Effect of intracanal cryotreated sodium hypochlorite on postoperative pain after root canal treatment - A randomized controlled clinical trial

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Abstract

Introduction: The postendodontic pain is caused by either microbial, mechanical, or chemical factors or combinations of these. The incidence of postoperative pain ranges from 1.4% to 53%. The management of postendodontic pain is a crucial factor for a successful practitioner. Cryotherapy is a new therapeutic option applied in sports medicine and surgery for the management of pain and for postoperative care.

Aim: The purpose of this study was to evaluate and to compare the effect of intracanal cryotreated sodium hypochlorite and room temperature sodium hypochlorite on postoperative pain after root canal treatment.

Materials and Methods: Sixty-four patients were selected according to inclusion criteria and baseline score was recorded. After obtaining consent, the access cavity was opened under local anesthesia. On the completion of cleaning and shaping, the patients were randomly divided into two groups: Group A: Normal Room temperature NaOCl and Group B: Cryotreated NaOCl (2°C–4°C), each of the canals further received 20 ml of the respective irrigants based on the groups allocated. The final rinse was done with saline, and canals were dried and obturated in the same appointment. Postoperative visual analogue scale pain levels were recorded at 6, 24, and 48 h over the phone.

Results: The data were analyzed using SPSS software. The results of the present study showed that cryotherapy group showed a statistically significant reduction in postoperative pain levels at all tested time intervals and reduced analgesic intake at 6 h postoperatively.

Conclusion: Cryotherapy could be used as an easy and cost-effective technique for controlling postendodontic pain in the day-to-day clinical practice.

Keywords: Cryotherapy; intracanal cryotherapy postendodontic pain control; postoperative pain; visual analog scale

INTRODUCTION

The ultimate goal of endodontic treatment is to completely clean and shape the root canal system and to provide a hermetic seal with no discomfort to the patient, thereby providing optimum conditions for periradicular healing.[1] Even with utmost care while performing root canal treatment, postoperative pain and flare-ups are commonly encountered by the clinicians. The incidence of postoperative pain ranges from 1.4% to 53%.[2] The postendodontic pain is caused by either microbial, mechanical or chemical factors or combinations of these.[3] The outgrowth of microbes from the root canal system through the apical foramen into the periapical area is one of the primary...
causes of apical periodontitis. Violation of apical foramen by overzealous preparation can cause extrusion of irrigants and intracanal medicaments and obturating materials that cause chemical irritation and pain after entering the periradicular tissues. Therefore, postoperative pain is a synergistic effect of the above-stated causes and cannot be exclusively attributed to a single definite cause.

Management of postendodontic pain is a crucial factor for a successful practitioner. Several techniques have been tried to reduce the incidence of postoperative pain ranging from prescribing preprocedural analgesics, administering long-standing local anesthesia, optimal instrumentation, and appropriate use of irrigants and occlusal reduction, psychological management.

Cryotherapy is a new therapeutic option applied in sports medicine and general surgery for the management of pain and for postoperative care. According to Van’t Hoff’s law, application of cold to the tissues causes vasoconstriction, decreases cellular metabolism, and inhibits the neural receptors in the skin and subcutaneous tissues. In dentistry, cryotherapy is employed for postoperative pain control in intraoral surgical procedures. Recently Vera et al., (2015) in an in vitro study reported that cold saline solution (2.5°C) employed as a final irrigant for 5 min, reduced the external root surface temperature by 10°C, which may produce the local anti-inflammatory effect in periradicular tissues.

Therefore, the purpose of this study was to evaluate and to compare the effect of cryotreated sodium hypochlorite and room temperature sodium hypochlorite on postoperative pain after root canal treatment. Null hypothesis (H0) postulated no difference in postoperative pain after intracanal irrigation with cryotreated sodium hypochlorite and room temperature sodium hypochlorite. The alternate hypothesis (Ha) postulated there is a difference in postoperative pain after intracanal irrigation with cryotreated sodium hypochlorite and room temperature sodium hypochlorite.

MATERIALS AND METHODS

Study design
This was a prospective randomized controlled clinical trial; the sample size was calculated using Statistical Package for the Social Sciences (SPSS) 13.0 computer software, with a power of 85%, and was found to be 64. Computer generated block randomization was done with a block size of 4. Allocation concealment was done using sequentially numbered opaque sealed envelope method.

Inclusion criteria
1. The age group of 18–70 years who signed the informed consent
2. The patient requiring endodontic therapy
3. Molars that were diagnosed with symptomatic irreversible pulpitis/apical periodontitis
4. Healthy patients without systemic disease
5. Patients with pain score ranging from moderate to severe (3–10) on a visual analog scale (VAS) (0–10).

Exclusion criteria
1. Patient who are medically compromised
2. Pregnant patients
3. Teeth with incomplete apex formation
4. Teeth with calcified canals
5. Sinus opening
6. Periapical abscess
7. Patients on antibiotic therapy
8. Patients on analgesics.

Double blinding is done because the patient and the evaluator do not know the type of intervention being used.

After obtaining approval from the institutional review board, patients fulfilling the inclusion criteria were recruited for this study. Preoperative data for each patient was recorded in the predesigned patient’s chart, which includes age, sex, and tooth number before the treatment. The treatment and the study design were explained to the qualifying patients, and informed consent was obtained from the voluntary patients who were willing to participate in the study.

Treatment protocol
Vitality was assessed using cold tests and electric pulp testing before the procedure was carried out for the teeth. All the patients received local anesthesia. Each tooth was isolated using a rubber dam, and the access cavity was prepared using Endo access bur size 2 under copious water cooling. After removal of pulp tissues with a broach, working length was determined with stainless steel hand K-files size #10 (Mani, Tochigi, Japan) and the use of an apex locator (Propex Pixi, Dentsply). It was confirmed using intraoral periapical radiographs, and it was repeatedly checked throughout the procedure. Hand instrumentation was done until 20 size K-file. All the canals were prepared using with Protaper Gold rotary files (Dentsply Maillefer, Ballaigues, Switzerland) till the file F2 or F3 (20/0.06, 25/0.6) following the full sequence recommended by the manufacturer using an electric motor (X-Smart; Dentsply). Apical patency was maintained throughout the shaping procedure using #10 file between each instrument.

All the canals were irrigated with 10 mL of 3% NaOCl between each file during the whole preparation procedure that was delivered with RC twents (Prime Dental, Mumbai). After cleaning and shaping, all samples were divided into two groups:
• Group A: 20 ml of normal room temperature sodium hypochlorite was irrigated for 5 min in each canal
• Group B: 20 ml cryotreated sodium hypochlorite maintained at temperature 2°C–4°C was irrigated for 5 min in each canal.

The temperature of the cold hypochlorite was preserved for 5 min irrigation period by keeping the irrigation syringes, which were used one by one, in a special box filled with ice after removal from the refrigerator with thermocouple inserted inside to confirm the 2°C–4°C temperature range.

After the irrigation procedure, all the canals were flushed with a final rinse of saline and were dried using appropriate size paper points and obturated using cold lateral compaction technique, and permanent composite access cavity restoration was given.

All participants received a sheet containing VAS after the procedure. After 6, 24, and 48 h, patients were called by telephone and asked for their general feeling in the area of the root canal, pain intensity both numeric and verbal (using VAS), and the number of analgesic pills that had been taken by the patient at each follow-up period, and they were recorded on patient’s chart.

RESULTS

The data were tabulated and analyzed using SPSS software. Mann–Whitney U-test was done for intergroup comparison of the pain levels of both the groups [Table 1]. From Table 1, it can be observed that the pain values are seen to be highest at 6 h, which gradually decreases and is shown to be the least at 48 h. The results show that there was a statistically significant difference between normal and cryotreated NaOCl group at 6, 24, and 48 h [Graph 1], preoperative VAS values did not show a significant difference between the two groups. Wilcoxon Signed-Ranks Test was performed for pairwise comparison of the study intervals for both the groups. For both Group A [Table 2] and Group B [Table 3], the intragroup comparison showed a highly statistically significant difference for all the observed study pairs. Chi-square test was done to assess the rate of analgesic consumption in Group A and Group B at all tested intervals [Table 4]. At 6 and 24 h, there was significantly less number of analgesic consumption in the cryotreated NaOCl group [Graph 2].

DISCUSSION

The purpose of this randomized controlled clinical trial was to compare the difference in postoperative pain after using normal room temperature sodium hypochlorite irrigant and cryotreated sodium hypochlorite irrigant. H0 was rejected as there was a difference in postoperative pain values between room temperature sodium hypochlorite

| Study period | Group               | n  | Mean rank | Significance P |
|--------------|---------------------|----|-----------|----------------|
| Preoperative | Normal NaOCl        | 32 | 33.02     | 0.81           |
| VAS          | Cryotreated NaOCl   | 32 | 31.98     | 0.000          |
| VAS at 6 h   | Normal NaOCl        | 32 | 37.05     | 0.043          |
| VAS at 6 h   | Cryotreated NaOCl   | 32 | 27.95     | 0.049          |
| VAS at 48 h  | Normal NaOCl        | 32 | 36.19     | 0.043          |
| VAS at 48 h  | Cryotreated NaOCl   | 32 | 28.81     | 0.021          |

VAS: Visual analog scale

| Study group | Mean | SD  | P     |
|-------------|------|-----|-------|
| Pair 1      | 4.66 | 1.096 | 0.000 |
| VAS at 6 h  | 2.28 | 1.971 |       |
| Pair 2      | 4.66 | 1.096 | 0.000 |
| VAS at 24 h | 1.00 | 1.524 |       |
| Pair 3      | 4.66 | 1.096 | 0.000 |
| VAS at 48 h | 0.25 | 0.672 |       |
| Pair 4      | 2.28 | 1.971 | 0.000 |
| VAS at 48 h | 0.25 | 0.672 | 0.003 |

VAS: Visual analog scale, SD: Standard deviation

| Study group | Mean | SD  | P     |
|-------------|------|-----|-------|
| Pair 1      | 4.72 | 1.373 | 0.000 |
| Preoperative VAS |      |      |       |
| VAS at 6 h  | 1.38 | 1.212 |       |
| Pair 2      | 4.72 | 1.373 | 0.000 |
| Preoperative VAS |      |      |       |
| VAS at 24 h | 0.44 | 1.216 |       |
| Pair 3      | 4.72 | 1.373 | 0.000 |
| Preoperative VAS |      |      |       |
| VAS at 48 h | 0.00 | 0.000 |       |
| Pair 4      | 1.38 | 1.212 | 0.000 |
| VAS at 24 h | 0.44 | 1.216 |       |
| Pair 5      | 1.38 | 1.212 | 0.000 |
| VAS at 48 h | 0.00 | 0.000 |       |
| Pair 6      | 0.44 | 1.216 | 0.026 |
| VAS at 24 h | 0.00 | 0.000 |       |
| VAS at 48 h | 0.00 | 0.000 |       |

VAS: Visual analogue scale, SD: Standard deviation
In the present study, care was taken to avoid all possible preoperative factors and to minimize any unavoidable causes of postoperative discomfort. Teeth with necrotic pulp, with periapical pathology, retreatment cases were not considered due to the complex and extensive microbial load, which could serve as a possible cause for postoperative pain. To avoid using intracanal medicament and also since only vital tooth were included in this study, all the teeth were obturated in the same visit (single visit endodontic treatment).

A parallel-group design was followed, and no patients with two symptomatic teeth were included because the pain from one may influence the other. Preoperative pain is one of the potential risk factors for postoperative pain. Therefore, in our study, we limited to symptomatic teeth with moderate pain level (VAS score of 3–6) for two reasons: one was to standardize all the patients and second was to evaluate the effect of cryotherapy in an actual clinical scenario because most of the clinical situation demands for managing symptomatic teeth rather than asymptomatic teeth. Only patients without a noncontributing history who did not take analgesic medication recently were included so that no other pain source or drug interaction could interfere with the pain resulting from endodontic therapy.

Posterior teeth including molars and premolars were selected for this study, to evaluate the effect of cryotherapy in multi-rooted teeth, by following the same irrigation protocol in each canal, considering each canal as a separate root surface.

Factors such as age, sex, pulpal status, allergies, and preoperative pain play a significant role in postoperative pain. In our study, there was no significant difference in gender, age distribution, and baseline preoperative pain score between the two groups; therefore, the effects of these variables were considered to be minimized.

In this study, we administered 10 cm VAS scale ranging from 0 to 10 to measure the postoperative pain intensity. To reduce the possible opportunities of errors in recording the pain score during the follow-up period, we instructed and helped all the patients in recording baseline pain scores, which made them familiar in recording it.

| Postoperative Interval | Number of Analgesic tablet | Count | Percentage within group | P Value |
|------------------------|---------------------------|-------|-------------------------|---------|
|                        | Normal NaOCl | Cryotreated NaOCl | Normal NaOCl | Cryotreated NaOCl |       |
| At 6 hours             | Nil          | 17    | 26                      | 53.1    | 81.3% | 0.032 |
|                        | One          | 12    | 6                       | 37.5%   | 18.8% |       |
|                        | Two          | 3     | 0                       | 9.4%    | 0%    |       |
| At 24 hours            | One          | 27    | 31                      | 84.4%   | 96.9% | 0.086 |
|                        | Two          | 5     | 1                       | 15.6%   | 3.1%  |       |
| At 48 hours            | One          | 31    | 32                      | 96.9%   | 100%  | 0.313 |
|                        | Two          | 1     | 0                       | 3.1%    | 0%    |       |

**Table 4: Analgesic consumption using Chi-square test**

**Graph 1: Mean of visual analog scale scores**

**Graph 2: Percentage of analgesic consumption**
In a systematic review by Pak and White in 2011, on pain prevalence and severity before, during, and after root canal treatment, it was concluded that pain prevalence was the most intense in the first 6 h. At 24 h, the pain prevalence reduced to about 40%, which gradually declined further to 11% at 1 week.[8] Therefore, in our study, the time interval for the evaluation of pain was 6 h, 24 h, and 48 h, to assess and evaluate the dynamics of pain reduction after endodontic treatment.

Cryotherapy is derived from a Greek word, “cryos” meaning cold. Cryotherapy is a long-standing therapeutic procedure applied in sports medicine and in surgery to minimize postoperative discomfort and controlling pain and inflammation.[9] Cryotherapy has been reported to be effective at reducing edema, pain, inflammation, and recovery time with short term applications in orthopedic, abdominal, gynecological and hernia operations.[10-13]

Though cryotherapy refers to lowering or reducing the tissue temperature for therapeutic purposes, it does not imply only implementing cold but rather extracting heat.[14] The magnitude of temperature applied governs the type of biophysical alterations that occurs in the tissues. Furthermore, exposure time, the thermal conductivity of the tissues, and type of the heat or cold agents employed influence the intensity of the therapeutic effect on the target tissues.[15]

In recent years, few studies have reported the use of intracanal cryotherapy for the reduction of postendodontic pain. Vera et al. was the first to describe the use of cryotherapy in endodontics. In their in vitro study, they had assessed the effect of cold saline solution (2.5°C) as a final irrigant for 5 min and concluded that the use of cold saline caused the reduction of external root surface temperature by more than 10°C which was maintained for 4 min, it was suggested that this temperature reduction would be enough to produce the local anti-inflammatory effect in the periradicular tissues.[16]

However, the first clinical trial employing this concept was done by Keskin et al. The outcome of this study revealed that 2.5°C cold saline irrigation as a final irrigant resulted in a significant reduction of postoperative pain levels as compared to the control group.[17] In another clinical study by Al-Nahlawi et al., it was concluded that the use of intracanal cryotherapy along with EndoVac system resulted in complete elimination of postendodontic pain clinically.[18]

In 2018, Vera had conducted a multicenter trial, there was a significant reduction of postendodontic pain and medication intake in the cryotherapy group.[19]

In the present study, sodium hypochlorite was cryotreated to the temperature of 2.5°C–4°C and was used for irrigating each canal for 4 min. The rationale for using sodium hypochlorite is that it is the most common irrigant used for its excellent tissue dissolving property and antimicrobial activity. The antimicrobial activity of cryotreated sodium hypochlorite against Enterococcus faecalis showed a significant reduction in the number of E. faecalis compared to normal sodium hypochlorite.[20] In another study, it was proven that there was a significantly higher amount of free chlorine released from sodium hypochlorite stored in the refrigerator than at room temperature, a higher amount of active chlorine indirectly implies higher the antimicrobial efficacy.[21]

The results of the present study showed that cryotherapy group showed a significant reduction in postoperative pain levels at all tested time intervals, which is 6 h, 24 h, and 48 h and reduced analgesic intake at 6 h postoperatively. This could be attributed to the synergistic effect of the cold treated irrigant, reducing the external root surface temperature, thereby producing anti-inflammatory effect in the periradicular tissues.

The possible reason for the reduction of postoperative pain by cryotherapy was that cold causes vasoconstriction with antioedematic effect, also reduces the blood supply and oxygen supply to that region, thereby reducing cellular metabolism and limiting the tissue damage. Cold also diminishes the number of leukocytes migrating to the affected site, thereby reducing endothelial dysfunction and inflammatory response. In addition, it affects the peripheral nerve endings by diminishing the threshold needed to activate the tissue nociceptors and the speed of painful nerve impulses. The irrigant used being sodium hypochlorite; the cryotreatment may have enhanced the antimicrobial efficacy of sodium hypochlorite, causing further reduction of the bacterial load, which could have additionally resulted in the reduction of postoperative pain.

**CONCLUSION**

From the present study, it was concluded that:
1. That there was a statistically significant reduction of postoperative pain in Cryotreated NaOCl group at 6 h, 24 h, and 48 h than normal NaOCl
2. There was minimal postoperative pain in cryotreated NaOCl group at 6 and 24 h and almost no pain at 48 h, showing that the postendodontic pain is maximum in the first 24 h after which it gradually reduces
3. There was less number of analgesic consumption in cryotreated NaOCl group at 6 h.

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**Conflicts of interest**
There are no conflicts of interest.
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