DOI:10.34084/bshr.1512256 e-ISSN 2587-1641

Journal of Biotechnology and Strategic Health Research

Araştırma Makalesi /Research Article

http://dergipark.org.tr/tr/pub/bshr

The Effects of Sonic Activation of the Irrigation Solution on Postoperative Pain

Sonik Olarak Aktive Edilmiş İrrigasyon Solusyonunun Postoperatif Ağrı Üzerine Etkileri

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Geliş Tarihi / Received : 08-07-2024 **Kabul Tarihi / Accepted:** 27-07-2024 **Yayın Tarihi / Online Published:** 31-08-2024

Bilgili D. The Effects of Sonic Activation of the Irrigation Solution on Postoperative Pain. J Biotechnol and Strategic Health Res. 2024;8(1):125-132

Abstract

Aim The aim of this study was to assess and compare the Vibringe Sonic Irrigation System and conventional needle irrigation (bevel open-ended) in terms of postoperative pain.

Material and Method Ninety asymptomatic, non-vital, single-rooted, and single-canal teeth were evaluated for present clinical study. The included teeth were separated into two treatment groups [Group CNI: Conventional needle irrigation, control (pink card), Group V: Vibringe (blue card)] via cards selected by the patients. After treatment, all participants were given a verbal descriptor scale for the assessment of the pain and taken analgesics at the 6th, 12th, 24th, and 72nd hours.

Results Although there was no significant difference in the number of teeth with pain between the groups at the 6th, 24th, and 72nd hours, there was statistically more teeth with pain in group V in the 12th hour evaluation. However, in group CNI, pain severity was significantly less than group V at all time periods.

Conclusion The outcome of this study denotes that the use of the Vibringe may cause an increase in the postoperative pain in comparison to conventional needle irrigation for asymptomatic teeth.

Keywords Disinfection, postoperative pain, root canal therapy

Özet

Amaç *Bu çalışmanın amacı, Vibringe Sonik İrrigasyon Sistemi ile geleneksel iğne irrigasyonu (açılı ucu açık) postoperatif ağrı bakımından değerlendirmek ve karşılaştırmaktır.*

Gereç ve Yöntem *Asemptomatik, nonvital, tek köklü ve tek kanallı olan doksan diş bu klinik çalışma için değerlendirmeye alınmıştır. Dahil edilen dişler, hastalara seçtirilen kartlar aracılığı ile iki tedavi grubuna [Grup Gİİ: Geleneksel iğne irrigasyonu (pembe kart), Grup V: Vibringe (mavi kart)] ayrılmıştır. Endodontik tedaviler tek seansta, tek bir klinisyen tarafından yapılmıştır. Tedaviden sonra, 6., 12., 24. ve 72. saatteki ağrıyı ve alınan analjeziği değerlendirmek için bütün katılımcılara sözel tarif skalası verilmiştir.*

Bulgular *Gruplar arasında ağrılı diş sayısı bakımından 6., 24. ve 72. saatlerde anlamlı fark bulunmaz iken; 12. saat değerlendirmesinde ağrılı diş sayısı grup V'de istatistiksel olarak daha fazla olmuştur. Bununla birlikte; tüm zaman dilimlerinde ağrı şiddeti, grup Gİİ'de, grup V'ye göre anlamlı derecede daha düşük çıkmıştır.*

Sonuç *Bu çalışmanın sonucu; asemptomatik dişlerde Vibringe'in kullanımının geleneksel iğne irrigasyonu ile kıyaslandığında postoperatif ağrıda artışa neden olabileceğini göstermektedir.*

Anahtar Kelimeler *Dezenfeksiyon, postoperatif ağrı, kök kanal tedavisi*

INTRODUCTION

After endodontic treatment postoperative pain may be observed in the range of 3% to 58 %.[1] Depending on the severity of pain, the use of analgesics may also varies.[2] The possibility of pain occurring during or after root canal treatment is really scary for many patients, so this fear may cause the extraction to be preferred to root canal treatment.[3] Postoperative pain is caused by microbiological, chemical or mechanical factors which injure periapical region and provoke an inflammation.[4,5]

One of the most important procedures is the chemomechanical debridement of all canal systems for the successful root canal treatment.[6] Using an effective irrigating protocol is required for the most effective chemomechanical preparation.[7] However, extrusion of debris and the irrigation solutions and into the periradicular tissues may occur, which causes pain, swelling, and damaging of the vital tissue.[8-10] The balance between safety and effectiveness of the irrigation solution is specially important for the periradicular area.[11] Devices have been improved to enhance the irrigation efficacy and inhibit damage to the vital tissue, and lessen postoperative pain.[5,12] The activation of solutions (e.g., manual-dynamic activation, ultrasonic, sonic, and laser system) benefits more than conventional needle irrigation for cleaning canal systems.[13-16] However, the irrigation method may be related with the extrusion of the solution beyond the working length, affects pain.[9]

The Vibringe (Vibringe, Amsterdam, Netherlands) consist of cordless handpiece that fits into a disposable 10-mL Luer-Lock syringe. It includes both sonic activation (frequency: 2–3 kHz) and manual delivery of the irrigation solution.[15,17,18] Although there have been many studies comparing conventional needle irrigation and the Vibringe in terms of apical extrusion of debris[19] and debris removal efficacy[14,15,17], there is limited literature[20,21] regarding postoperative pain. Consequently, in present study, we aimed to assess and contrast the postoperative pain between Vibringe and conventional needle irrigation for non-vital, asymptomatic, teeth with one canal.

MATERIALS and METHODS

The present study was produced from the "thesis" which is registered to the "National The sis Center" in Türkiye (https://tez.yok.gov.tr/UlusalTezMerkezi/) with the thesis number 408462 [Name of the thesis: The effects of sonic activation of the solution on postoperatif pain (in Turkish with an abstract in English)]. Thi s prospective single-blind, controlled clinical study was conducted with the permission of the Republic of Türkiye Ministry of Health Turkish Medicines and Medical Devices Acency (protocol number 71146310 [2013-AC-CE-49]) and approval of Ethics Committee of Çukurova University for Clinical Research. All participants were treated in Çukurova University, Faculty of Dentistry, Department of Endodontics. Patients were informed about the study and informed consent form signed by the participants.

Patient Selection

All teeth were thoroughly examined radiologically and clinically. Pulp vitality was assessed through an electric pulp-testing device. Participants who were aged 18-60 years and having asymptomatic (no preoperative pain), non-vital, single-rooted teeth with one canal were incorporated into the study. The presence of periapical lesions in the teeth was not evaluated as a criterion. Exclusion criteria included patients with cardiac problems, diabetics, psychological and neurological problems who need to take medication, having allergy to local anesthetic agents. Participants who were breastfeeding, pregnant and had taken analgesic, anti-infla mmatory or antibiotic drugs at least one week before the treatment were excluded from the study. Teeth which needed retreatment were not included in this study. However, teeth which had only initiation treatment long before were included in the study as it was thought not to affect the result. Ninety teeth were incorporated into the inferential statistical analysis. Root canal treatment was performed in a single-visit by a single clinician.

Definition of Irrigation Systems

There were two groups with 45 samples in each one. There were pink and blue cards assigned for the groups. The pink card indicated group CNI (conventional needle irrigation, control), the blue card indicated group V (Vibringe). Before the treatments of the teeth, patients were asked to choose one of the cards. The number of men and women was statistically balanced for two groups because of eliminating the effect of the card color representing the groups. None of the patients knew which irrigation technique would be used during their treatments.

Endodontic Protocol

Patients were given local anesthetics (Maxicaine, İdol Medicine Refill, İstanbul, Türkiye). Coronal part of the root canal was instrumented with #25/.04 taper rotary system (Twisted-file, SybronEndo, Orange, CA, USA). When there was a large entrance of the canal, procedure of the coronal expansion was not applied. The root canals were irrigated according to the chosen card with a 0.5 mL saline solution and an electronic apex locater (Raypex 6, VDW, Munich, Germany) was used. The canals were mainly instrumented with the rotary system, while manual files were also used for shaping large root canals. Although the final instrumentation size was generally determined as three times larger than the first file which was binded at the working length, the final instrumentation size was sometimes increased since the needle tip reached up to 2 mm from the working length. The canals were irrigated with 2 % NaOCl solution during instrumentation up to 6 mL in total. Conventional needle (bevel open-ended) (Ayset Medical Products, Adana, Türkiye) and side-vented needle (I-tip, Medicinos, Linija UAB, Lithuania) were used in group CNI and group V, respectively. Since the flow rate of the solution in the Vibringe was stable, group CNI was adapted to group V to ensure equality (approximate 4.6 mL/min). An appropriate gutta percha (Diadent Group International Inc., Burnaby, BC, Canada) was placed into the canal, after a periapical radiograph was taken to verify working length. Afterwards, 3 mL NaOCl (2 %) and 3 mL saline solutions were performed as the final irrigation.

After the canals dried, they were filled using gutta percha plus 2Seal (VDW, Munich, Germany). Radiograph was taken to check the canal filling and the teeth were restored with composite (Premise, Kerr Corporation, Orange, CA, USA) filling in one visit.

Evaluation of Pain

A verbal descriptor scale[22,23] [0: not pain feel, 1: slight pain (not requiring analgesic), 2: medium pain, (relieved by analgesic), 3: serious pain (analgesics are not effective for reducing the pain)] was given to all patients for the assessment of the pain and analgesics were taken at the 6th, 12th, 24th, and 72nd hrs (hours) after the endodontic treatment. All participants were recommended to use analgesics [200 mg (milligram) ibuprofen] if required. All the patients took the clinician's telephone number to contact in case of an emergency. After the patients completed the questionaire forms, they came back to check and deliver the forms.

Statistical Analysis

The findings were analyzed by SPSS; Version 20.0 (IBM SPSS Inc., Chicago, IL, USA). For comparing categorical measurements between groups, Chi-square test was performed. For comparing age measurement between groups, independent samples t test was used. In all test, the significance level was considered to be 0.05.

RESULTS

Statistical difference has not detected between the groups in terms of age and sex. Table 1. shows the distribution of the demographic data ($p<0.05$).

Table 1. Distribution of the demographic			
	Group CNI	Group V	p
The average age	33.69	35.89	0.349
Standard deviation	±11.375	±10.760	
Female	24	17	0.204
Male	21	28	

Patients who marked "0" in the questionaire form were included in the "no pain" group and patients who marked "1, 2 or 3" in the form were included in the "pain" group to determine the presence of the pain (Table 2.). When all the time periods were evaluated, less tooth pain was observed in group CNI than group V. However, statistical difference has not detected in terms of the number of teeth with pain between the groups at at the 6th, 24th, and 72nd hrs, while there was statistically more teeth with pain in group V in the 12th hour.

Table 2. Descriptive analysis of the teeth distribution according to presence of pain			
PRESENCE OF THE PAIN			
Hours	Group CNI	Group V	p
6th	6 (13.3 %)	13 (28.9 %)	0.120
12th	2 (4.4 %)	10 (22.2 %)	0.027
24th	2 (4.4 %)	7 (15.6 %)	0.157
72nd	0 (0.0 %)	5 (11.1 %)	0.056

To determine the degree of the pain, pain intensities represented by "0, 1, 2, 3" were evaluated separately for the 6th, 24th, and 72nd hrs (Table 3.) after the treatment. Accordingly, postoperatif pain intensity in group CNI was less than it was in group V, statistically ($p<0.05$ significant over the 0.060 limit). However, pain severity could not be interpreted since there were few patients with severe (3) and moderate (2) pain. Furthermore, as the analgesic intake of the patients was low, it was not statistically significant.

Two patients (one of them was a female in group CNI, the other was a male in group V) had a mild pain in the gum area in the assessments at the 6th and 12th hrs, although there was no tooth pain. Furthermore, another patient (male, group V) had experienced pain in the injected site and took diclofenac potassium instead of ibuprofen 2 hrs after the treatment despite the absence of tooth pain. Another patient (female, group V) took a drug only at the 14th hour. One patient (male, group V) received a 400 mg drug instead of 200 mg at the 6th and 24th hrs. These patients were not excluded from the study. Besides, postoperative flare-up reaction developed in the teeth of three patients (one of them was in group CNI). Although one of them (in group V) did not contact the clinician about this reaction, the others came to the endodontic department and antibiotics were prescribed. One of the patients (group V) had a swelling at the gingiva one day after the treatment and the swelling was drained by the clinician.

Statistical difference has not detected between the number of teeth located in the maxilla or mandible. When the presence of postoperative pain was examined according to the jaws, in group V, postoperatif pain of the teeth in the maxilla was statistically higher than group CNI at the 6th and 12th hrs. However, statistical difference has not detected between the two groups in the way of the teeth in the mandible (Table 4).

Table 3. Pain intensity distribution at the 6th, 12th, 24th, and 72nd hrs					
FREQUENCIES and VALID PERCENT					
Groups	**Intensity**	**6th hrs**	**12th hrs**	**24th hrs**	**72nd hrs**
Group CNI	0	39 (86.7 %)	43 (95.6 %)	43 (95.6 %)	45 (100 %)
	1	6 (13.3 %)	2 (4.4 %)	2 (4.4 %)	0 (0.0 %)
	2	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
	3	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
Group V	0	32 (71.1 %)	35 (77.8 %)	38 (84.4 %)	40 (88.9 %)
	1	11 (24.4 %)	8 (17.8 %)	5 (11.1 %)	3 (6.7 %)
	2	1 (2.2 %)	1 (2.2 %)	2 (4.4 %)	2 (4.4 %)
	3	1 (2.2 %)	1 (2.2 %)	0 (0.0 %)	0 (0.0 %)
	p Value	0.045	0.016	0.060	0.031

Table 4. Pain asssessments of the teeth according to the included maxilla or mandibula						
FREQUENCIES and VALID PERCENT						
Jaws	**Groups**	**6th hrs**	**12th hrs**	**24th hrs**	**72nd hrs**	**Count**
Maxilla	**Group CNI**	1 (4.0 %)	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)	25 (100 %)
	Group V	8 (27.6 %)	6 (20.7 %)	4 (13.8 %)	2 (6.9 %)	29 (100 %)
	p Value	0.028	0.025	0.115	0.493	
Mandibula	**Group CNI**	5 (25.0 %)	2 (10.0 %)	2 (10.0 %)	0 (0.0%)	20(100 %)
	Group V	5 (31.2 %)	4 (25.0 %)	3 (18.8 %)	3 (18.8%)	16 (100 %)
	p Value	0.722	0.374	0.637	0.078	

DISCUSSION

There are many studies[2,5,24-26] in the literature about pain after root canal treatment and it is important to assess the currently used irrigation systems regarding postoperative pain. The aim of present study was to determine whether there was a difference postoperative pain after using the Vibringe against conventional needle irrigation for asymptomatic teeth. The findings showed that there was statistically more teeth with pain in group V only at the 12th hour evaluation. It is thought that the sonic vibration in group V increased the apical extrusion and postoperative pain since vibration increased the activation of the solution. However, in a systematic review[27] (included another type of sonic device, EndoActivator) concluded that mechanical activation of the irrigation solution reduced postoperative pain. In this systematic review; it was stated that more postoperative pain occured due to the fact that positive pressure of the conventional needle (open-ended or side-vented needle) produces more hydraulic pressure. Furthermore, it has been reported that the remaining pulp residues may cause pain since the full working length can not be reached with the conventional needle.[27] Nevertheless, EndoActivator and Vibringe can also give different results in studies, though both are sonic systems. Although a study[28] with EndoActivator showed that the amount of irrigant extrusion was statistically lower than the side-vented needle, in another study[19] on the Vibringe and side-vented needle, statistical difference has not detect in the way of extruded debris.

In the present study, postoperative pain intensity was statistically lower in group CNI than in group V at all evaluation times after treatment. This result demonstrated that irrigation system may have a greater impact on intensity than the presence of postoperative pain. However, according to a meta-analysis study[29] machine-assisted agitation (included ultrasonic or sonic devices and negative apical pressure devices) reduces postoperative pain contrasted with conventional needle irrigation at both 24 hrs and 48 hrs. In a study[30] comparing EndoActivator and conventional open ended needle irrigation, statistically more pain intensity occurred in the group using the conventional needle at all time periods (8, 24, 48h). In this study,[30] it was stated that the inequality of the irrigation solution extrusion treated with conventional needle or agitation technique may cause this difference in postoperative pain. It has also been mentioned that direct comparison of the conventional needle irrigation and agitation techniques may be a limitation.[30] Moreover in a study[2] comparing Eddy, another sonic irrigation system, and a side-port needle irrigation; statistical difference has not detect in postoperative pain level among the irrigation procedures. For this reasons, using a device with both syringe delivery and agitation techniques, such as the Vibringe, may be more useful to contrast the influence of the conventional needle irrigation and sonic system.

Nevertheless, two different studies[20,21] comparing Vibringe and the conventional needle irrigation has not detected statistically significant difference between the groups in the way of postoperative pain. However, symptomatic vital teeth were used in these studies, contrary to our study. Furthermore, the preoperative pain severity was generally high in these studies. In addition, although the verbal descriptor scale was used for pain assessment in our study, these two studies employed the numerical rating scale. Because of these differences, the postoperative pain results may have been different from our study.

The bone structures of the maxilla and mandible are different from each other. Therefore, in our study, the mandible group CNI may have been affected more than the maxilla group. For this reason, in our study, while statistically significant has not detected between the two groups in the way of postoperative pain in the mandibular teeth, there was a difference at the 6th and 12th hrs in the maxillary teeth. This result related to the mandibular teeth in our study is similar to the study[21] evaluating the Vibringe and conventional needle irrigation in terms of postoperative pain, in which only mandibular premolars and molars

were used.

Apart from the irrigation system, there are many factors affecting postoperative pain.[31] Some studies suggested that the presence of preoperative pain,[32,33] the type of tooth, sex,[34] age of patients,[22] vitality of pulp, treatment visit,[35] and medical situation[36] affect postoperative pain. The inclusion criteria were determined by considering these factors. In addition to these factors, increased pressure in the irrigation solution may increase the risk of irrigation extrusion which may also affect postoperative pain.[37] The increase of the apical pressure in the irrigation solution is affected by the flow rate of the irrigant.[38] For this reason, the flow rate of the irrigant in group CNI was determined according to the constant flow rate of group V.

In this study, the difference in the types of needle tips used between the two groups may be a limitation. To minimize the effect of confounding variables, patients were assigned to groups by choosing cards and blinding. Attaching the needle to the Vibringe and applying with and without activating may be suggested for future studies. Nonetheless, there are a lot of factors that affect postoperative pain which is not eliminated. For example, postoperative pain may be related to periapical trauma because of the material's apical extrusion, missed root canal, injuring soft tissue because of the rubber dam or injection application, and maxillo-facial pain unrelated from teeth, as Gondim et al.[5] cited. Dorner et al.[39] reported; in addition to tissue damage, the feeling of damage is also defined as pain. Furthermore, pain caused by root canal treatment can be affected by previous experiences, conversations with others, and the media.[4] In other words, pain is a subjective pheno-menon and it would be beneficial to evaluate it considering the biopsychosocial model[40] suggested for the assessment of diseases. For this reason, it would be wise to be careful in generalizing the results of the this study.

CONCLUSION

Using of the Vibringe can increase the presence and severity of postoperative pain in comparison to conventional needle irrigation for asymptomatic non-vital teeth. It may also affect the severity of pain more than the presence of pain in comparison to conventional needle irrigation. However, it is important to conduct more studies on the Vibringe in terms of postoperative pain assessment.

Acknowledgment

This study was produced from the author's own thesis. The author thanks thesis advisor Assoc. Prof. Adile Şehnaz Yılmaz for their contributions to the thesis stages, from the ethical decision making stage of the thesis. Furthermore, the author thanks academic personnel of Çukurova University, Faculty of Dentistry, for the contributions of thesis stages.

This study has not been previously presented.

Ethical Committee Approval

This prospective single-blind, controlled clinical study was conducted with the permission of the Republic of Türkiye Ministry of Health Turkish Medicines and Medical Devices Acency [protocol number 71146310 (2013-AC-CE-49)] and approval of Ethics Committee of Çukurova University for Clinical Research.

Peer-review

Externally and internally peer-reviewed.

Conflict of Interest

The author has declared that there were no conflicts of interested related to this study. This literature was produced from the author's own thesis (https://tez.yok.gov.tr/UlusalTezMerkezi/ Name of thesis: The effects of sonic activation of the solution on postoperative pain).

Funding

This research was supported by Çukurova University Scientific Research Projects Unit (DHF2013LTP1).

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