Comparative evaluation of the effectiveness of intracanal and intraoral cryotherapy on postendodontic pain in patients with symptomatic apical periodontitis: A randomized clinical trial

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Abstract

Introduction: There is a rising need for controlling postendodontic pain (PEP) without using analgesics and other conventional methods.

Aims: The aim of the study is to compare the effectiveness of various cryotherapy applications on controlling PEP in patients with symptomatic apical periodontitis.

Methods: One hundred and eight patients were selected and preoperative pain and pain on percussion scores were recorded using Numeric Rating Scale (NRS) and Visual Analog Scale (VAS), respectively. After obtaining consent, the access cavity was prepared under local anesthesia. After cleaning and shaping, the patients were randomized into the following groups: Group A: Canals were given final irrigation with 20 mL room temperature saline solution for 5 min, Group B: Canals were given final irrigation with 20 mL room temperature saline solution for 5 min, Group B: Canals were given final irrigation with 20 mL cold ($2^{\circ}C-4^{\circ}C$) saline solution for 5 min, and Group C: After obturation and restoration procedures, small ice packs of size 2 cm \times 2 cm \times 2.5 cm (wrapped in sterile gauze) were placed intraorally on the vestibular surface of the treated tooth. At 6 h, postoperative pain was measured using NRS and at 24 h, pain and pain on percussion were measured using NRS and VAS, respectively.

Results: Data were analyzed using SPSS software. There was a significant reduction in postoperative pain in the intracanal and intraoral groups at 6 and 24 h when compared with the control group individually. There was no significant difference in postendodontic between intracanal and intraoral cryotherapy groups at 6 and 24 h.

Conclusions: Both intracanal and intraoral cryotherapy applications are effective in reducing PEP in patients with symptomatic apical periodontitis.

Keywords: Intracanal cryotherapy; intraoral cryotherapy; Numeric Rating Scale; postendodontic pain; symptomatic apical periodontitis; Visual Analog Scale

INTRODUCTION

Pain is one of the main reasons why patients seek dental treatment. Postendodontic pain (PEP) is described as the

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sensation of discomfort experienced following endodontic intervention and is reported by 25%–40% of patients, regardless of pulp and periradicular status.^[1,2]

Several studies have researched the management of postoperative pain, including pharmacologic management using analgesics, steroids, the use of intracanal

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medications, and occlusal reduction. However, each one of these strategies has its limitations. Postoperative pain can be predicted, especially in teeth with preoperative pain, pulp necrosis, and symptomatic apical periodontitis. Pulp irritants initiate cellular, humoral, and neurovascular responses in the pulp tissue and lead to the development of irreversible pulpitis or pulp necrosis. If it extends to the periapical tissues, it may lead to the development of symptomatic apical periodontitis. In cases with symptomatic apical periodontitis, inflammation, usually in the apical periodontium, produces clinical symptoms ranging from mild discomfort to an exquisitely painful response to biting and/or percussion.^[3]

Cryotherapy is a technique that has frequently been applied in the medical field as well as oral surgery for managing pain postoperatively. The present study was conducted to assess and compare the effectiveness of intracanal and intraoral cryotherapy on PEP in patients with symptomatic apical periodontitis.

METHODS

This randomized clinical trial was conducted after obtaining approval from Institutional Ethics Committee (register no: ECR/673/Inst/KL/2014/RR-20). The study was registered with the Clinical Trials Registry–India (ICMR-NIMS) with CTRI Reg No – CTRI/2021/04/033256.

Inclusion criteria

One hundred and eight healthy patients in the age group of 18–55 years with single-rooted teeth diagnosed with symptomatic irreversible pulpitis or necrotic pulp with symptomatic apical periodontitis having preoperative pain score ranging from moderate to severe (6–10) and Numeric Rating Scale (NRS) (0–10).

Exclusion criteria

Patients with severe periodontal diseases, teeth with incomplete apex formation, excessively curved roots and calcified canals, acute exacerbation of chronic periapical lesion, periapical abscess and sinus, patients on analgesics or on antibiotic therapy for the past 7 days, pregnant patients and lactating mothers, and patients for whom cryotherapy is contraindicated such as those with Raynaud's disease, Hemoglobinuria, and cold hypersensitivity were excluded from the study.^[4]

Randomization

Computer-generated block randomization was done with a block size of six using the Sealed Envelope website (www. sealedenvelope.com). Allocation concealment was done using a sequentially numbered, opaque, sealed envelope method. Single blinding was done as the evaluator was unaware of the type of intervention being used. Preoperative data for each patient were recorded in the patient's chart, which included demographic data, diagnosis, and tooth number before the treatment. The study design and treatment protocol were explained to the qualifying patients, and informed consent was obtained.

Treatment protocol

Preoperative pain and preoperative pain on percussion were assessed using NRS and Visual Analog Scale (VAS), respectively. After providing local anesthesia, access cavity preparation was done under rubber dam isolation using Endo Access Bur. Working length was determined with stainless steel hand K-files size #10 (Mani, Japan) and the use of an apex locator (Root ZX Mini, J. Morita, Japan). It was confirmed using intraoral periapical radiographs. All the canals were prepared using ProTaper Universal rotary files (Dentsply Maillefer, Switzerland) following the full sequence recommended by the manufacturer using an endomotor (CanalPro CL2i, Coltene, Switzerland). The canal was irrigated with 2 ml of 5.25% sodium hypochlorite and 2 ml of 17% ethylenediaminetetraacetic acid (EDTA) solution in between instrumentation. Apical patency was maintained throughout the shaping procedure using #10 file between each instrumentation.

After cleaning and shaping, depending on the group to which the patient belongs to the following protocol was followed.

Group A: (Control) After completion of the sodium hypochlorite and EDTA irrigation, the root canals were given final irrigation with 20 mL room temperature saline solution for 5 min using a side-vented needle.

Group B: (Intracanal) Four 5-ml syringes filled with saline were placed in an ice carrier. A digital thermometer was placed on the syringe to monitor the temperature $(2^{\circ}C-4^{\circ}C)$ of the saline in the syringes. The root canals were given final irrigation with 20 mL cold $(2^{\circ}C-4^{\circ}C)$ saline solution for 5 min.

Group C: (Intraoral) The root canals in this group were given final irrigation with 20 mL of room temperature saline solution for 5 min.

In all three groups, canal was dried using paper points of appropriate size after final irrigation and obturation was done using the cold lateral condensation technique and universal composite restoration (Tetric Prime, Ivoclar) was given. High occlusal contacts were checked and reduced.

In the intraoral group, small ice packs of size $2 \text{ cm} \times 2 \text{ cm} \times 2.5 \text{ cm}$ (wrapped in sterile gauze) were placed intraorally on the vestibular surface of the treated tooth. Participants were instructed to keep the ice pack in their mouth for 15 min and to remove the intraoral ice pack

intermittently if they felt extremely cold or had a burning sensation and time was recorded [Figure 1].

An intraoral periapical radiograph using the bisecting angle technique was taken to assess the obturation quality in all three groups. Cases with an extruded sealer or overfilling were excluded from the study.

The evaluator assessed the postoperative pain using the NRS scale at 6 h through telephone and the participant was reviewed at 24 h to assess the postoperative pain and pain on percussion using VAS and NRS, respectively. The quality of the postendodontic restoration was assessed for any marginal breakage or dislodgment.

Statistical analysis was performed with SPSS, IBM, (New York, USA). The values of study variables were analyzed using mean, standard deviation, and other descriptive statistics. Preoperative and postoperative values were analyzed using paired sample *t*-test. Values of variables for three groups were compared using one-way analysis of variance and pairwise comparison was made by Tukey's *post hoc* test. Variables were considered to be significant if P < 0.05.

RESULTS

- A total of one hundred and eight patients took part in the study. The recall rate was 100% at 24 h. Mean and standard deviation were calculated [Table 1]
- There was a significant reduction in PEP in all the three groups at 6 and 24 h (P < 0.05)
- There was a considerable reduction in pain in the intracanal group at 6 and 24 h when compared with control group (P < 0.05) [Table 2]
- There was a considerable reduction in pain in the intraoral group at 6 and 24 h when compared with control group (P < 0.05) [Table 2]
- There was no significant difference between



Figure 1: Intraoral cryotherapy application

the intracanal and intraoral groups at 6 and 24 h (P > 0.05) [Table 2]

 When teeth in maxillary and mandibular arches were assessed in the intraoral cryotherapy group, it was found that although there was no significant difference in postoperative pain, the mean pain score was higher in the mandibular arch than maxillary arch (*P* > 0.05) [Graph 1].

Table 1: Mean and standard deviation of the studied
groups at various time periods

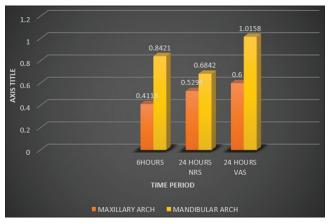
Studied period	Group	n	Mean	SD
Pain after 6 h (NRS)	Normal saline	36	2.27	1.00
	Intracanal cryotherapy	36	0.69	0.62
	Intraoral cryotherapy	36	0.64	0.96
Pain after 24 h (NRS)	Normal saline	36	1.27	0.91
	Intracanal cryotherapy	36	0.22	0.42
	Intraoral cryotherapy	36	0.61	0.73
Pain on percussion after	Normal saline	36	1.97	1.12
24 h (VAS)	Intracanal cryotherapy	36	0.63	0.85
	Intraoral cryotherapy	36	0.77	0.91

VAS: Visual Analog Scale, NRS: Numeric Rating Scale, SD: Standard deviation

Table 2: Tukey's *post hoc* test - results to know if there were significant pairwise differences on pain after 6 h and 24 h between studied groups

Studied period	Studied group	Studied group	Р	Significant difference
Pain after	Normal saline	Intracanal cryotherapy	0.00	Yes
6 h (NRS)	Normal saline	Intraoral cryotherapy	0.00	Yes
	Intracanal cryotherapy	Intraoral cryotherapy	0.96	No
Pain after	Normal saline	Intracanal cryotherapy	0.00	Yes
24 h (NRS)	Normal saline	Intraoral cryotherapy	0.00	Yes
	Intracanal cryotherapy	Intraoral cryotherapy	0.60	No
Pain on	Normal saline	Intracanal cryotherapy	0.00	Yes
percussion	Normal saline	Intraoral cryotherapy	0.00	Yes
after 24 h (VAS)	Intracanal cryotherapy	Intraoral cryotherapy	0.81	No

VAS: Visual Analog Scale, NRS: Numeric Rating Scale



Graph 1: Comparison of postendodontic pain between maxillary and mandibular arches in the intraoral cryotherapy group. NRS: Numeric Rating Scale, VAS: Visual Analog Scale

DISCUSSION

The purpose of this study was to examine the effects of intracanal and intraoral cryotherapy applications on postoperative pain in single-rooted teeth with symptomatic apical periodontitis.

In the present study, care was taken to avoid all possible preoperative factors and to minimize any unavoidable causes of postoperative discomfort. Teeth with vital or necrotic pulp with symptomatic apical periodontitis were included, whereas those with periapical abscess, cysts, and acute exacerbation of chronic periapical lesion were not considered.^[5]

The strong evidence of a correlation between preoperative and postoperative pain demonstrates that patients experiencing preoperative pain tend to have a higher intensity of postoperative pain when compared with patients who had no preoperative symptoms.^[6] Thus, patients with moderate-to-severe pain in the NRS scale were selected.

In the present study, there was no significant difference in gender, age distribution, and baseline preoperative pain score between the three groups; therefore, the effects of these variables were considered to be minimal.

Both VAS and NRS were used to assess pain since postoperative pain intensity can be more precisely measured when more than one scale is used – comparing the relationship between each intensity scale and a derived composite represents the "best possible" assessment of a self-reported construct.^[7]

Postoperative pain is commonly caused by acute periradicular inflammation, which can be triggered by any type of insult to the root canal system. The severity of the inflammation is directly proportional to the intensity of the injury. Injury to periradicular tissues results in the release or activation of various chemical substances that mediate the events of inflammation. These include histamine, arachidonic acid metabolites, cytokines, neuropeptides, lysosomal enzymes, nitric oxide, oxygen-derived free radicals, and plasma-derived factors. Vasodilation, an increase in vascular permeability, and chemotaxis to inflammatory cells are among the inflammatory events mediated by these substances. Periradicular lesions contain most of these mediators.^[8] Although some mediators can cause pain by direct effects on sensory nerve fibers, the major inflammatory event responsible for periradicular pain is the increase in vascular permeability and the consequent edema, which leads to the compression of nerve fibers.

According to an *in vitro* study done by Vera *et al.*,^[9] the intracanal delivery of cold (2.5°C) saline solution reduced

the external root surface temperature more than 10°C and maintained it long enough to possibly produce a local anti-inflammatory effect in the periradicular tissues.

Significant reduction in the PEP in the intracanal group when compared with the control group at 6 and 24 h could be attributed to the synergistic effect of the cold-treated irrigant, reducing the external root surface temperature, thereby producing an anti-inflammatory effect in the periradicular tissues of the treated tooth. This is by studies done maintaining the temperature of cold saline at 2°C–4°C as the final irrigant by various authors.^[3,10-12]

A study done by Gundogdu and Arslan^[13] has only assessed the effectiveness of intraoral cryotherapy application for 30 min on PEP. In the present study, small ice packs wrapped in sterile gauze were placed for 15 min intraorally in the vestibular region of the obturated tooth.

The application of cold initially causes vasoconstriction of blood vessels, which can reduce hemorrhage and fluid perfusion, leading to decreased edema after an injury. Despite the continued use of cold, vasodilation may occur as a result of reactive hyperemia. This phenomenon is known as the "hunting response" and is believed to represent the flow of blood through arteriovenous anastomoses, which may be a compensatory mechanism to prevent injury from extremely cold temperatures. The hunting response occurs after 20–30 min of exposure to cold, and it has been suggested that ice should not be applied for that long because it could induce the hunting response, which may cause increased edema.^[14]

The same principles could be attributed to the reduction in the temperature of the alveolar bone surrounding the apical portion of the treated tooth resulting in reduction of PEP in the intraoral group. Another aspect of intraoral cryotherapy concerns its psychological effect. Providing a task for patients after surgery may distract them from focusing on their discomfort. Furthermore, it may be constructive if patients perceive their actions as contributing to pain reduction. Therefore, ice application after root canal treatment may provide a psychological as well as a physiological benefit for some patients.^[15]

In the present study, when teeth in the maxillary and mandibular arches were assessed in the intraoral cryotherapy group, it was found that although there was no significant difference in postoperative pain, mean pain score was higher in the mandibular arch than the maxillary arch. This might be because the mandible has a dense trabeculae pattern, and thus, there is reduced blood flow and more localization of infection and inflammation, which might lead to delayed healing.^[16] Therefore, the thickness of the buccal cortical bone could influence the transmission of cold in the intraoral group.^[17]

A major limitation of the study is the different pain thresholds of the patients. Anxiety and rubber dam placement may accentuate postoperative pain in some patients.^[18]

CONCLUSIONS

Within the limitations of the study, the following conclusions can be drawn:

- 1. Intracanal and intraoral cryotherapy are effective methods in managing PEP for the first 24 h after root canal treatment
- 2. Intracanal cryotherapy is a convenient method as it can be easily incorporated into routine root canal treatment workflow
- 3. There is a need for arriving at a protocol that best serves both maxillary and mandibular teeth while using intraoral cryotherapy.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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