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## Original Research Article Effect of cold saline irrigation on postoperative pain – A randomized control trial

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#### A B S T R A C T

**Introduction:** A randomized control trial was conducted, to assess the effect of cold saline irrigation on post-operative pain in patients presenting with pain due to pulpal and periapical diseases.

**Materials and Methods:** A total of 30 patients with pulpal necrosis and symptomatic apical periodontitis presenting in teeth, (whose preoperative visual analog scale (vas) was higher than 3, Out of 5), were chosen for the randomized trial. The patients were randomly allocated into control and experimental groups, after completion of cleaning and shaping. The experimental group received 20ml cold saline  $(2.5^{\circ}c)$  irrigation delivered to the working length, with a sterile cold needle for 5 mins. The same protocol was used in the control group with normal saline solution at room temperature. The patients were then instructed to record the presence, duration and level of postoperative pain at 6 hours and 24 hours, and analgesic intake. Chi-square test was used to compare, the incidence of postoperative pain. Comparison of number of analgesics between two groups, duration of pain and differences in post-operative pain intensity (at 6 and 24 hours) was analyzed using Mann-Whitney test.

**Result :** There was no statistical difference between the two groups.

**Conclusion:** There is no significant difference between the experimental and the control group. Further studies are required with a larger sample size to get statistically significant results.

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#### 1. Introduction

CRYOTHERAPY is derived from Greek word: "cryos" = COLD .In reality, cryotherapy does not imply implementing cold but rather withdrawing heat. The management of postoperative pain is of utmost importance in an endodontic practice. Hargreaves and Hutter told that this condition can be foretold in teeth with preoperative pain, pulp necrosis, and symptomatic apical periodontitis.<sup>1</sup>

Irritants can cause a cellular, humoral, and neurovascular tissue response in pulp . A biphasic response in the pulp (vasodilation, increased blood flow, intravascular fluid extravasation) causes increased pulpal pressure, and reduced blood flow leading to the development of irreversible pulpitis or pulp necrosis. If this condition proceeds to the periradicular tissues, it can cause a painful condition such as Symptomatic apical periodontitis. Symptoms associated with symptomatic irreversible pulpitis, pulp necrosis , and symptomatic apical periodontitis can be attributed to different factors including changes in periapical pressure, microbial factors, chemical mediators of pain, and psychological factors, which ultimately causes the patients to visit the dentist in utmost hurry <sup>1</sup>

One way to reverse the inflammatory process and control pain is with drugs such as Nonsteroidal anti-inflammatory drugs, corticosteroids etc.<sup>1</sup>

However, despite being comparatively safe drugs, side effects such as gastrointestinal intolerance and renal, hepatic, and respiratory disorders such as asthma have been reported with these drugs. Cold saline plays a vital role in reducing postoperative pain and inflammation, by Vasoconstriction. The first physiologic tissue response to cryotherapy is a drop in local temperature, leading to reduced cellular metabolism, which in turn causes cells

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to use less oxygen and reduces blood flow as induced by vasoconstriction, leading to limitation of the damage.<sup>1</sup> In addition, it affects peripheral nerve endings by diminishing the threshold needed to activate the tissue nociceptors and decreases the speed of painful nerve impulses.<sup>1</sup>

Cold saline is found to reduce pain and dependence on Non-steroidal anti-inflammatory drugs, from studies conducted earlier in this field of cryotherapy. This field still remains unexplored and could be a boon to Endodontic field to reduce dependence on Non-steroidal anti-inflammatory drugs, and also manage postoperative pain which is of prime importance in maintaining a patient rapport and assuring a boon to clinical endodontic practice.

With a very few studies conducted earlier, a lot of research needs to be done in this field to establish the importance and effectiveness of cryotherapy in reducing postoperative pain in clinical endodontic practice.

#### 2. Materials and methods

An in-vivo study was performed which included thirty (30) patients diagnosed with symptomatic apical periodontitis and pulp necrosis. The study was conducted in the Deptartment of Conservative Dentistry and Endodontics, Maratha Mandal's Nathagirao G. Halgekar Institute of Dental Science And Research Centre, Belagavi. Materials used for the study were Endofrost [Figure 1 a] Access opening burs [Figure 1b] and air rotor handpiece. K files and protaper hand files(Sx to F2)[Figure 1c], dentsply endomotor[Figure 1d],Sodium hypochlorite 5.2%[Figure 1e], Edta 17 %[Figure 1f], Cold saline (2.5 degree Celsius)[Figure 1g], Gutta percha [Figure 1h].

Patients fulfilling the following criteria were included in the study :

Patient having symptomatic apical periodontitis, differentiated from periapical abscess (breach in lamina dura) was strictly adhered to and Patient having pupal necrosis patient having pain vas score of 3-5.

The exclusion criteria was patients with systemic conditions such as Raynauds disease, Cold allergy and Hemoglobinuria, periapical abscess, pregnancy and difficult root structure among those that were excluded from the study.

# 2.1. Clinical examination was carried out based on 4 parameters

History of the patient, visual analog scale, percussion test and cold test, intra and extra oral examination were the prerequisites required. In the first appointment, the patient was asked to fill a questionnaire regarding the level of preoperative pain experienced by the patient [Figure 2]. Local anesthesia ([1:200000] lidocaine with epinephrine) was administered to the patient, Access opening was done using access opening burs followed by extirpation of pulpal



**Fig. 1:** Endofrost, B)Endoaccess bur,C)Protaper rotary files,D)Dentsply endomotor,E)Sodium hypochlorite,F)Edta,G) Cold saline at 2.5 degree celsius,H) Guttapercha cones.i) Access opening and biomechanical prepration under rubberdam



Fig. 2: VAS Scale rating for preoperative pain and pain during procedure.

tissue and cleaning and shaping was done using protaper rotary system. [Fig 1 i] During cleaning and shaping, irrigation was done using common irrigants namely Sodium hypochorite and Edta 17%. After the completion of cleaning and shaping, the final irrigation was done by 20 ml of 2.5 degree celsius cold saline for 5 minutes for the experimental group and Similar irrigation protocol was followed for control group but saline at room temperature was used for irrigation. Temporary restoration was placed and the cavity was sealed. The patient was asked to fill a form to rate pain experienced during the procedure [Figure 2]. The patient was handed a second questionnaire which also contained 2 VAS scale for pain experienced at 6 hours and 24 hours. It also contained questions regarding the duration of pain, Number of analgesic intake. [Figure 3] Patient was asked to take analgesics only on SOS basis. Patient was asked to



Fig. 3: Questionnaire handed over to the patient

submit this questionnaire at 2 nd appointment. Obturation was performed at the second appointment.

#### 2.2. Experimental groups

Group A (n=15): Patient who received final irrigation with saline at room temperature.

Group B (n=15): Patient who received final irrigation with saline at 2.5 degree Celsius.

#### 2.3. Statistical analysis

Chi-square test was used to compare, the incidence of postoperative pain.

Mann-Whitney test used for Comparison of number of analgesics between two groups and differences in postoperative pain intensity (at 6 and 24 hours)

#### 3. Results

There is no statistical difference between both the groups.

There was no statistical difference between both the groups. However Table 2 shows that there were more number of cases that experienced only mild pain in cryotherapy (11 patients) group compared to that of normal saline group (8 patients), and only 4 patients experienced moderate pain in cryotherapy group whereas 6 patients experienced moderate pain in normal saline group and 1 patient experienced intense pain in normal saline group which is suggestive of reduced pain scores in the cryotherapy group.

#### 4. Discussion

This prospective, randomized clinical trial was conducted to determine whether an innovative approach can reduce the

#### postoperative pain.

The benefits of cryotherapy have been reported in the medical literature. Physiologic and clinical evidence implies that applying cold through various techniques may decrease the conduction velocity of nerve signals, hemorrhage, edema, and local inflammation and is therefore effective in the reducing musculoskeletal pain, muscular spasm, and connective tissue distension.<sup>1</sup>

Cryotherapy causes vasoconstriction with an antiedema effect.<sup>2</sup> It reduces number of leukocytes migrating to the affected tissues thus reducing endothelial dysfunction and the inflammatory response. It also diminishes the speed of painful nerve impulses.<sup>1</sup>

Key receptors to environmental cold include the TRP subfamily ionic channel M, member 8, and TRP cationic channel subfamily A, member 1, plays a role in Inducing hyperalgesia. Cold saline Irrigation induces a local anesthetic effect by lowering the activation threshold of these tissue nociceptors and the conduction velocity of pain signals.

A Study by Ernst and Fialka showed that the nerve conduction of C fibres was not decreased by application of moderate cold. Cryotherapy also triggers thermal receptors, which reduce the transmission of painful stimuli. This influence has been referred to as the 'counterirritant effect' in the older literature and it results in cold-induced neuropraxia. The decreased temperature of the external root surface might limit inflammatory reactions, production of the release of pain-producing substances, and oedema occurring in the periapical region. Cryotherapy has been shown to decelerate peripheral nerve conduction. As the temperature decreases, the conduction velocity of nerve fibres decreases until it stops completely.<sup>3</sup>

The use of cooled saline also decreases the outer root surface temperature by a little more than 10 degree C when maintained for a period of 4 minutes. Theoretically speaking this drop in temperature is sufficient to create a local anti-inflammatory effect in the underlying tissues.<sup>1</sup>

A favorable dosage for cryotherapy has not been fixed, it is variable and differs from one to tissue to another. When minimum amount of fat and muscle are present for e.g. a finger, recommended time of cryotherapy is 3 to 5 minutes . This time is minimal compared to that of more deeply affected tissue like the hip for which the recommended time is approximately 20 minutes. The transmission of Cold to the periodontal ligament may also be different in apical and coronal portions of the radicular dentin because of differences in properties (width and mineralization) at both levels. Cervical dentin tends to have more dentinal tubules, which are also larger, both making it more difficult to transmit therapeutic effects to the adjacent tissues, apical dentin on the other side is more mineralized and denser with fewer tubules that would facilitate more efficient and effective cold transmission

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Group		Incidence	POP 6 HRS	POP 24 HRS	Analgesic
Cryotherapy	Mean	1.2667	1.0000	0.5333	0.6667
	Std. Deviation	0.45774	1.36277	0.83381	0.81650
Normal Saline	Mean	1.5333	1.2000	0.8000	1.1333
	Std. Deviation	0.63994	1.42428	1.20712	1.18723
Comparision with mann whitney test		0.325	0.624	0.624	0.345
		NS	NS	NS	NS

<b>Table 1:</b> POP: postoperative pain. NS: not sign	nificant
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**Table 2:** Showing number of cases experiencing mild, moderate and severe pain.

	Cryo therapy	Normal saline	Total
Mild	11	8	19
Moderate	4	6	10
Intense	0	1	1
	15	15	30
P value 0.325(NS)			

The extent of the temperature change and the biophysical changes in the tissues is dependent on the difference between the object's temperature and the method of application of cold or heat, duration of exposure time, and tissues thermal conductivity, and type of agent used to apply the heat or cold. The use of this type of therapy in human tissues causes changes in the host's local temperature.<sup>2</sup>

Two earlier studies by Keskin C et al. and Al Nahlawi et al. have used intracanal cryotherapy to evaluate its effect on postoperative pain. Both studies showed significant lower postoperative pain levels when cryotherapy was applied and compared with control groups.<sup>43</sup>

There are few contraindications for cryotherapy such as Patients diagnosed with systemic conditions such as Raynauds disease which affects small blood vessels in the vicinity, Cold allergy which can present alongside urticaria because histamine is released after reheating the zone, which leads to red dots in the skin and cold-induced erythema, resulting in post-therapy redness, itchiness, muscle contraction and relaxation, unbearable pain and Hemoglobinuria a disease of red blood cells, in which they disintegrate so hastily that hemoglobin is not able to combine with blood proteins. Most importantly, cold therapy is not suggested in cases of altered nerve sensitivity or on areas where larger nerves are close to the surface. Vasoconstriction raises blood pressure making it controversial in patients having certain systemic diseases or cardiac conditions like arrhythmia, angina pectoris, and hypertension. It Also has a drawback in difficult root curvature which restricts the irrigant.<sup>1</sup>

Managing post-operative pain after root canal treatment of utmost importance in endodontic practice. It is a feeling which is unpleasant and is expressed as discomfort experienced by patients, it is reported with a high incidence rate ranging between 3 and 58%.<sup>3</sup> It needs to be addressed by the Endodontist to reduce the incidence of postoperative pain.

In this study the results were not statistically significant even though cryotherapy group showed reduced pain scores, and reduced analgesic intake. However a larger sample size is required to prove the effectiveness of this novel technique of reducing postoperative pain.

#### 5. Conclusion

In dentistry, cold application has been frequently used following intraoral surgical procedures for postoperative pain control. The mechanism of action and effectiveness of cryotherapy are well-described however, strong evidence to support its conclusions is limited besides standardization of crucial factors such as the time period, duration, application mode and cold agent used.

Postoperative pain is the result of a complex multifactorial process that is influenced by factors inherent in patients, the tooth, and the operator, Prior studies have identified patient- and tooth-related factors that influence the incidence and duration of postoperative pain hence concluding within the limitations of the study that, though there is lesser incidence of post operative pain and reduced analgesic consumption for the cold saline group, Significant difference between the experimental and the control group is not there in this study conducted and future research in this field looks promising.

Further studies are required to be carried out with a larger sample size to get statistically significant results in this field.

#### 6. Source of funding

None.

#### 7. Conflict of Interest

None.

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