

Special Article – Rubber Materials

Reduction of Post-Endodontic Pain after One-Visit Root Canal Treatment Using Three Cryotherapy Protocols with Different Temperature

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Received: October 16, 2018; Accepted: November 03, 2018; Published: November 10, 2018

Abstract

Objective: The aim of this clinical trial was to assess whether controlled irrigation with three cryotherapy protocols with different temperature would result in a reduced of post-endodontic pain after one-visit root canal treatment. The null hypothesis was that there would be no difference between the control group and cryotherapy groups in terms of post-endodontic pain.

Materials and Methods: Two hundred and forty patients aged 18-65 years were treated with three cryotherapy protocols with different temperature after one-visit root canal treatment for prosthetic reasons detected with only vital pulps. All canals were clean and shaped with Reciproc instruments. Final irrigation with cold (6°C, 2.5°C and room temperature) 17% EDTA and 10 mL cold saline solution.

Results: No statistically relevant modification ($p > .05$) between control group and group A were encountered concerning level or period of pain. There was no statistically relevant difference ($p > .05$) among Group A and CG compared with Group B. Group B showed less pain than the rest of the groups. Cryotherapy protocols used in the two experimental groups can help dentists to manage pain in root canal treatments with vital pulps.

Conclusion: The methodology in both selecting the participants in the study and analyzing the data in this randomized clinical trial permitted us to conclude that cryotherapy aids clinical procedures to clean and shape the canals in order to reduce the occurrence of post-endodontic pain and the need for prescription in patients with a diagnosis of vital pulp.

Keywords: Cryotherapy; Post-operative pain; Post-endodontic pain; Pain

Introduction

Post-endodontic pain can be distressing to both the patient and the dental professional. It is an unwanted but common sensation reported by more than 35% patients, regardless of the pre-operative periapical condition of the tooth treated. Therefore, pain prevention and management during and after root therapy is essential with regard to endodontic practice [1]. Debris, organic tissue, microbes, and irrigant solutions extruded outside the apical foramen during root canal procedures initiate inflammation and post-operative problems, such as mild to severe pain or flare-ups [2-4].

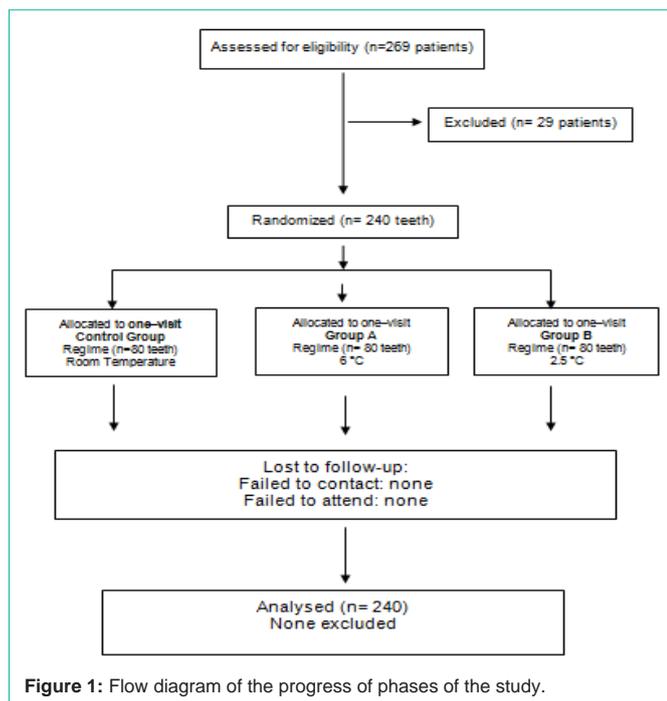
The composition and the degree of bacterial contamination of the debris and the reactions of the patient's immune system will play an important role in post-endodontic pain. Meticulous determination and maintenance of working length may reduce the amount of debris extruded through the main foramen, but may not avoid this entirely [5,6]. Accumulation of tissue remnants and dentin in the apical constriction is usual and can produce obstruction of root canal [7]. This condition can be prevented if working length and patency of the apical foramen is maintained [8,9].

Several strategies have been developed to mitigate post-endodontic pain, which include prescribing prophylactic analgesics

and corticosteroids, administering long-lasting anesthesia, root canal preparation using the crown down technique, and utilizing glide path applications and occlusal reduction [10,11].

Some authors indicated that maintaining apical patency would not produce more post-endodontic complications [12]. A newly issued *in vitro* study exhibited that intracanal carriage of cold irrigant at 2.5°C with Endo-Vac irrigation decreased the exterior side temperature by about 10°C, preserving such a temperature for five minutes [13], which, according to the abovementioned scenario, would be adequate to create a confined anti-inflammatory beneficial consequence in periradicular tissues. Cryotherapy is derived from the Greek term cryos, which means "very cold" [14]. Hence, cryotherapy uses low temperatures to treat harms and inflammation. Cryotherapy aims at removing heat and thus gaining an advantage by reducing inflammation [15].

Cryotherapy is a long-standing method that has been regularly applied in sports injuries and medical procedures for pain management and post-operative care. Cryotherapy, by itself, suggests that applying cold through several methods may reduce the transmission speed of nerve motions, hemorrhage, edema, and local inflammation. It is therefore effective in the reduction of musculoskeletal pain, muscular



spasm, and connective tissue distension [13].

Hence, the goal of this clinical trial was to assess whether controlled irrigation with three cryotherapy protocols along with different temperatures would result in a reduction of post-endodontic pain after a one-visit root canal treatment. The null hypothesis was that there would be no difference between the control group and cryotherapy groups in terms of post-endodontic pain.

Materials and Methods

This clinical study was carried out at the Autonomous University of Baja California, School of Dentistry, Tijuana, Mexico. The protocol was accepted by the Ethics Commission of the University (number: 47/2018), registered under the ClinicalTrials.gov Identifier: NCT03559127 (06/2018), and managed in agreement with ethical principles of the last update of the Declaration of Helsinki [16].

Three specialized endodontists with an average clinical practice of 18 years and qualified in the techniques, strategies, and methods studied were incorporated in the study. They performed 80 root canal treatments each (n= 240) in maxillary/mandibular anterior or posterior teeth, having irreversible pulpitis established by pulp sensitivity testing with heat and cold. Pulpal response was assessed with previous Root Canal Treatment (RCT) using EndoIce (Hygenic Co, Ak, OH), and proper palpation and percussion examinations were conducted.

Another condition taken into account was the nonexistence of roentgen graphic signs of apical pathology. The above-mentioned analysis was established on a sample size calculation that expected, at least, 40 subjects per clinician were essential in order to identify changes among the two experimental and control groups for an effect size of 0.85 with an alpha error of 0.05 [17]. All RCTs were performed over one visit. RCTs and written agreement of all individuals

participating in the study were obtained.

Pulpal sensibility tests were performed by the principal author, and digital radiographic diagnosis was recognized by two certified clinicians. Further clinical requirements for patients' inclusion were as follows: 1) Requirements of the clinical trial were understood and freely accepted. 2) Patients in adequate physical and mental health were included. 3) Teeth with sufficient coronal structure and diagnosed with irreversible pulpitis. 4) No previous root canal treatment. 5) No intake of analgesics or antibiotics seven days prior to the root canal treatment.

Exclusion criteria

Previously root canal treated teeth, pregnancy, and failure to obtain patient's authorization, patients with a record of treatment for long-lasting pain, patients less than 18 years of age and more than 65 years of age. Non-vital teeth and teeth with apical radiolucency, internal or external resorption, open apex, severe curvatures (>36°), or a radio graphically canal calcifications were all rejected from the study. Mishaps or difficulties during RCT (impossibility to achieve working length) also resulted in exclusion of patients from the study.

The diagnosis of vital pulp was confirmed by the existence of bleeding after gaining access to the pulp chamber. If the sensibility test was affirmative and there was bleeding following pulp exposure, the tooth was recognized as vital. Presence or absence of pain seven days previous to the event (yes/no) was observed.

Patient selection and distribution. A total of 240 of 269 patients (129 females and 111 male) aged between 18-65 years were integrated in this clinical trial, while 29 were rejected as not completing the requirements needed. Patients with a vital maxillary or mandibular molar, premolar or front teeth designated for intentional endodontic therapy were included for prosthetic reasons.

Any patient who declined to agree with the study, rejected one-visit RCT, and consumed analgesics or NSAIDs were eliminated also. Each qualifying patient was informed about the intentions, hazards, and plan of the trial, and written informed consent authorizations were obtained prior their enrollment. A clinician who did not participate in the study carried out the randomization procedure using a processor random table generator (www.random.org 2018).

Each patient received a consecutive number. Two-hundred and forty patients met the inclusion criteria and were integrated in the study. Of the complete sample, 80 were randomly allocated to one of the three irrigating regimes with different temperatures (Figure 1).

Clinical Methodology

RCT was planned to be completed over one visit. Topical anesthetic (Anesthesia Topica, Astra Mexico) was applied before infiltration. Patients received 2 carpules of articaine 2% with epinephrine 1:200,000 (Septodont, Saint-Maur des-Fosses, France). In circumstances in which additional anesthesia was necessary, intra-ligamental anesthesia (2 mL articaine 2%) was administered. For the maxillary teeth, the solution was injected by gentle and gradual local infiltration. For the mandibular teeth, one of the carpules was used for an inferior alveolar nerve block and the other for a gentle labial infiltration near the tooth to be treated.

Table 1: Distribution by group of teeth and location.

Variables	Control Group (n=80)	Irrigant protocols	
		Group A (n=80)	Group B (n=80)
Sex			
Male	37	37	37
Female	43	43	43
Age group			
18-30	25	21	29
31-43	40	43	41
44-56	11	13	7
57-65	4	3	3
Arch			
Maxilla	41	38	39
Mandible	39	42	41
Occlusal contact			
Yes	6	4	4
No	74	76	76

Table 2: Kruskal-Wallis test applied to the post-endodontic pain.

Occurrence of pain	n	Mean	Standard deviation
Pain after 24h			
Control Group	80	0.59	0.83
Group A	80	0.67	0.84
Group B	80	0.89	0.98
Pain after 48h			
Control Group	80	0.23	0.44
Group A	80	0.25	0.45
Group B	80	0.26	0.61
Pain after 72h			
Control Group	80	0.02	0.84
Group A	80	0.05	0.83
Group B	80	0.06	0.98

A rubber dam was placed and the tooth was cleaned with sterile gauze embedded with 2.5% NaOCl. The access cavity was accomplished using sterile #331 bur (Dentsply Int, York, PA), with high-speed and refrigeration. 2.5% NaOCl was employed to disinfect the coronal access. The canals were cautiously explored with #10 K-type file (Flex-R files, Moyco/Union Broach, York PA, USA). The working length was established with a #15 k-file and the Root ZX electronic apex locator (J Morita, Irvine CA, USA) and confirmed radio graphically (Schick Technologies, NY, USA). 1.5 mL of liquid 17% EDTA (Roth International, Chicago, IL) was administered at the entrance of the canals.

Cervical and middle thirds of the canal were flared with a K3XF 25/10 rotary instrument (Kerr Endo, Orange County, CA) at 500 rpm. The root canal was flushed with 3 mL 5.25% Sodium Hypochlorite (NaOCl). A glide path to the WL was then established. Preparations of the canals were completed with an electric motor (VDW Silver Motor, VDW, Munich Germany) in reciprocating mode.

Dentinal remains were removed from the instrument with a sterile gauze embedded with 2.5% NaOCl, immediately post the instrument change and after two-three pull in-and-pull out (pecking) movements (Reciproc) following the manufacturers' recommendations.

Each root canal was flushed with 2.5mL 2.5% NaOCl. Irrigation was achieved using a 24-gauge needle (Max-I-Probe; Tulsa Dental, York, PA) and a 31-G NaviTip needle (Ultradent Products Inc, South Jordan, UT) when getting the WL after each instrument insertion. A size #10 K file was used to maintain WL after each Reciproc instrument. The established WL was checked repeatedly throughout the clinical procedures. After instrumentation, the root canals were flushed with 3 mL 2.5% NaOCl and activated ultrasonically. It was carried out by means of an Irrisafe ultrasonic 20.00 tip (Satelec, Merignac, France) at 50% power of the Mini-Endo ultrasonic device (Kerr Endo), with the tip placed three mm from the WL for thirty seconds per root canal.

Irrigating Regimens

Group A

The R25 (size 25/ .08) instrument was used in narrow and curved canals, and R40 files (40/ .06) were used in broad root canals. Three in/out pecking cycles were employed with a fullness of not more than 3 mm until obtaining the established WL. Patients belonging to this group received a final irrigation with 5 mL cold (6°C) 17% EDTA followed with 10 mL cold (6°C) sterile saline solution dispensed to the WL using a cold (6°C) metallic micro-cannula included in the Endo Vac System (Kerr Endo) and maintained intracanal for one minute.

Group B

Canals were prepared as in group A. Patients belonging to this group received a final irrigation with 5 mL cold (2.5°C) 17% EDTA followed with 10 mL cold (2.5°C) sterile saline solution dispensed to the WL using a cold (2.5°C) metallic micro-cannula included in the Endo Vac System for one minute.

Control Group (CG)

Patients belonging to this group were treated in a manner identical to the experimental groups (A and B), except that they received a final flush with 5 mL (room temperature) 17% EDTA followed with 10 mL (room temperature) sterile saline solution delivered to the WL using a metallic micro-cannula included in the Endo Vac System for one minute.

Each experimental and control group was flushed with the irrigant described above. Care was taken to confirm that the metallic cannula would aspirate properly by noticing the system's translucent evacuation duct. In case there was some obstacle, the metallic device was promptly replaced.

The working length was performed again by using an apex locator, as described, before using #35 and #40 files.

The root canals were desiccated with sterile paper cones and filled at the same appointment. Gutta-percha points (Dentsply Maillefer) were laterally condensed with #25 nickel-titanium spreaders (Dentsply Maillefer) and AH-plus as the sealer (Dentsply Maillefer). The access cavities were etched and fixed with Fuji IX (GC Corp, Tokyo, Japan). After completing the irrigation protocols, the patients were warned of

the possible occurrence of pain for hours following RCT and provided an evaluation form (VAS questionnaire) to be completed and returned 72 hours later. The forms confirmed the presence/absence of pain. The pain level was measured using a validated pain scale known as VAS [18]. The VAS scale is a continuous measure comprised of a straight line, which is 10 cm in length. For pain intensity, the VAS is anchored by “no pain” (score of 0) and “pain as bad as it could be” (score of 10). The cut points on the pain VAS are no pain (0-0.5 cm), mild pain (0.6-4.0 cm), moderate pain (0.45-7.4 cm), and severe pain (7.5-10 cm) [23]. The pain VAS was completed by the patients. The patients were asked to put a mark perpendicular to the pain VAS line at the point that indicated their pain severity during the three days after the endodontic treatment.

Statistical Analysis

The associated issues pre-operatively recorded were incorporated into the analysis as follows: age, sex, presence of occlusal contacts, and maxillary or mandibular teeth. Differences in the general intensity of pain between groups were analyzed using the ordinal (linear) Chi-square test. Dissimilarities in VAS recorded values after 24, 48 and 72 hours and in the amount of analgesic intake between the two groups tested.

The results were statistically evaluated with the ordinal Chi-Square test for the existence of post-endodontic pain with a level of significance of $p=0.05$.

Results

The study results showed statistically significant dissimilarities among the control group and group B throughout all time periods for post-operative pain. (Table 1) shows the distribution of clinical variables; a total of 240 patients took part in this study: 129 (53.75%) were women and 111 (46.25%) were men. Their ages ranged between 18 and 65 years; 118 (49.16%) of the treated teeth were in the maxilla and 122 (52.83%) were in the mandible.

The clinical organization of the participants is presented in (Table 1). No statistically relevant modification ($p > .05$) between control group and group A were encountered concerning level or period of pain. According to the VAS examination, marks were seen 24-72 hours later in the three groups with an important decline subsequently (Table 2).

No statistically relevant distinction was appreciated among the three groups assessed in the trial in terms of level and quantity of analgesic intake ($p > .05$), (Table 3). Analgesic intake was regulated in the 24 hours subsequent to the RCT in all the groups assessed. Two of the 240 patients indicated severe pain through the phase of the investigation corresponding to 1 and 1 for Group A and control group respectively (Table 4).

There was no statistically relevant difference ($p > .05$) among Group A and CG compared with Group B. Group B showed less pain than the rest of the groups in relation to the existence of pain at any of the three time points measured (Table 2).

Patients in the CG had a significantly higher occurrence of post-endodontic pain than the rest (Tables 2&4). Participants in groups A and B suffered significantly less pain after 24, 48 and 72 hours and

Table 3: Quantity of analgesics intake.

24 hrs. after	Control Group (n=80) (%)	Group A (n=80) (%)	Group B (n=80) (%)
Quantity			
None	54 (70.83)	57 (70.83)	57 (75)
One tablet	14 (16.66)	13 (18.05)	13 (15.27)
Two tables	12 (12.5)	10 (9.72)	10 (9.72)
Three tables	0	0	0

Table 4: Results of VAS. Intensity of Pain.

Occurrence	Control Group (n=80)	Group A (n=80)	Group (n=80)
No	54	57	57
Yes	26	23	23
Mild	13	10	11
Moderate	13	12	12
Intense	1	1	0

needed less analgesics post-treatment ($p < .05$). Participants in the control group exhibited significantly higher frequency of pain in general and lengthier period ($p < .05$).

Discussion

Pain by itself is difficult to understand and measure, especially when it happens suddenly in patients. The principal difficulty in learning aching and discomfort is the participant's idiosyncratic assessment and dimension. For this purpose, planning the evaluation form has to be completely comprehended by the participants.

Pre-operative pain is one of the highest predictors of post-endodontic pain [18]. Thus, only teeth with IP indicated for RCT because prosthodontic purposes were chosen for this research. All treatments were performed over one visit to avoid the possible influence of intra canal medication or other issues generating pain; the involucrate teeth in the three groups were released of any early occlusal points after endodontic procedures, so that unsuitable traumatic occlusion would not disturb the outcomes. WL was estimated with an EAL and confirmed with a radiograph. Root ZX EAL was employed because its exactitude has been established in two clinical environments [19-22]. As suggested by Herrera et al. [23], electronic WL measurement was repetitive after cervical and middle thirds shaping.

This study is in agreement with that of Yaylali et al. [24], who described that the incidence of post-operative pain was significantly lower when apical patency was maintained but in non-vital teeth. In our study, clean and shape procedures were performed on root thirds using reciprocating movements, respectively, followed by a final irrigation with cold (6 and 2.5°C) 17% EDTA gently delivered to the WL using a cold (6 and 2.5°C) sterile metallic micro cannula attached to the Endovac, which was supported in early scientific reports [25-30]. The standardized and controlled procedures used in this study may also have contributed to the reduction of post-endodontic pain. We used cold saline solution in the two experimental groups as the final irrigant that decreases the external root surface temperature may be sufficient to generate a local anti-inflammatory result in the periradicular tissues. Bleakley et al. [31,32], evaluated the efficiency

of cryotherapy applications in soft tissue injuries. These effects can explain the reduced pain levels of the cryotherapy groups in the present study.

The study results showed statistically significant differences between the control group and one cryotherapy group (2.5°C) throughout all time periods for post-endodontic pain. Therefore, the null hypothesis of the study was rejected. Intracanal cryotherapy can be simply and safely included in the non-surgical root canal treatment.

Conclusion

The methodology in both selecting the participants in the study and analyzing the data in this randomized clinical trial permitted us to conclude that cryotherapy aids clinical procedures to clean and shape the canals in order to reduce the occurrence of post-endodontic pain and the need for prescription in patients with a diagnosis of vital pulp.

Acknowledgement

We thank Prof. Dr. Michael Hülsmann for his valuable assistance in reviewing this manuscript.

ClinicalTrials.gov Identifier: NCT03559127.

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