Intracanal Cryotherapy Reduces Postoperative Pain in Teeth with Symptomatic Apical Periodontitis: A Randomized Multicenter Clinical Trial

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Abstract

Introduction: A prospective, multicentered, randomized clinical trial was designed to assess if controlled irrigation with cold saline could result in less incidence and intensity of postoperative pain in patients presenting with pulp necrosis and symptomatic apical periodontitis. **Methods:** A total of 210 patients (presenting with necrotic uniradicular teeth with a diagnosis of symptomatic apical periodontitis and a preoperative visual analog scale (VAS) score higher than 7) were randomly allocated in the control or experimental group after the completion of shaping and cleaning procedures. The experimental group received a final irrigation with 20 mL sterile cold (2.5°C) saline solution delivered to the working length with a sterile, cold (2.5°C) Endovac microcannula (Kerr Endo, Orange Country, CA) for 5 minutes. The same protocol was used in the control group with room temperature saline solution. Patients were instructed to record the presence, duration and level of postoperative pain, and analgesic medication intake. A logistic regression was used to compare the incidence of postoperative pain and the need for painkillers between groups. Differences in general pain intensity between groups were analyzed using the ordinal (linear) chi-square test. Postoperative pain after 6, 24, and 72 hours (recorded in a VAS scale) and the need for analgesic medication intake between the 2 groups were assessed using the Mann-Whitney *U* test. **Results:** Patients in the control group presented a significantly higher incidence of postoperative pain, intensity, and need for medication intake ($P < .05$). **Conclusions:** Cryotherapy reduced the incidence of postoperative pain and the need for medication intake in patients presenting with a diagnosis of necrotic pulp and symptomatic apical periodontitis. (*J Endod 2018;44:4–8*)

Key Words

Analgesics, cryotherapy, endodontic pain, postoperative pain, symptomatic apical periodontitis

Significance

Cryotherapy reduced the incidence of postoperative pain and the need for medication in patients presenting with a diagnosis of necrotic pulp and symptomatic apical periodontitis.

The management of postoperative pain is essential in endodontic practice. Hargreaves and Hutter (1) stated that this painful situation can be predicted, especially in teeth with preoperative pain, pulp necrosis, and symptomatic apical periodontitis. Pulp irritants initiate cellular, humoral, and neurovascular responses in pulp tissue (2). The biphasic response in the pulp (vasodilation, increased blood flow, intravascular fluid extravasation leading to increased pulpal pressure, and diminished pulpal blood flow) (3) leads to the development of irreversible pulpitis or pulp necrosis. If this situation extends to the periapical tissues, it may lead to the development of symptomatic apical periodontitis.

Symptoms associated with symptomatic irreversible pulpitis, pulp necrosis (4), and symptomatic apical periodontitis can be related to different factors including changes in periapical pressure, microbial factors, chemical mediators of pain, and psychological factors (5), which ultimately lead patients to seek emergency dental care (6).

One way to reverse the inflammatory process and control pain is with medication such as nonsteroidal anti-inflammatory drugs, paracetamol, or corticosteroids. However, despite being relatively safe drugs, side effects such as gastrointestinal intolerance (7–10) and renal, hepatic, and respiratory disorders such as asthma have been reported (11, 12). Even nonsteroidal analgesics with an enteric coating have been

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related to colon pathology, such as intestinal inflammatory disease, enteropathy with protein loss, iron deficiency anemia, and ulcers (7–9). To avoid these secondary effects, treatments such as manual lymphatic drainage, lasers, and cryotherapy (10) have been suggested.

Physiologic and clinical evidence suggests that applying cold through various methods may decrease the conduction velocity of nerve signals, hemorrhage, edema, and local inflammation and is therefore effective in the reduction of musculoskeletal pain, muscular spasm, and connective tissue distension (11).

A recently published *in vitro* study showed that constant intracanal delivery of cold saline solution at 2.5°C with negative pressure irrigation reduced the external root surface temperature more than 10°C, maintaining such a temperature for 5 minutes (13), which, according to the aforementioned studies, would be enough to produce a local anti-inflammatory effect in periradicular tissues.

Therefore, the aim of this randomized clinical trial was to assess whether controlled irrigation with cold saline after cleaning and shaping procedures would result in a reduced incidence and intensity of postoperative pain in patients presenting with uniradicular teeth with pulpal necrosis and symptomatic apical periodontitis.

Materials and Methods

A prospective, multicentered, randomized clinical trial was designed and conducted in accordance with ethical principles (including the World Medical Association Declaration of Helsinki) after being independently reviewed and approved by the university institutional ethics board. Seven certified endodontists with an average private clinical practice of 15.33 years performed 30 root canal treatments each (a total of 210) in uniradicular teeth having a diagnosis of necrotic pulp and symptomatic apical periodontitis after power analysis calculations.

The aforementioned analysis was based on a sample size calculation with information derived from a previously conducted trial by the first author. These data estimated that a minimum sample size of 25 individuals per endodontist was required in order to detect differences between the experimental and control group for an effect size of 0.80 with an alpha error of 0.05. Further estimations, taking into consideration 15% dropouts, suggested a total adjusted sample size of 30 patients per endodontist.

All treatments were performed over 2 appointments. Root canal treatments were undertaken with the understanding and written consent of all subjects included in the study.

Patient Selection and Allocation

A total of 315 patients presenting with pain in uniradicular teeth were referred for emergency treatment. All patients were informed of the aims and design of the study, and written consent was obtained before their enrollment.

Pulpal sensibility was assessed before treatment using EndoIce (Hygenic Corp, Akron, OH), and proper palpation and percussion tests were performed. Only patients presenting with uniradicular teeth with a single canal and a diagnosis of necrotic pulp (negative thermal stimulation with EndoIce confirmed with an absence of bleeding during access cavity preparation) and symptomatic apical periodontitis were included in the study.

The patient was required to fill out a preoperative questionnaire that included a visual analog scale (VAS) score (0–10, with 0 being the total absence of pain and 10 the most unbearable pain) to register the level of pretreatment pain. Only those patients registering 8, 9, or 10 were included in the study.

Cases with the following criteria were also excluded: root canal retreatment, pregnancy, a history of medication for chronic pain or those compromising the immune response, failure to obtain authorization from patients, presence of difficult root canal anatomy (root canals with an extreme curvature [>30°], internal or external resorption, teeth with open apices, or a radiographically untraceable canal path), or any accident or complication occurring during treatment. Patients whose forms were incompletely or inadequately filled out were excluded also.

A total of 210 patients met the inclusion criteria and were included in the study. Each facility participating in the study had a list of 30 random numbers (www.random.org) assigned either to the control or experimental group. All patients entering the facility and fulfilling the previously mentioned criteria who agreed to participate in the study received a consecutive number; an assistant checked the list to verify the group to which that patient would be assigned. At the end of the shaping procedure, the assistant provided the information to the clinician.

Patient-related factors, such as age and sex, as well as preoperative tooth-related factors (tooth location, presence or absence of occlusal contacts, and presence or absence of radiolucent lesions) were registered.

Root Canal Procedure

All treatments were performed over 2 appointments. At the first appointment, all patients were anesthetized with 2 carpules of articaine 2% with epinephrine 1:200,000 (Septodont, Saint-Maur des-Fosses, France); in cases in which supplemental anesthesia was needed, intraligamental articaine 2% was injected. For the maxillary teeth, the 2 carpules were injected by slow local infiltration in the buccal vestibule. For the mandibular teeth, 1 of the carpules was used for an inferior alveolar nerve block and the other for a slow buccal infiltration around the tooth to be treated. After absolute rubber dam isolation and disinfection, the cavity access was performed with a new, sterile round bur, and the cervical third of the root canal was flared with a K3XF 25/10 rotary instrument (Kerr Endo, Orange County, CA) at 500 rpm. The root canal was irrigated with 3 mL 5.25% sodium hypochlorite (NaOCl). The working length (WL) was first determined with an Apex ID apex locator (Kerr Endo, Orange Country, CA) using no. 10 and 15 K-files and later confirmed radiographically. A glide path to the WL was then established, and a TF Adaptive ML1 (25/08) instrument (Kerr Endo) was used to the WL. A size 10 K-file was used to maintain apical patency 1 mm beyond the WL, and 3 mL NaOCl was again delivered up to 1–2 mm from the WL using a side-vented needle. The same irrigation protocol and patency sequence were repeated using an ML2 (35/06) TF Adaptive instrument (Kerr Endo). After gauging, larger root canals were flared to an ML3 (50/04) instrument (Kerr Endo) and the last instrument recorded.

Ultrasonic activation of 3 mL fresh NaOCl was performed using an Irrisafe ultrasonic 20.00 tip (Satelec, Mérignac, France) at 50% power of the MiniEndo ultrasonic unit (Kerr Endo) to place the tip 3 mm from the WL; this was repeated 3 times for 20 seconds for each activation. Then, 17% EDTA was gently delivered to 1 mm from the WL as a final irrigant and maintained intracanally for 1 minute. The root canals were then dried with sterile paper points. At this time, the assistant informed the practitioner as to which group the patient should be allocated. The patient was blind to the intervention assigned.

Experimental Group (*n* = 105)

Patients assigned to the experimental group received a final irrigation with 20 mL cold (2.5°C) sterile saline solution delivered to the WL using a cold (2.5°C) sterile microcannula attached to the Endovac negative pressure irrigation system (Kerr Endo) for 5 minutes (13). Care was taken to ensure that the microcannula would suction properly