been shown that the acoustic streaming significantly improves debridement. It also improves the disruption of the smear layer and biofilm by activating irrigation solutions (Walsh et al. 2017)

However, the success of any irrigation devices don't depend only on removing debris from the root canal, but a safe irrigation device is also highly desirable to prevent periapical tissue damage and decrease post-endodontic pain.

Many studies have shown that dentin chips, pulp tissue, microorganisms, and/or irrigants may be extruded into the periradicular tissues during root canal preparation and irrigation procedures (Charara et al. 2016; Toyoğlu and Altunbaş 2017; Caviedes-Bucheli et al. 2016). This extrusion into the periapical tissues could cause postoperative discomforts such as pain, swelling, and persistent inflammation. However , The available data on extrusion of irrigant when using many of recent irrigation devices appears to be limited to laboratory studies(Desai and Himel 2009) . In a recent in vitro study , it was concluded that the Vibringe extruded more debris than conventional needle irrigation(Karatas et al. 2015).

There is scarcity of clinical studies evaluating the effect of recent irrigation devices on PP teeth with symptomatic irreversible pulpitis (Ramamoorthi et al. 2015) . So, this study will focus on evaluating PP after using sonic Vibringe irrigation device versus conventional needle irrigation in single rooted teeth with symptomatic irreversible pulpitis.

2. Subjects and Methods

This randomized clinical trial was approved by the Ethics Committee of the Faculty of Dentistry, Cairo University, Cairo, Egypt (624/2018). Each patient was informed to follow general instructions to sign a printed consent, explaining the aim of study, the nature of the procedure and possible discomforts. The study was registered at www.clinicaltrials.gov (20150117862). To determine the sample size, a pilot study was conducted. According to the data obtained from the pilot study, it was expected an effect size of approximately 0.4755. A total sample size of 12 cases (6 cases per each group) was sufficient to detect effect size of 0.4755, a power of 90% and a significance level of 5%. This number was increased to 14 cases (7 cases in each group) to account for the necessity to use non parametric test. Further increase to 18 cases (9 cases per each group) to compensate for possible losses during follow up was done. Sample size was calculated using G*Power program (University of Düsseldorf, Düsseldorf, Germany) .

Eligibility Criteria:

Healthy persons between 25-45 years old with single rooted teeth. "Anterior, lower premolars" with symptomatic irreversible pulpitis were only included. Normal periapical radiographic appearance or slight widening in lamina dura were also checked.

The exclusion criteria included patients taking analgesic, anti-inflammatory or antibiotic medications. Pregnancy or lactation ,teeth with calcified canals ,teeth with periodontal diseases "Greater than grade I mobility, Pocket depth greater than 5mm", teeth with sensitive to percussion and palpation ,teeth with root resorption ,teeth with immature/open apex *and* teeth with previous RCT were also excluded .

For each tooth, the diagnosis of symptomatic irreversible pulpitis was made from the chief complaint and the clinical examination. Preoperative pain was the main diagnostic sign of symptomatic irreversible pulpitis .The Numerical Pain Rating Scale (NRS) is a subjective measure in which individuals rate their pain on an eleven-point numerical scale. The scale is composed of 0 (no pain at all) to 10 (worst imaginable pain)(Haefeli et al. 2006). All patients were given a Numeric rating scale , for the evaluation of pain where "7-10" referred for severe pain which is indicated for the study illegibility .

Pulp sensitivity was confirmed by a positive response to electric pulp testing and a prolonged response with moderate to severe pain to cold testing. Periapical status was examined via periapical radiographs, and radiographic examination revealed healthy periapical tissues.

Randomization:

Blocks of 4 were generated on a Microsoft Excel sheet where the intervention and control were denoted A & B and randomly distributed. The table was kept with the assistant supervisor. After the operator found an eligible participant, a phone call was made to the assistant supervisor to confirm the patient eligibility then to assign the participant to either group according to the generated random sequence. The assistant supervisor was the one who generated the random sequence, assigned the participants to the intervention or control groups.

Because of the nature of the interventions, the operator who performed the treatment procedures was not blinded to the interventions. However, the patients were blinded and not informed of the allocation.

After the pre-operative pain for each patient was scored using the Numeric Rating scale (NRS), anesthesia was achieved using mepivacaine hydrochloride 2% with 1:100000 epinephrine (Scandonest, Septodont, France). Rubber dam was placed to isolate the affected tooth and the cavity access was prepared using high-speed burs (Dentsply Maillefer, Ballaigues, Switzerland). Pulp vitality was confirmed visually by the presence of bleeding when entering the pulp chamber.

After the canals were visible, patency was checked with #15 K-type hand files (Dentsply Maillefer, Ballaigues, Switzerland) using a watch-winding motion . The WL was established by a Root ZX mini apex locator (J Morita Corp, Kyoto, Japan), and was confirmed radiographically. A crown-down preparation technique was performed using nickel–titanium rotary instruments (Revo S , Micro-Mega® , Besanç on, France) with the electric gear reduction torque controlled motor (X-Smart plus, Dentsply-Maillefer, Ballaigues, Switzerland). The instruments were used with a rotation speed 300 rpm . Starting with SC1 (Shaper® & Cleaner 1) for coronal enlargement, followed by SC2 (Shaper® & Cleaner 2) to reach to apex without pressure, then SU (Shaper® universal) for reshaping of the whole length of canal in free progressive stroke without pressure. EDTA gel 19% (MD-ChelCreamViscous Chelator / EDTA Gel, Meta Biodent , Korea) was used as a lubricant. Between the uses of each instrument, recapitulation of the WL was performed with a size 15 K-file. Depending on the individual tooth, the final apical preparation size was determined as 3 sizes larger than the first file binding at the WL "MAF size was ranging from size 35-50".

Irrigation Protocols:

During the instrumentation procedures, the root canals were irrigated with 5mL of 2.5% NaOCl between each file for a period of one minute. For the final irrigation, 5 mL of NaOCl was used and the needle was introduced 2 mm short of the WL for a period of one minute.

The irrigation system used during the treatments was as follows:

A. Experimental group (Vibringe group):

The irrigant was delivered and sonically activated by pressing the button (short and gentle) with a Luer-Lock syringe 30-G side-vented closed-end needle after each file insertion.

B. Control group (Conventional needle group):

Irrigation was performed using a conventional needle with 30-G side-vented closed-end needle after each file insertion.

Each root canal was dried with paper points and the equivalent gutta-percha cone from MM-GP Points (Micro-Mega®, Besanç on, France) that reached the WL without resistance, and it was used as the master gutta-percha cone. The master cone was confirmed with a periapical radiograph. All root canals were filled with gutta-percha and resin-based sealer (ADSEAL, Meta Biomed Co., LTD, Korea) using the lateral condensation technique; and the treatment was terminated with sealing the access cavity with a temporary restoration (cavit, 3M ESPE).

Postoperative pain evaluation: Patients were contacted by telephone after 6 hours,12 hours, 24 hours, 48 hours and asked to provide their perceived pain rating according to the NRS where; 0; No pain, 1-3; mild pain, 4-6; moderate pain, 7-10; severe pain "severe pain, analgesic had no effect in relieving the pain".

Patients verbally selected a value that was most in line with the intensity of pain that they have experienced.

3. Results

No patients were lost during follow-up (Fig.1). No statistically significant differences were found between the groups in terms of demographic data (age and sex) ($P > .05$) (Table 1), and no statistically significant differences were found between the groups in terms of preoperative pain ($P > .05$) (Table 2).

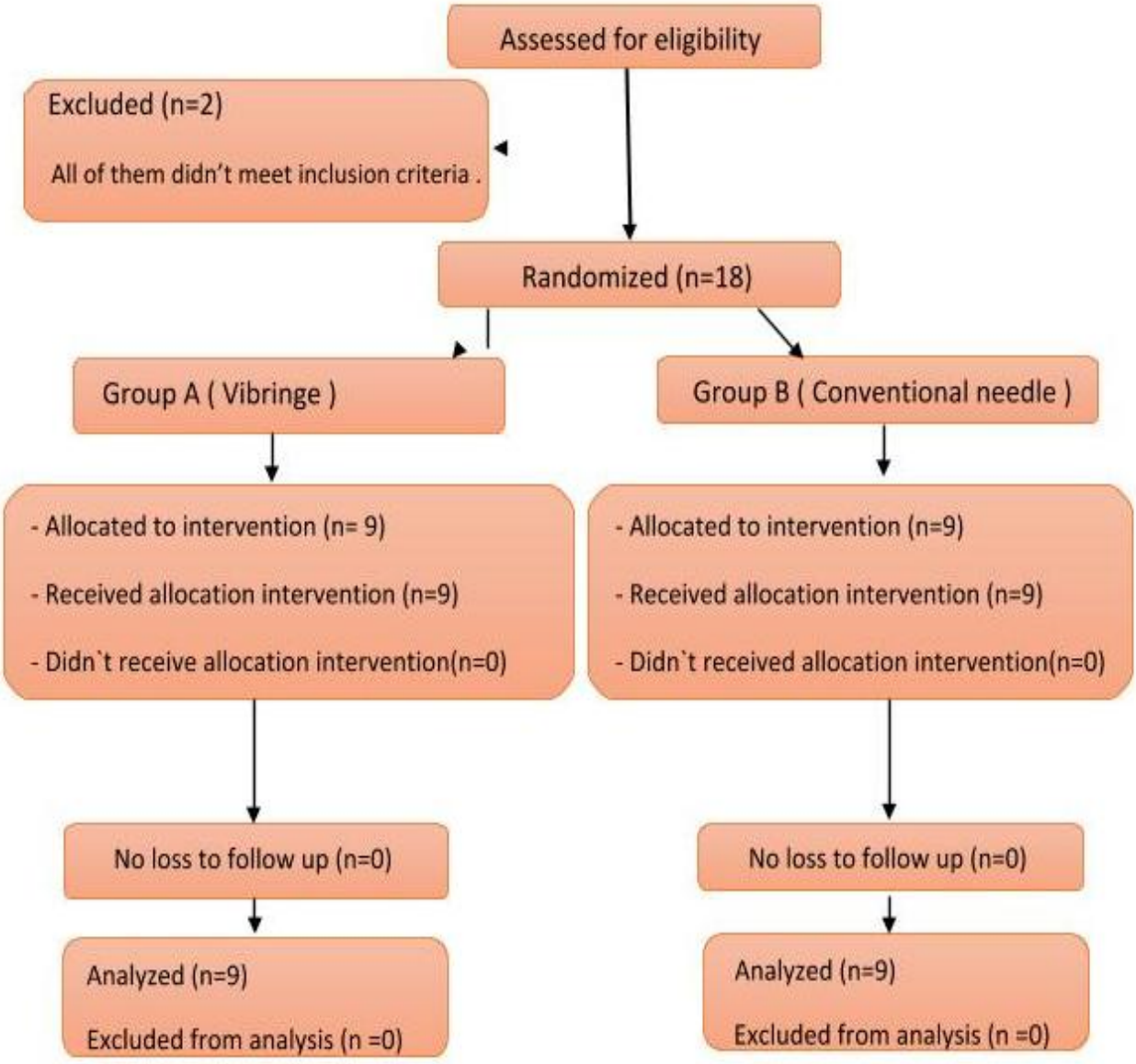

Fig. (1): CONSORT flow diagram of the study.

At base line, 6, 12, 24 and 48 hours; there was no statistically significant difference between the two groups (Table 2). Statistically significant decrease in pain scores in both Vibringe and conventional needle groups was found (from baseline to 6 hours post-operatively) during pair-wise comparisons which had been made between the time intervals (*P*-value = 0.007) (Fig.2).

Comparison between percentage changes in pain scores in the two groups showed that there was no statistically significant difference between percentage reductions in pain scores in the two groups (*P*-value = 0.580) (Fig.3).

Also, a statistically significant change in severity of pain by time in both Vibringe and Control groups (*P*-value <0.001, Effect size = 0.768) *(P*-value = 0.007) was found (Fig.4).

4. Discussion

The occurrence and the control of PP are of highly clinical interest.

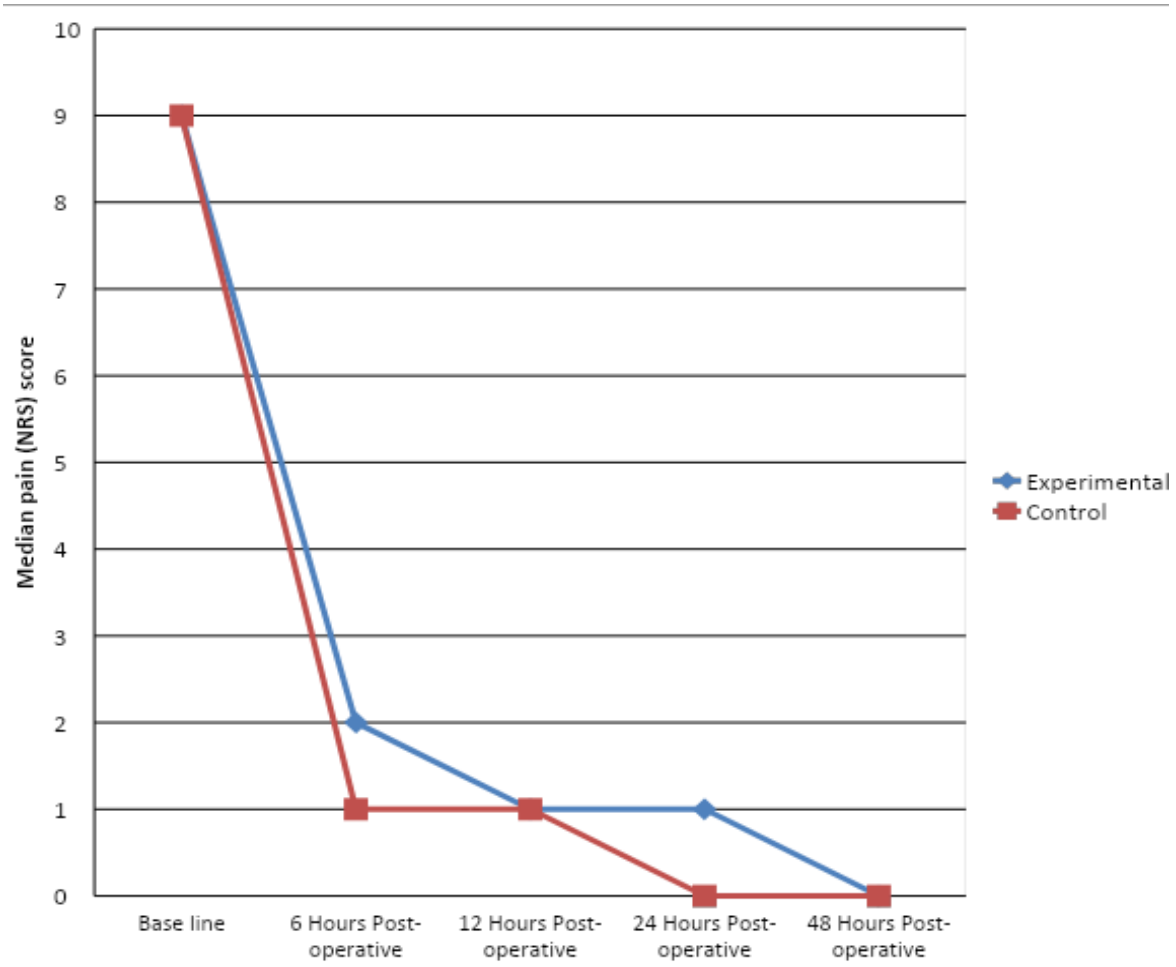

Fig (2) : Line chart representing change by time in pain scores within each group

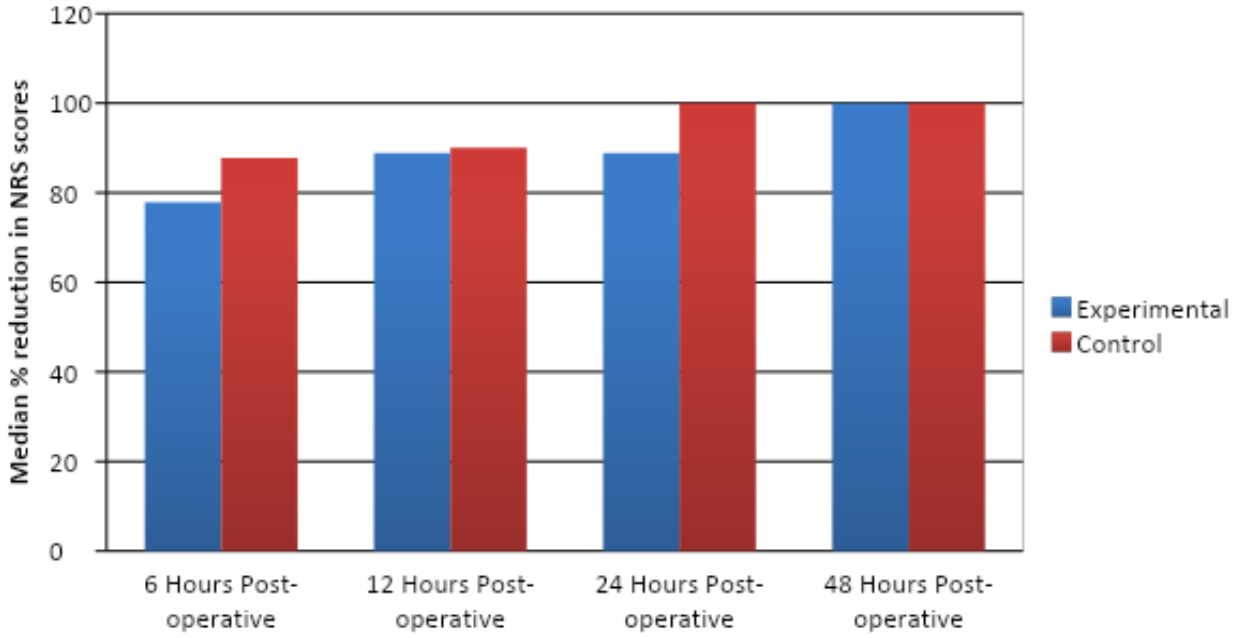

Fig (3) : Bar chart representing mean percentage reduction in pain scores in the two groups

Table (1) : Mean, standard deviation (SD), frequencies (n), percentages and results of Student's t-test and Fisher's Exact test for comparisons of demographic data in the two groups

	Experimental (n = 9)	**Control (n = 9)**	***P*-value**
Age (Years)			
Mean (SD)	27.8 (5.2)	28.8 (5.6)	0.700
Gender [n (%)]			
Male	3 (33.3%)	4 (44.4%)	1.000
Female	6 (66.7%)	5 (55.6%)	
Tooth position [n (%)]			
Maxillary	4 (44.4%)	5 (55.6%)	0.335
Mandibular	5 (55.6%)	4 (44.4%)	

**: Significant at P ≤ 0.05*

Table (2) : Descriptive statistics and results of Mann-Whitney U test for comparison between pain scores of the two groups

Time	**Experimental (n = 9)**	**Control (n = 9)**	***P*-value**	***Effect size (r)***
Base line				
Median (Range)	9 (7 - 10)	9 (7 - 10)	0.927	0.022
Mean (SD)	8.9 (0.9)	8.9 (1.2)		
6 Hours Post-operative				
Median (Range)	2 (0 - 2)	1 (0 - 3)	0.711	0.087
Mean (SD)	1.2 (1)	1.4 (1.1)		
12 Hours Post-operative				
Median (Range)	1 (0 - 4)	1 (0 - 4)	0.642	0.110
Mean (SD)	1.4 (1.6)	1 (1.3)		
24 Hours Post-operative				
Median (Range)	1 (0 - 3)	0 (0 - 3)	0.465	0.172
Mean (SD)	1.1 (1.3)	0.8 (1.2)		
48 Hours Post-operative				
Median (Range)	0 (0 - 2)	0 (0 - 2)	0.758	0.073
Mean (SD)	0.8 (1)	0.7 (1)		

**: Significant at P ≤ 0.05*

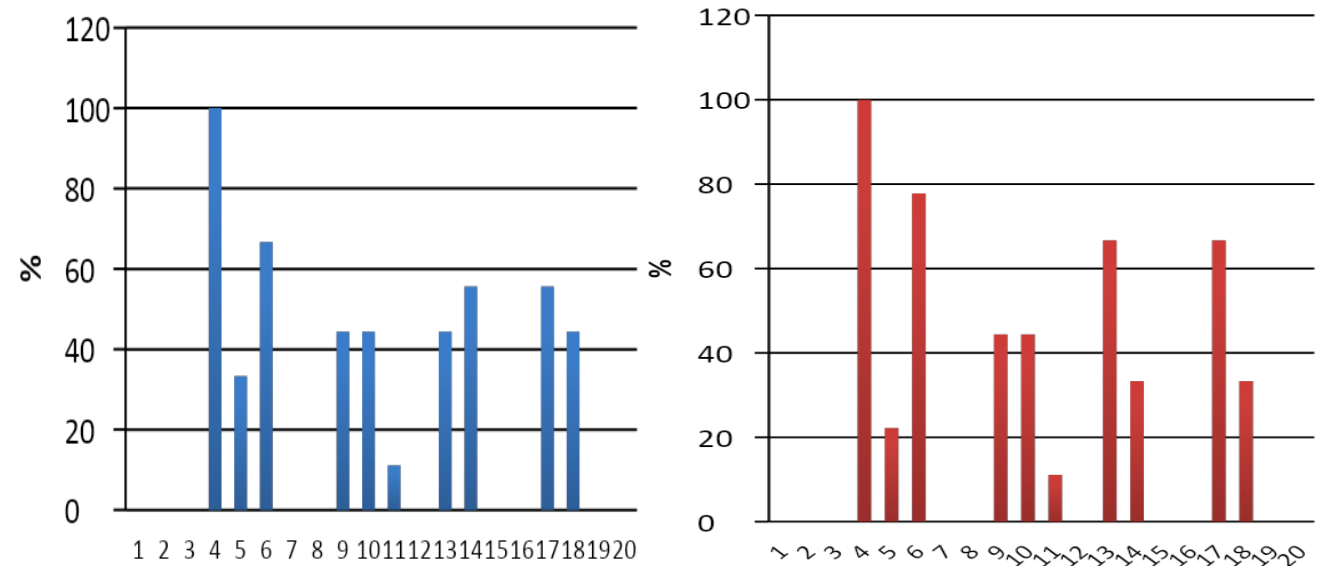

Fig (4) : Bar chart representing mean percentage reduction in pain scores in the Experimental (Left) and the Control groups (Right)

Many studies have evaluated the effect of preparation techniques, the number of appointments, and intracanal medicaments on PP during RCT(Gama et al. 2008; Su et al. 2011; Kherlakian et al. 2016).

The type of root canal irrigation technique could affect the amount of apically extruded debris or irrigant(Karatas et al. 2015). Any root canal irrigation delivery system that reduces the risk of extrusion into periapical tissues would help patients and clinicians because the system could decrease postoperative discomforts. When a literature search was conducted, there was limited information about the effect of irrigation techniques on the incidence and severity of PP after RCT in symptomatic teeth(Ramamoorthi et al. 2015).Therefore, the present study aimed to compare the effect of 2 irrigation delivery methods "Vibringe Vs Conventional needle" on the severity of PP after RCT.

Risso et al (Risso et al. 2008) , stated that the limitations of the research evaluating PP are related to the difficulty and differences in the preoperative conditions of the tooth and treatment protocol. Therefore, the present study only included patients who had spontaneous pain associated with irreversible pulpitis with no clinical or radio-graphic signs or symptoms of acute or chronic apical periodontitis. Moreover ,They were selected for two reasons: firstly, controlling this type of pain is challenging for clinicians and, secondly, because the greatest predictor for post-operative pain intensity is the severity of pre-operative pain(O'Keefe 1976).

On the other hand, one of the main problems in studying pain is the patient's subjective evaluation and its measurement. As the experience of pain is a complex phenomenon, influenced by psychological, environmental and physical factors, thus, the method used in assessing pain level is critical and must ensure that it will be fully understood by the patients and easily interpreted by the researchers. The present study used The (NRS) which ranks pain by a scale from 0 to 10. The NRS is a valid and reliable scale to measure pain intensity. It's easy to use, with reproducible results, and can be applied in a variety of practice settings. It has many strengths of over the VAS including the ability to be administered both verbally and in writing, as well as its simplicity of scoring(Haefeli et al. 2006) .

To ensure standardization, in both groups, the same treatment protocol during RCT, except for the irrigation method, was also performed with one limitation of the current study which was that the apical preparation sizes were different for the patients. To minimize the bias, randomization and blinding were done. One limitation of this study is the lack of clinician blinding. This is because the only difference between the groups was the technique

performed, so the clinician would obviously have known which technique to follow.

Tooth type and number of canals performed are also accepted as factors that can predict the intensity of post-endodontic pain. Thus, the only teeth included in the study were maxillary or mandibular incisors and mandibular premolars with one canal.

Also in this study, root canal treatment was completed in one visit as Direnzo et al(DiRenzo et al. 2002) found that there was no difference in postoperative pain between patients treated in one-visit and patients treated in two-visits. Prashanth et al(Prashanth et al. 2011) showed no significant difference in the success, postoperative pain and tenderness for teeth treated with either single-visit or multiple-visit therapy. Moreover, Single-visit root canal treatment is more favorable to the patients because it saves time and would probably reduce the cost of the procedure.

In general, the pain levels experienced by patients in this investigation were low. Results showed no significance difference between the Vibringe and conventional needle irrigation in postoperative pain , this was in contrary to Karatas et al.(Karatas et al. 2015) who reported that there was more extrusion of debris from the Vibringe compared with the non-activated SAF (self-adjusting file), EndoVac, and needle irrigation, which could be associated with pain under clinical conditions. This is because the studies that investigate apical extrusion of debris or liquid have limitations in experimental design and, it is not possible to directly extrapolate the results to the clinical situations. In this randomized clinical study, possible debris extrusion when used the sonically activated device did not affect the postoperative discomfort of the patients.

Also, the postoperative level of pain after root canal therapy using either endodontic needle irrigation or a negative apical pressure device was studied. The outcome of this study indicated that the use of a negative apical pressure irrigation device can result in a significant reduction of postoperative pain levels in comparison to conventional needle irrigation(Gondim et al. 2010).

On the other hand, Comparisons which had been made between the time periods revealed that there was statistically significant decrease in pain scores from baseline to 6 hours post-operatively in both Vibringe and Conventional needle irrigation. This is compatible with several studies evaluating the duration of PP after RCT (Pak et al. 2011).

Conclusions

The sonically activated Vibringe irrigation system and conventional needle irrigation are equally safe with low incidence of post-operative at 6, 12 , 24 and 48 hours intervals

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