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Passive ultrasonic irrigation on postoperative pain after endodontic treatment: a randomized clinical trial

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Abstract

Objective:This randomized clinical trial evaluated the effect of passive ultrasonic irrigation (PUI) protocol employed during endodontic treatment on the incidence of postoperative pain. Methods: Sixty adult patients with non-vital asymptomatic premolar and molars were included. The treatments were performed using ProTaper Universal instruments with working length set 1.0 mm short of the apical foramen. The patients were randomly divided to receive one of the following two final cleansing protocols (n = 30): PUI - the canals were rinsed with 2.5% NaOCl, 17% EDTA, and 1.0% NaOCl sequentially, with 3 cycles of 20 seconds in each irrigation solution, under ultrasonic agitation; Control (CON) - similar final irrigation protocol was employed without any agitation. To evaluate postoperative pain, a numerical rating scale was applied every 24 hours until the fifth day. Data were statically analyzed with Pearson's Chi-square, Friedman's and ANOVA tests with 5% of significance. Results: There were no significant differences in any of the periods (P=0.46). The great majority of patients in both groups showed no pain symptoms. No patient reported severe pain (≥ 7), with moderate pain occurring in only 2 patients in the CON group (7.4%) and 4 patients in the PUI group (16.7%), exclusively in the first 24 hours. Conclusions: The use of passive ultrasonic irrigation protocol did not influence the occurrence of postoperative pain in patients submitted to endodontic treatment.

KEYWORDS: Endodontics; Clinical trial; Pain, postoperative; Ultrasonics.

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Introduction

During root canal preparation, endodontic instruments and irrigation solutions were used to allow a correct cleaning and shaping of canals. In this way, it will be possible a three-dimensional quality seal, avoiding reinfection by microorganisms, thus guaranteeing the success of endodontic treatment[1,2]. The effective cleaning of this canal system requires the use of irrigating solutions that have a marked antibacterial action and preferably, tissue dissolution capacity and chelating action[3,4]. Irrigation and aspiration complement the cleansing achieved by mechanical instrumentation, improving physical and chemical means, facilitating the removal of microorganisms, debris and necrotic remains, especially in areas such as isthmus, accessory canals and intracanal flattening[5,6]. Because of these anatomical difficulties it becomes challenging for the irrigant to fulfill the entire apical region and lateral canals[7].

Several studies have suggested the use of passive ultrasonic irrigation (PUI) as a way to improve the action of irrigating substances, assisting their penetration into complex anatomical areas[8,9].The literature confirms that the use of ultrasonic activation potentiates the action of the chemical agent by cavitation and agitation of the particles. It can increase the efficiency in the cleansing and disinfection of root canals[10-14], allowing access to an under wise inaccessible area by instrumentation[11,15-18] and reducing the number of microorganisms compared to conventional irrigation[19].

Postoperative pain has been related as a consequence of mechanical trauma (over instrumentation), chemical irritation (irrigating solutions, intracanal medications), response of microorganism's toxins, and mainly the union of several of these factors through the extrusion of debris into the periapical region[20]. The amount of extruded material is directly related to forced instrumentation, inadequate irrigation and lack of recapitulation, which can lead to inflammation of the periapical tissues, postoperative pain or even a flare-up[21].

Although root canal cleansing and modeling procedures clearly reduce the incidence of pain, in some cases it may assume higher pain levels than those found prior to treatment[22]. Tasdemir *et al.*[23] (2008) studied the influence of passive ultrasonic irrigation on the apical extrusion of irrigating solution. Their results suggest that conventional irrigation render significantly less extrusion than the ultrasonic activation of irrigating solutions.

Considering that the extrusion of debris directly relates to postoperative pain, and otherwise, the use of irrigation solutions agitation/activation methods improves for proper root canal decontamination, it seems important to evaluate the relationship between ultrasonic activation and the occurrence of postoperative pain. Hence, the present study aimed to evaluate the effect of PUI used during the final irrigation protocol in endodontic treatment on the incidence of postoperative pain.

Materials and methods

This study consisted of a randomized, parallel, double-blind clinical trial, in which clinical intervention and the application of a questionnaire containing a range of pain severity levels after endodontic therapy were performed. Clinical procedures were performed at the Endodontics Clinic of a Dental Specialties Center and was carried out after approved by the Local Ethics Committee (#1.966.374).

Study population, sample calculation and treatment allocation

Sixty patients with need for endodontic treatment in premolars and molars, without pulp vitality and asymptomatic were selected for the present study as indicated in the sample calculations. This calculation was done by using the G*Power v3.1 software for Mac (Heinrich Heine, Universität Düsseldorf, Germany), and by applying the Wilcoxon-Mann Whitney T test. Data from Gambarini *et al.*[24] (2012) were considered for determination effect

expected for the present study. Alpha-type error was set at 0.05 and beta power at 0.80; N2/N1 ratio of 1 was established. A total of 25 patients were determined, however, due to the possibility of loss of some patients, the sample was increased by 20%, totaling 30 patients per group (n = 30).

Inclusion criteria, besides those previously listed, were the fact that the patients were between 18 and 62 years of age and had good general health conditions. Patients who were taking antibiotics, analgesics, anxiolytics, sedatives or antidepressants prior to initiation of treatment, as well as pregnant, allergic or intolerant to the prescribed analgesic medication were excluded.

Patients with open root apices, calcifications, sharp curvatures (>30°) or any anatomical alterations that prevented foraminal patency were also excluded. Internal resorption, previous history of trauma, malocclusion related to occlusal trauma, teeth with periodontal problems, mobility and periodontal pocket greater than 3.0 mm were also excluded. Finally, the refusal to sign the Free and Informed Consent Term was also a reason for exclusion from the study sample.

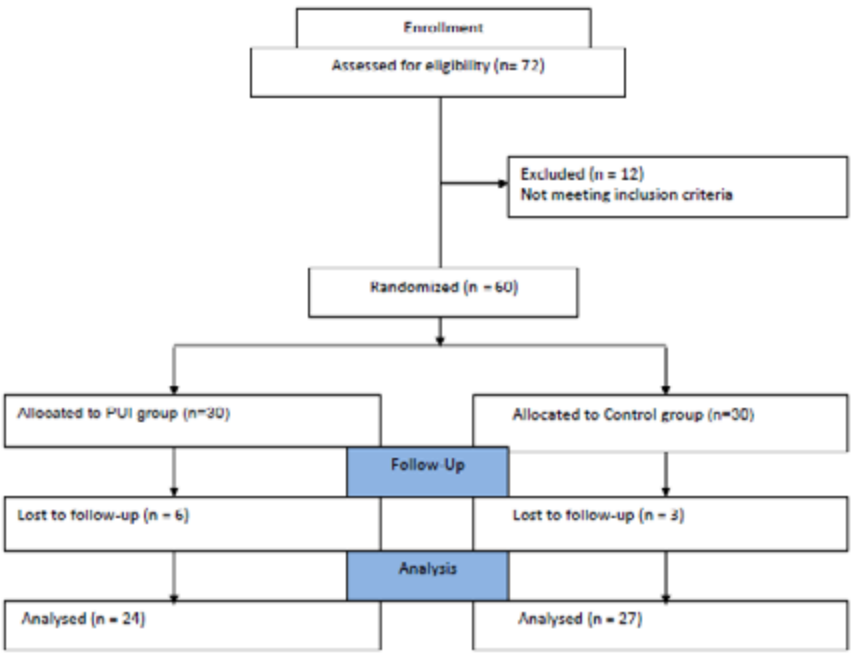
At the intraoral exam, all patients included had good clinical conditions, absence of fistula, periapical abscess or facial cellulitis. All dental crowns were able to receive rubber dam isolation and coronary restorations at the end of treatment. Ofthe 72 patients considered eligible for the study, 12 did not meet the inclusion criteria and were excluded. Recruitment of patients occurred within two years. The randomization, performed by the researcher, with the sixty participants in two groups of 30 patients, was performed as shown in the Figure 1. To search similarity between the groups, a randomized division of patients considered the patient profiles and their clinical characteristics in order to form groups similar to the age of the patients (mean age), gender, tooth type (pre-molars and molars) and number of roots canal. The random sequence generation for each group was generated using the website www.random.org. The patients were unaware of their allocation.

Study interventions

A clinical profile was developed to record the age and gender of the patient, the tooth to be treated, the pulpal sensitivity, and the presence or absence of a radiographically visible lesion. Before the start of treatment, the teeth were examined for the presence or absence of preoperative pain. Examination by palpation, vertical percussion and periodontal probing were performed. Thermal sensitivity test was performed (Endo-Ice; Maquira, Maringá, PR, Brazil) to confirm the pulp condition. The teeth were classified as having lesions of endodontic origin when the hard tissues were not visible and/or the thickening of the periodontal ligament was greater than 2.0 mm, observed in the diagnostic radiograph.

A single examiner evaluated all patients by radiographs and clinical findings; it was also up to the same professional to treat all cases, including the orientation of filling out the pain questionnaire. Based on the clinical and radiographic findings, the clinical procedures were initiated by the application of regional anesthesia for the lower molars and infiltrative terminal for the other teeth;

FIGURE 1· CONSORT flow diagram.



2% Mepivacaine with 1:100.000 epinephrine (DFL, Rio de Janeiro, RJ, Brazil) was used. After coronary access, location and flooding of root canals with 2.5% sodium hypochlorite solution (LAFEPE, Recife, PE, Brazil), the root canal was explored until the apparent length of the tooth by means of small caliber C-Pilot instruments (#8, #10, #15; VDWGmbH, Munich, Germany) was reached.

For root canal preparation ProTaper Universal system (Dentsply-Sirona, Ballaigues, Switzerland) files were used following manufacturer´s recommendation. They were driven by an Endo Mate DT electric motor (NSKNakanishi, Kanuma City, Japan), at a speed of 300 RPM and torque set at 2 N/cm. The crown-down instrumentation technique was used with small-forward and reverse movements. Every three movements the instruments were removed, inspected and cleaned with sterile gauze, so that the dentin scrapings adhered to its active part were removed; the instruments were reintroduced into the canal if they had not reached the established length. This procedure was repeated until the preparation was completed.

The apical patency was maintained during the preparation by means of small #10 to #20 manual K-files compatible with the initial apical foramen diameter. After the use of each instrument of the preparation system, was performed a recapitulation in the canal real length to avoid the accumulation of debris, leaving the apical patency. During chemical-mechanical preparation, at each instrument exchange, a careful irrigation of 2 mL of 2,5% sodium hypochlorite was performed. Disposable hypodermic syringes were used (Becton, Dickinson and Company, Curitiba, PR, Brazil) associated with a 24 G hypodermic needle (Becton, Dickinson and Company) with penetration limited to 2.0 mm short of apparent tooth length/real tooth length.

The S1 instrument was selected to begin the preparation of the cervical third. The Sx instrument was then used until it reached 5.0 mm above the apparent tooth length; recapitulation was performed with small C-Pilot instrument at each change. After

the preparation of the cervical and middle thirds, the actual canal length was measured using an Electronic Foramen Locator (RomiApex A-15; Romidan, RishonLezion, Israel). With the wet root canal, the device handle was adapted to the patient's labial commissure while the other electrode of the instrument was coupled to a manual K-file type instrument (Dentsply-Sirona) that best fitted the canal, the real canal length being determined in the 0.0 (zero) reading of the locator. With this measure, the working length was established 1.0 mm below the real canal length; periapical radiography was also performed. When it was not possible to passively perform the foraminal patency, additional procedures were used to reach it.

For preparation of the apical third, the instruments S1, S2, F1, F2 were used sequentially until two sizes larger than the initial apical instrument reached the working length. Thus, depending on the anatomy of the root canal system, according to the instrument used in root canal measurement, instruments F3, F4 and F5 were included for shaping the apical third. As described previously, after each instrument change was performed irrigation, aspiration, flood and recapitulation in the real canal length.

Since the preparation was completed, the patients were randomly divided into two groups (n = 30) to be used as a function of the final cleaning protocol. In the control group (CON) the canals were irrigated with 2.5% NaOCl, 17% EDTA (Biodynamic, Ibiporã, PR, Brazil) and NaOCl at 1.0% (LAFEPE) sequentially. The solutions were taken to the canals by the same irrigation set used during the preparation, having as apical limit 2.0 mm short of working length; the solutions remained in the canals for 1 minute (60 seconds) without any shaking, however, with solution renewal with each 20 second cycle. The ultrasonic tip was inserted into root canal by the operator for the purpose of patient blinding, but activation was not performed.

In the experimental group (PUI) the irrigation protocol followed exactly the same sequence based in Van der Sluis *et al.*[15] (2005);

however, in this group three activating cycles of 20 seconds in each of the solutions were performed. Ultrasonic agitation of the solutions was performed with E1 insert (Irrisonic; HelseUltrassonics, Santa Rosa de Viterbo, SP, Brazil), triggered 2.0 mm short of the working length using a piezoelectric ultrasound device (Emisonic 230; MMOptics, São Carlos, SP, Brazil); the activation was directed to the root flattened areas[14]. At the end of the irrigation/activation sequence, copious irrigation with 5.0 mL of physiological saline for final rising was performed in both groups.

After the preparation and final cleaning of the canals, regardless of the group, they were aspirated using suction cannulas and dried with sterile absorbent paper cones of a caliber compatible with the diameter of the last instrument used in the working length. A calcium hydroxide paste was used as intracanal medication between the sessions (Ultracal XS; Ultradent, Indaiatuba, SP, Brazil), carefully applied with its own syringe and NaviTip FX 29 G needles (Ultradent), with a rubber slider delimiting 2 mm above short of working length. The teeth were than provisionally sealed with sterile cotton balls and temporary restoration (Coltosol; Vigodent, Bonsucesso, RJ, Brazil). Finally, the occlusion was checked, and adjusted when necessary. The patients were informed of the possibility of pain even a few days postoperatively, and were advised to take one tablet containing 500 mg sodium dipirone every 6 hours if needed for pain control. This medication was provided for all patients. They were also advised that in cases of severe pain they could use 400 mg Ibuprofen every 6 hours, intercalating with the analgesic. If the patients have any adverse effects from the use of the indicated medications, they should report to the endodontist; in this case they would be removed from the survey.

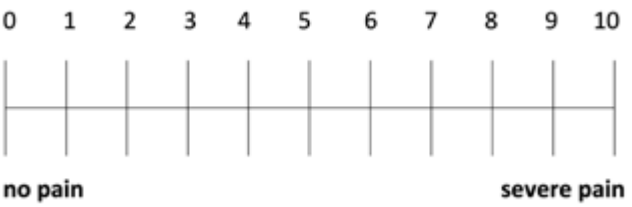
The symptoms were followed up every 24 hours with the completion of the pain questionnaire. Follow-up and evaluation of postoperative pain were made up to the fifth day after the first consultation was attended, without the patient being aware of

which group was under evaluation. The patients received a clinical form with a questionnaire containing a numerical descriptive scale of pain for evaluation during 5 days. The amount of analgesic should also be recorded. The presence or absence of pain, and the quantification of the intensity of this symptom reported by the patient was classified into levels using a numerical scale suggested by Lohbauer *et al.*[25] (2005) presented in the Figure 2.

The questionnaire was completed by the patients selecting the descriptor that best represented their clinical condition during the period evaluated and the return visit. The patient was instructed to indicate in the table only integers (from 0 to 10). In addition to verbal guidance, patients received an instruction sheet containing examples for demonstration of responses, as well as a form sheet containing the pain numeric table used.

At the follow-up appointment, irrespective of groups, the canals were then filled with gutta-percha ProTaper points (Dentsply-Sirona) of caliper corresponding to the instrument that formatted the apical third. A zinc oxide and eugenol sealer (Endofill; Dentsply do Brasil, Petrópolis, RJ, Brazil) was also used by lateral condensation technique. The sealing of the cavity with temporary material and the final radiography were realized. The patients were referred to the final restoration in the same Dental Specialties Center.

FIGURE 2 · Numerical pain scale; numeric characters refer to the following parameters.



0: The zero should be assigned by the patient when there was no pain, the treated tooth appeared normal, without any discomfort,
1, 2 and 3: Mild pain when the procedure seems perceptible, but not so uncomfortable, not requiring the use of analgesics, and if distracted, the patient does not feel pain,
4, 5, and 6: Moderate pain, uncomfortable pain, and supportive pain may have required the use of analgesics, but if used, these were effective in pain control,
7, 8 and 9: Severe pain, difficult to bear, analgesics had little or no effect on pain relief, when it was necessary to stop routine activities,
10: Maximum pain: severe pain, not relieved by the use of associated analgesics, where clinical attention was required.

Statistical analysis

Clinical data were expressed as absolute and percentage frequency and analyzed using the Pearson's Chi-square test and Friedman's StatPlus6 software for Windows. Initially, a general comparative descriptive analysis per day of the 2 groups was performed considering the minimum, maximum, median of pain scores and analgesic consumption patterns, on each day of the period evaluated. Subsequently, the groups were compared to each other, regarding pain scores and analgesic consumption in each day of the period evaluated by means of cross-tabulation and chi-square test. Through the Friedman test, a temporal comparison of the variation of pain within each group was made. The ANOVA test analyzed the regression of symptoms in each of the teeth of the two groups. A significance level of 5% was established for all analyzes.

Results

Of the patients treated, 9 did not attend the return visit, being 3 patients from the CON and 6 from the PUI, thus, the final sample consisted of 27 and 24 patients, respectively. The demographic data and the clinical characteristics of the patients of each of the groups were presented in Table 1.

TABLE 1 · Demographic data and clinical characteristics of patients included in the study

	S/PUI n = 27		C/PUI n = 24		Total 51
Men	9	33.33%	5	20.83%	14
Women	18	66.66%	19	79.16%	37
Mean age (years)	34.7		37.2		-
Premolars	12	44.44%	12	50%	24
Molars	15	55.56%	12	50%	27

The chi-square test was used to evaluate possible distribution differences and their consequences between the groups. The youngest patient included in the survey was 18 years old and the oldest 62 years old. The mean age of the patients was 35.9 years, and did not differ significantly between the groups. In both groups was observed predominance of female patients, however, the statistical analysis showed that no significant difference when isolated the gender factor ($P = 0.52$). The sample statistical analysis also showed no difference between the pattern of symptoms shown by patients treated according to the tooth group ($P = 0.41$). In this way, it was demonstrated that possible variations in the distribution of patients and teeth between the groups did not affect the observed result.

The median, minimum and maximum values of symptoms reported by patients, depending on the groups are described in Table 2. Statistical analysis showed no significant differences between groups over the follow-up period. The data point to the absence of painful symptomatology in the vast majority of patients in both groups. In addition to these findings, no patient reported severe pain (≥ 7) during the evaluation, with moderate pain occurring in only 2 patients in the CON group (7.41%) and 4 patients in the PUI group (16.67%); these reports were collected only in the first 24 hours. The ANOVA test was used to evaluate the regression of symptoms in the groups over the period evaluated. Data on pain variation in patients treated in both groups are described in Table 3.

The majority of the patients did not use analgesics, however, those who needed medication used it in the first 2 days, as described in Table 4. Of the patients treated, 4 of the control group (14.81%) and 6 of the experimental group (25%) required the medication on the first day. The amount varied up to a maximum of 3 tablets per patient in the control group and 4 tablets in the PUI group throughout the experimental period. The Chi-square test and cross-tabulation showed that there was no significant difference between groups ($P = 0.46$).

TABLE 2 · Median (minimum and maximum values) of the reported symptoms and the use of analgesics by the patients in the tested groups

Groups	Day1	Day 2	Day 3	Day 4	Day 5	Analgesics
S/PUI	0	0	0	0	0	0
	(0-6)	(0-3)	(0-3)	(0-2)	(0-2)	(0-3)
C/PUI	0.5	0	0	0	0	0
	(0-6)	(0-3)	(0-3)	(0-2)	(0-2)	(0-4)
*P** Values	0.61	0.77	0.59	0.23	0.56	0.46

**P* values calculated by Chi-square test with significance set at *P* <0.05.

TABLE 3 · Variation of the intensity of symptoms in the CON and PUI groups during the period of evaluation

Group		Day 1	Day 2	Day 3	Day 4	Day 5	Total
CON	Absent	17 (63%)	21 (81%)	25 (93%)	26 (96%)	26(96%)	27 (100%)
	Mild	8 (30%)	5 (19%)	2 (7%)	1 (4%)	1(4%)	27 (100%)
	Moderate	2 (8%)	0	0	0	0	27 (100%)
PUI	Absent	12 (50%)	20 (84%)	21 (88%)	21 (88%)	22 (92%)	24 (100%)
	Mild	8 (33%)	4(16%)	3 (12%)	3 (12%)	2 (8%)	24 (100%)
	Moderate	4 (16%)	0	0	0	0	24 (100%)

TABLE 4 · Consumption of analgesics by patients in the CON (n = 27) and PUI (n = 24) groups.

Group	Day 1	Day 2	Day 3	Day 4	Day 5	Total
Control	4	3	0	0	0	7
	14%	11%	0	0	0	25%
PUI	6	4	1	0	0	11
	25%	17%	4%	0	0	45%
Total (51)	10	7	1	0	0	18
	19%	13%	2%	0	0	35%

Discussion

Considering that conventional irrigation is not able to adequately clean the anatomical complexity of the root canal system[26,17,18], PUI was used to improve the mechanical action of the irrigant by acoustic flow and cavitation[27] and potentiate the chemical action of NaOCl by raising the temperature[15]. The PUI during irrigation of the root canal provides greater cleaning and disinfection, being more effective in the removal of dentinal debris from the canals[19].

The subjective evaluation of patient's symptom and analysis of the results is one of the main limitations in clinical trials of pain[28]. The numerical scale of pain was chosen based on studies that demonstrated its good sensitivity, easiness of understanding by the patient in provides the necessary information and generation of data that can be analyzed statistically[29].

The prevalence and severity of pain was assessed for five days after the procedure, as according to Pak & White[30] (2011); the intensity regresses substantially after the first three days of the procedure. Based on our results, the absence of pain was observed in the great majority of patients in both groups, without significant differences over the period of evaluation. No patient reported severe pain (≥ 7) and moderate pain was reported in only 7.41% in the CON group and 16.67% in the PUI group, solely in the first 24 hours. Due to our results, it is suggested that PUI does not increase pain and may be related to the fact that there is no increase in extrusion of debris, as shown by *ex vivo* studies by Tasdemir *et al.*[23] (2008), in which the authors show that PUI causes less extrusion than conventional irrigation. This finding had already been highlighted in *ex vivo* condition[31]. There is no similar study described in the literature that evaluates the influence of PUI on the incidence of postoperative pain, and the symptom has been related to mechanical, chemical, microbial injuries[20] and mainly to the apical extrusion of debris[21]. The postoperative pain, when present, is mainly of mild intensity[32].

The prevalence of postoperative pain declined over time. According to Arias *et al.*[33] (2015) study in which they reported that the peak of traumatic inflammation occurs within 24 hours, and that this decreases with time. A similar result was described by Pak & White[30] (2011), where, according to the authors, the prevalence and severity of pain decrease substantially in the first 48 hours. These findings corroborate with those of the present study where the highest incidence of pain occurred in the first 24 hours of the postoperative period, in both groups, with a decline of this intensity over the period evaluated.

The vast majority of patients did not use analgesics. However, those who needed medication, used them in the first 48 hours, and there was no significant difference in consumption between groups. As previously mentioned in relation to the occurrence of pain, such findings corroborate with several other studies that point out a small need for systemic medication and, when necessary, it is limited to the first 48 hours[30].

Considering the results of the study, which show the safety of the use of ultrasonic agitation in the final protocol of irrigation in relation to postoperative pain; and the literature findings regarding the potentialize of cleaning and decontamination by the activation of the irrigating solution, it is recommended the clinical use of PUI in endodontic treatment.

Conclusion

According to the methodology used and the results obtained in the present clinical study it was possible to conclude that the use of ultrasonic agitation in the final cleaning protocol did not significantly influence the occurrence of postoperative pain in patients submitted to endodontic treatment in teeth with pulp necrosis; yet, that no differences were observed regarding the intensity, duration or use of analgesics.

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Conflict of interest

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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Irrigação ultrassônica passiva na dor pós-operatória após tratamento endodôntico: ensaio clínico randomizado

Resumo

Objetivo: Este ensaio clínico randomizado avaliou o efeito do protocolo de irrigação ultrassônica passiva (PUI) empregado durante o tratamento endodôntico na incidência de dor pós-operatória. Métodos: Sessenta pacientes adultos com pré-molares e molares assintomáticos não vitais foram incluídos. Os tratamentos foram realizados com instrumentos ProTaper Universal com comprimento de trabalho ajustado 1,0 mm abaixo do forame apical. Os pacientes foram divididos aleatoriamente para receber um dos dois protocolos finais de limpeza (n = 30): PUI - os canais foram enxaguados com NaOCl 2,5%, EDTA 17% e NaOCl 1,0% sequencialmente, com 3 ciclos de 20 segundos cada, solução de irrigação, sob agitação ultrassônica; Controle (CON) - protocolo final de irrigação semelhante foi empregado sem qualquer agitação. Para avaliar a dor pós-operatória, foi aplicada uma escala numérica de avaliação a cada 24 horas até o quinto dia. Os dados foram analisados estatisticamente pelos testes Qui-quadrado de Pearson, Friedman e ANOVA com 5% de significância. Resultados: Não houve diferenças significativas em nenhum dos períodos (P=0,46). A grande maioria dos pacientes em ambos os grupos não apresentou sintomas de dor. Nenhum paciente relatou dor intensa (≥ 7), sendo que dor moderada ocorreu em apenas 2 pacientes do grupo CON (7,4%) e 4 pacientes do grupo PUI (16,7%), exclusivamente nas primeiras 24 horas. Conclusões: A utilização do protocolo de irrigação ultrassônica passiva não influenciou a ocorrência de dor pós-operatória em pacientes submetidos a tratamento endodôntico.

PALAVRAS-CHAVE: Endodontia; Ensaio clínico; Dor pós-operatória; Ultrassônico.

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