

# Effect of Cryotherapy on Postoperative Pain: Randomized Controlled Trial

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## Abstract

**Context:** Postoperative pain (POP) as a consequence of root canal preparation, is a major side effect, of endodontic treatment. It can be prevented by the use of cryotherapy. This randomized control trial was carried out, to test the latter's efficacy, so that it can be recommended, as a preventive measure for POP, during endodontic treatment. **Aims:** To evaluate the effect of cryotherapy on post-operative pain (POP) during endodontic treatment. **Setting and design:** Randomized controlled trial was conducted on 40 patients based on inclusion and exclusion criteria (Table 1) in mandibular premolars, diagnosed with symptomatic irreversible pulpitis and normal periapical tissues. **Methods & Material:** 40 patients were randomly distributed into two groups, Experimental and Control. In the experimental group, 10ml cold saline solution, at - , while in the control group, 10ml of saline solution at room temperature, was used as the final irrigant. Patients were asked to fill a questionnaire, pre-operatively and post-operatively at 6, 24, 48 and 72 hours. **Statistical analysis:** The obtained data was subjected to statistical analysis using SPSS version ' .0' software. **Results:** Incidence and intensity of POP, was found to be lower in patients treated with cold saline. **Conclusion:** Use of cold saline solution as final irrigant, during endodontic treatment, reduces the incidence and intensity of post endodontic pain.

**Keywords:** Postoperative pain, inflammation, cold saline solution, cryotherapy

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## INTRODUCTION

Postoperative pain (POP) is one of the undesirable complications, after the endodontic intervention. It has been reported, with a high incidence rate, ranging between 3% and 58%.<sup>[1,2]</sup> The various precipitating factors of POP are mechanical, chemical,<sup>[3]</sup> preoperative condition of pulp and periradicular tissues,<sup>[4]</sup> preoperative pain, and presence of periapical radiolucency.<sup>[5]</sup> To overcome this challenge, various treatment modalities have been advised. They include administration of analgesic combination therapies, involving corticosteroids, administration of long-lasting anesthesia,<sup>[6]</sup> and occlusal reduction.<sup>[7]</sup>

In recent years, cryotherapy has attained prominence, as a useful adjunct for the treatment of POP. It may be explained, as the therapeutic application of any substance to the body that removes heat, resulting in decreased tissue temperature.<sup>[8,9]</sup> Cryotherapy tends to induce effects, at the site of application as well as at the level of the spinal cord, through neurologic and vascular mechanism.<sup>[10]</sup>

Cryotherapy has been reported, to be effective in diminishing edema, pain, inflammation, and recovery time, by countering, heat from tissues and producing vasoconstriction. Thereby, it decreases cell metabolism, reducing the oxygen demand, and limits the production of free radicals.<sup>[11,12]</sup> Vera *et al.* observed decrease in temperature on the outer surface of the root by 10°C, through cold saline application within the root canal for 5 min, along with anti-inflammatory effect on the periradicular tissue.<sup>[13]</sup>

It has been suggested that cryotherapy might be effective, in countering future pain, during endodontic treatment. Applying this hypothesis, the present study was conceived, to evaluate the effect of cryotherapy on POP. The null hypothesis for this study was that there would be no difference in pain experienced after biomechanical preparation, with or without cryotherapy.

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## MATERIALS AND METHODS

**Ethics:** Permission for carrying out this study was granted by the Institutional Ethics Committee of Teerthanker Mahaveer Dental College and Research Centre, Moradabad, Uttar Pradesh.

**Study design:** Patients reporting to the Outpatient Department of Conservative Dentistry and Endodontics, with complaint of pain in relation to lower posterior teeth, were screened for eligibility, for this randomized control trial.

Patients were clinically examined, after taking a detailed history. The involved mandibular premolars, were subjected to radiographic, cold, EPT, mobility, palpation and percussion test. Healthy patients, between 18 to 30 years, diagnosed with symptomatic irreversible pulpitis with normal periradicular tissue, in mandibular premolar teeth, were shortlisted. On the basis of inclusion and exclusion criteria, listed in Table 1, 64 patients were selected for this RCT.

They were randomly divided, into 2 groups, without any gender discrimination. The block randomization process was used; slips with the name of the group were placed in separate envelopes and patients were asked to pick up one envelope. Single blinding was maintained throughout the study, with patients not being aware of their group/used irrigant.

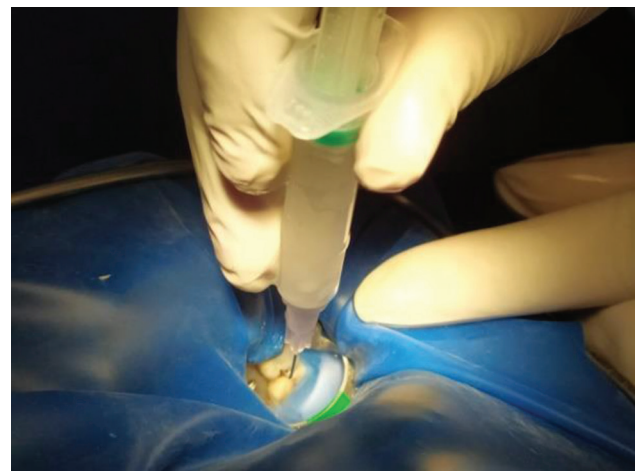
Each patient was explained about the study and asked to sign, an informed consent form. Root canal procedure was initiated, after administration of local anesthesia, rubber dam isolation was obtained, and access cavity was prepared. Initial canal working length was established, with Propex Pixi Apex Locator and was later confirmed, radiographically. Canal instrumentation was performed with ProTaper Gold, according to manufacturer's instructions, using ethylenediaminetetraacetic acid as a canal lubricant and 2% NaOCl solution.

In the experimental group, following completion of biomechanical preparation, root canal was finally irrigated with 10 mL cold saline, at a temperature of 1°C–2°C for 2 min. This temperature was achieved, by placing the solution in

refrigerator and maintained until use [Figure 1]. In the control group, final irrigation was carried out with 10 mL physiological saline at room temperature, for 2 min. After the final irrigation, the closed dressing was given.

Each patient was asked to fill a questionnaire, before starting the procedure and at 6, 24, 48, and 72 h, after the procedure. Pre-operative pain and POP were assessed on the basis of the questionnaire filled by each patient. Pain was estimated on the basis of the Heft-Parker pain scale. The questionnaire contained questions, pertaining to incidence and intensity of pain, based on the Heft-Parker pain scale [Figure 2]. In case of any flare-up, patients, who were recalled for assessment, kept on medications, and were later, were excluded from the study. In patients, who reported to be completely asymptomatic, after 72 h, obturation was performed [Table 2].

**Statistics:** Data was collected from the filled questionnaire and analyzed by SPSS version ' .0' for windows. he obtained data was subjected to statistical analysis, using Descriptive Statistics like Mean, Standard Deviation, Confidence Interval and Analysis of Variance (ANOVA) to determine statistical difference among the groups and ukey's test was be used to calculate p-value between two groups.



**Figure 1:** Final irrigation with cold saline solution

**Table 1: Selection criteria**

Inclusion criteria	Exclusion criteria
18-30 years	Patient younger than 18 years or older than 30 years
Single-rooted mandibular premolar with single canal	Teeth with multiple canals
Teeth with mature roots and free of defects	Previously endodontically treated or initiated teeth
Healthy patient	Root resorption
No history of medical complication	Open apex
Premolars diagnosed with symptomatic irreversible pulpitis with normal periradicular tissue	Periapical pathosis
Disrupted lamina dura	Pulp necrosis
Widened periodontal ligamental space	Asymptomatic irreversible pulpitis
No history of taking analgesic or antibiotic in the past 3 months	Fractured teeth
	Medically compromised patients
	Patient who used analgesic or anti-inflammatory before treatment for the involved teeth

## RESULTS

Of the enrolled 64 patients, 17 took analgesic and were considered a failure, while 6 dropped out. Thus, only 41 patients completely filled the questionnaire, so as to keep the evaluation and statistical parameters, similar in both the groups. One patient from the control group was not considered. Data of these 41 patients were collected, recorded, and statistically evaluated.

The incidence of POP was found, to be higher in the control group, ranging from 90% to 60%, while in the experimental group, it ranged from 55% to 20% at different time interval [Figure 3]. The overall pain incidence was found to decrease with time, in both groups.

The mean POP intensity was found to be significantly higher in the control group compared to the experimental group, across all time intervals [Table 3]. In the control group, overall mean POP intensity reduced significantly from 92.37 to 12.6; however, at 24-h interval, it was found to be progressively higher (20.15), but later, it decreased over time [Figure 4]. In the experimental group, mean POP intensity reduced significantly over different time intervals, from 94.16 to 4.18.

## DISCUSSION

Endodontic treatment provides an environment in the periradicular region; conducive for healing but the process itself may precipitate pain. To prevent this pain, various strategies have been suggested.<sup>[14,15]</sup> Among these, cryotherapy is relative newer and untested.<sup>[16]</sup> Hence, this randomized clinical trial was conducted to determine, whether cryotherapy application can reduce the POP in patients undergoing root canal treatment in symptomatic irreversible pulpitis with normal periradicular tissue. The application of cryotherapy is a long-standing therapeutic technique that has been frequently applied, in sports injuries and surgical procedures, for pain management and postoperative care.<sup>[17]</sup>

In the present study, the reported incidence and intensity of POP were significantly lower in patients treated with cryotherapy than those with saline at room temperature. Moreover, none of the patients reported severe symptoms or complications such as swelling or paresthesia. Keskin *et al.* in a study on teeth with vital pulps, in single-visit root canal treatment, reported significantly less POP with cryotherapy, using saline at 2.5°C compared with saline solution at room temperature.<sup>[16]</sup> Vera *et al.* in their study, on patients with necrotic pulp and symptomatic apical periodontitis, using 2.5°C cold saline solution for 5 min, found that postendodontic pain can be minimized by intracanal cryotherapy.<sup>[17]</sup> Similarly, AlNahlawi *et al.* using cryotherapy in their study found that cold normal saline was more effective, in reducing postendodontic pain than normal saline at room temperature when used as the last irrigation solution.<sup>[11]</sup>

Contrary to our findings, Sipaviciute and Maneliene reported 47%–60% of patients with asymptomatic necrotic pulp tissue, experiencing postendodontic pain, with cryotherapy. They concluded that the pulp status effect on postendodontic pain is controversial.<sup>[18]</sup>

Figure 2: Questionnaire (Heft-Parker pain scale)

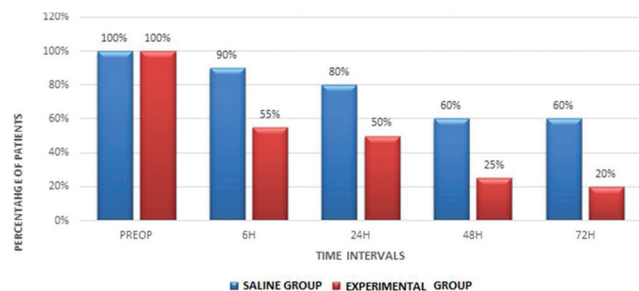


Figure 3: Incidence rate of post-operative pain (POP) at different time intervals

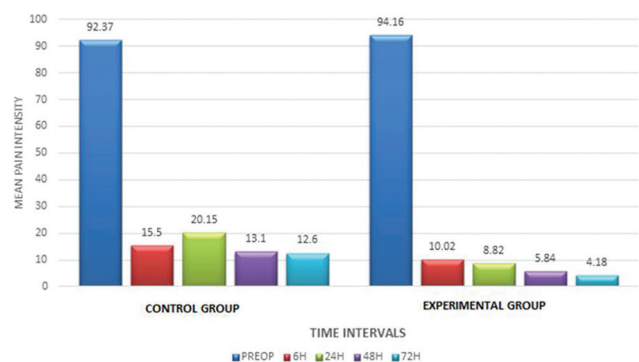
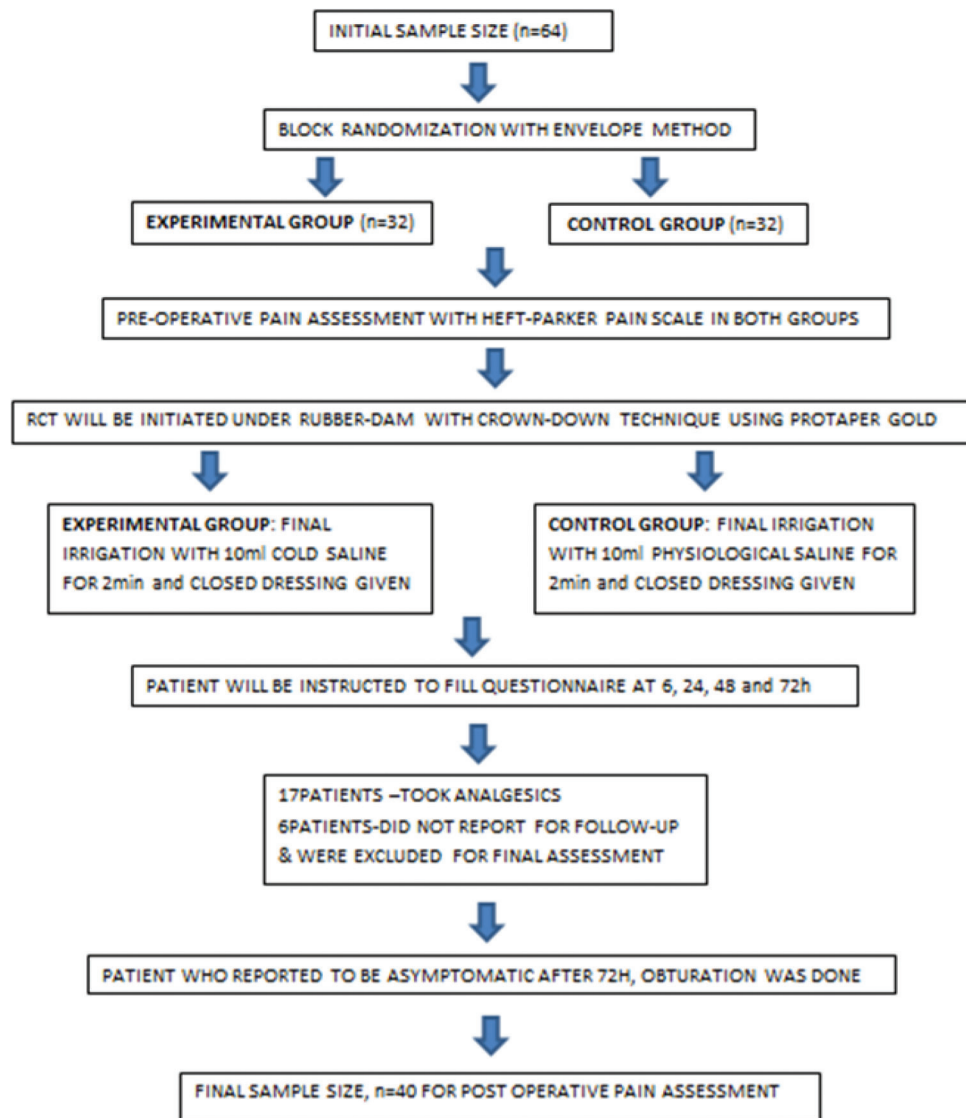


Figure 4: Mean post-operative pain intensity at different time intervals

Cryotherapy is a long-standing technique, which activates thermoreceptors (temperature-sensitive nerve endings) by blocking nociception.<sup>[10]</sup> Numerous studies have provided clinical evidence, suggesting that cold therapy can reduce

**Table 2: Flow-chart showing stages of the Randomized Control Trial****Table 3: Mean post-operative pain**

Time-intervals	Mean±SD		P
	Control group	Experimental group	
Preoperative pain	92.37±2.16	94.19±1.44	0.0014
6 h	15.5±2.32	10.02±0.94	0.0012
24 h	20.15±2.06	8.82±1.01	0.0050
48 h	13.1±2.29	5.84±1.15	0.0031
72 h	12.6±2.43	4.18±1.23	0.0004
T statistic	1697.002	429.563	
95% CI	42.2642-44.4358	28.4201-29.2999	
Significance level, P	<0.0005	<0.0005	

SD: Standard deviation, CI: Confidence interval

musculoskeletal pain, muscular spasm, connective tissue distension, nerve conductivity time, hemorrhage, and inflammation, through blockade of the nerve endings, resulting

from cold application.<sup>[19,20]</sup> Cryotherapy, limits biochemical reactions by causing vasoconstriction, as suggested by Van't Hoff's law and slows down cellular metabolism, which minimizes, the degree of tissue damage and limits the production of free radicals, in tissues.<sup>[22]</sup>

In respect to the dental pulp, it has been reported that there is complete deactivation of myelinated A-δ fibers and deactivation of nonmyelinated C-fiber occurs at about 3°C, as lowering the body temperature decreases peripheral nerve conduction.<sup>[22,23]</sup>

In endodontics, the application of cryotherapy is frequently utilized for POP control. Cryotherapy works by decrease in localized temperature, leading to reduced cellular metabolism, which impacts the peripheral nerve endings, by diminishing the threshold needed, to activate the tissue nociceptors and the speed of painful nerve impulses.<sup>[24]</sup> The use of cold saline irrigation reduces the external root surface temperature



by  $>10^{\circ}\text{C}$  irrigation, which is maintained for 4 min.<sup>[13]</sup> This drop in temperature, is adequate, to produce a local anti-inflammatory effect, in the periradicular tissues. Thus, the application of cryotherapy is a simple, cost-effective, and nontoxic option for POP control, as indicated by the results of our study. The null hypothesis for this study that there would be no difference in pain experienced after biomechanical preparation, with or without cryotherapy, stands rejected.

## CONCLUSION

The use of the cold saline solution as final irrigant, during endodontic treatment of teeth with symptomatic irreversible pulpitis and normal periradicular tissue, helps in reducing the incidence and intensity of postendodontic pain.

## Financial support and sponsorship

Study was self-funded.

## Conflicts of interest

There are no conflicts of interest.

## Ethical clearance

Ethical clearance was given by Ethic Society of Teerthanker Mahaveer University.

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