

Original Article

Comparative Evaluation of the Efficacy of Intraoral Cryotherapy Versus Intracanal Cryotherapy on Postoperative Pain in Lower Molar Teeth with Irreversible Pulpitis and Symptomatic Apical Periodontitis: A Randomized Clinical Trial

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Abstract

Aim: This study aimed to compare postoperative pain and the amount of analgesic intake after intraoral (IO) cryotherapy versus intracanal (IC) cryotherapy in mandibular molar teeth with symptomatic irreversible pulpitis (SIP) and symptomatic apical periodontitis (SAP). **Subjects and methods:** Seventy-eight patients were randomly divided into two groups, intracanal cryotherapy group and intraoral cryotherapy group. The patients' postoperative pain was recorded at 6- 12- 24- 48- and 72 hours postoperatively and number of analgesic tablets taken up to 72 hours postoperatively. **Results:** For pain incidence and pain intensity, there were no statistically significant differences among the groups ($P > .05$). Intragroup comparisons showed a statistically significant pain reduction when comparing baseline to all other time intervals. **Conclusion:** Within the study limitations, intraoral cryotherapy proved to be as successful as intracanal cryotherapy in postoperative pain reduction. Both techniques can be used alternatively to keep postoperative pain minimal.

Keywords: Cryotherapy, Postoperative pain, Intracanal cryotherapy, Intraoral cryotherapy, Symptomatic irreversible pulpitis

I. INTRODUCTION

Postoperative endodontic pain is a common but unfortunate event, with a reported range of 3-58%¹. It appears within the first 24 to 48 hours following obturation and dissipates within a few hours². In some cases, it may persist for days³. The presence of postoperative pain negatively affects the patient-doctor relationship as it leads the patient to lose faith in his doctor and doubt his skills⁴. Preoperative pain, pre-existing pulp and peri-radicular tissue conditions, periapical

radiolucency, extrusion of irrigant or intracanal dressing or debris apically, hyper-occlusion and missed canals are some factors predisposing to postoperative pain⁵.

Many efforts have been directed towards finding a solution for this problem, including using long-lasting anaesthesia, prescribing prophylactic analgesics and corticosteroids, working length maintenance, and preventing irrigant extrusion and occlusal reduction^{6,7}. Recently, cryotherapy has been suggested for postoperative endodontic pain management.

Cryotherapy works by extracting the heat from the higher-body temperature to the lower-body temperature body. This causes vasoconstriction, lowering local blood flow and thus, decreasing local inflammation, swelling and edema⁸. Furthermore, it acts on peripheral nerves either by slowing down nerve conduction or through the Counterirritant effect. The cold activates thermal receptors, reducing the transmission of painful sensations⁹.

Uses of cryotherapy in medicine are numerous including sports injuries such as runner's knee or following hip or knee replacement procedures. Also, it is a cancer treatment modality through minimally invasive cryoablation surgeries¹⁰. In dentistry, its uses include treating gingival pigmentations and oral lesions, pain and swelling control following periodontal surgeries, extractions, and implant insertion¹¹ and vital pulp therapy¹².

An in-vitro study in the field of endodontics showed that employing cold saline solution as the last irrigant decreased the external root surface temperature by more than 10°C and maintained it for 4 minutes, which had an anti-inflammatory effect on the periradicular tissues¹³. In-vivo investigations showed that IC cryotherapy significantly reduces postoperative pain^{14,15}.

To our knowledge, only two studies compare IO cryotherapy with IC cryotherapy^{16,17}. In both studies, these two groups were compared with another two groups, extraoral cryotherapy and no cryotherapy. In both studies, cryotherapy groups, compared to no cryotherapy group, showed a statistically significant postoperative pain reduction and no statistically significant difference among the cryotherapy groups.

Our study aimed to compare between these two techniques in depth and to evaluate the postoperative pain and analgesic intake after application of IO cryotherapy using small ice packs versus IC cryotherapy using final irrigation with 2.5°C cold saline in patients with SIP and SAP in lower molar teeth.

II. SUBJECTS AND METHODS

This study was conducted in the Endodontics department, Faculty of Dentistry, Cairo University, Cairo, Egypt between November 2021 and June 2022. The protocol for the study was approved by the University's Research Ethics Board. Sample size was calculated using the (PS software) and was found to be 34 patients per group, making the total sample size 68 patients (2 groups), increased to 78 patients to compensate for

the 15% dropout. Patients were randomly assigned into two groups by using a Web program available at www.randomizer.org.

A. Inclusion and Exclusion Criteria

The inclusion criteria were healthy patients, aged 20-40, having restorable lower molar teeth with sharp pain (greater than 7 on a modified VAS chart) indicating SIP and pain on percussion indicating SAP. Radiographically, the teeth showed no or slight widening in the periodontal ligaments.

The exclusion criteria were medically compromised, allergic patients, pregnant women and lower molars that were non-restorable, necrotic, swelling, immature, mobile or with pockets deeper than 5mm. Radiographically, the tooth was excluded radiographically if the periapical radiolucency was larger than 8 mm or if there was any indication of external or internal root resorption, vertical root fracture, calcification, or perforation.

B. Treatment Procedure

Informed consents were signed. Age, gender, and tooth number were recorded as demographic data, and preoperative pain levels were taken on modified VAS charts.

A single operator performed all the procedures. Patients received 1 cartridge of mepivacaine hydrochloride 2% with 1:100000 epinephrine (Scandonest, Septodont, France). Rubber dam isolation and access cavity preparation were performed. The canals were explored using #8 hand stainless steel K files (Dentsply Maillefer, Ballaigues, Switzerland). Working length was determined using a Root ZX apex locator (J Morita Corp, Kyoto, Japan) and confirmed radiographically. Rotary MPro (IMD, Shanghai, China) system with a gear reduction torque-controlled motor X-Smart (X-Smart, Dentsply, Maillefer, USA) set to the instructions provided by the manufacturer was used to prepare the canals. The files were used sequentially. The coronal two-thirds of the canal was enlarged using MPro file (18/.09) as an orifice opener in a continuous motion (speed 500 rpm, torque 3Ncm) followed by, file (20/.04) and then (25/.06) (Speed 500 RPM, torque 1.5 Ncm). In and out motions were used in the cervical, middle, and apical thirds with stroke lengths no greater than 3 mm till the full working length. The final file reached in the case of 4 canaled molars was (25/.06), while in case of single distal canal, (35/.04) was used.

EDTA gel was applied on each file upon using it. Also, between every two subsequent instruments, 3 mL of a 2.5% NaOCl solution was irrigated. The canals were then irrigated with saline followed by 1ml of EDTA 17% for one minute. Final irrigation was done using room-temperature saline.

IC group: 20 mL cold saline (2.5°C) was used for 5 minutes at five successive times. The solution's temperature was checked using a digital thermometer. Obturation was done for all participants. Gutta-percha master cones (Gutta-percha points, Meta Biomed Co., Ltd. Chungbuuk, Korea) corresponding to the final file were used and confirmatory radiographs were taken. Canals were dried with paper points (Gutta-percha points, Meta Biomed Co., Ltd. Chungbuuk, Korea) corresponding to the sizes of the master cone and obturated by lateral condensation technique. A resin-based root canal sealer (ADseal, Meta Biomed CO., LTD, Korea) was used. A temporary restoration (MD Temp, Meta Biomed CO., LTD, Korea) was placed and a final radiograph was taken.

IO group: Small ice packs were prepared beforehand (Figure 1). A plastic sleeve was filled with saline and cut to dimensions (5 cm X 3 cm) and then kept in the freezer. After obturation, the pack was placed on the vestibular surface of the treated tooth. Patients maintained the ice pack in place for a total of 30 minutes⁽¹⁶⁾ and were monitored closely. As soon as the ice started to melt, the pack was replaced to keep the temperature as constant as possible. Ibuprofen 400 mg was prescribed in case of severe pain. Patients were instructed to record pain at 6, 12, 24, 48 and 72 hours postoperatively on a modified VAS chart and record the number of tablets taken. Patients returned for follow-up after the 3-days interval.

C. Statistical Analysis

MedCalc software, version 19 for Windows (MedCalc Software Ltd., Ostend, Belgium), was used to analyse the data. Using the Shapiro-Wilk test and the Kolmogorov-Smirnov test, data were examined for normality. Continuous data showed normal distribution and were described using mean and standard deviation. Independent t-test was used for intergroup comparison between continuous data, while ANOVA followed by Tukey post-hoc test was used for intragroup comparison. Categorical data were described as frequency and percentage and comparisons between categorical variables were performed using the chi-square test.

A value less than or equal to 0.05 was considered statistically significant and all tests were two-tailed.



Figure (1): pre-prepared icepacks

III. RESULTS

The Consort diagram is a summary of the study. (Figure 2). A total of 137 patients were assessed for eligibility in the department of Endodontics, Cairo University. After excluding 57 patients, 78 patients were divided at random into two groups of 39. Demographic data did not show any statistically significant differences between the groups ($P > .05$). (Table 1). The intergroup and intragroup comparisons are presented in Table (2) regarding pain intensity in both IO and IC groups. No statistically significant difference was found among the groups ($P > .05$). However, in each group, a statistically significant difference was found when comparing preoperative pain to all other time intervals ($P < 0.0001$) (Table 2). Intergroup comparisons between both techniques regarding analgesic intake have shown no statistically significant difference within different follow-up periods ($P > .05$). In the IO group, none of the participants took 2 or 3 analgesic tablets while in the IC group, one participant took 3 analgesic tablets 6 hours postoperatively. At all other remaining time intervals, no one took 3 analgesic tablets. Two tablets were taken by 3 participants at 12 hours postoperatively, but at the remaining time intervals, no one took 2 analgesic tablets. As for single tablet intake, at 6 hours postoperatively, 16 patients in each group took it. At 12 hours, 2 patients in the IO group took one analgesic compared to 1 patient in the IC group while at 24 hours, only one patient took 1 tablet in the IC group.

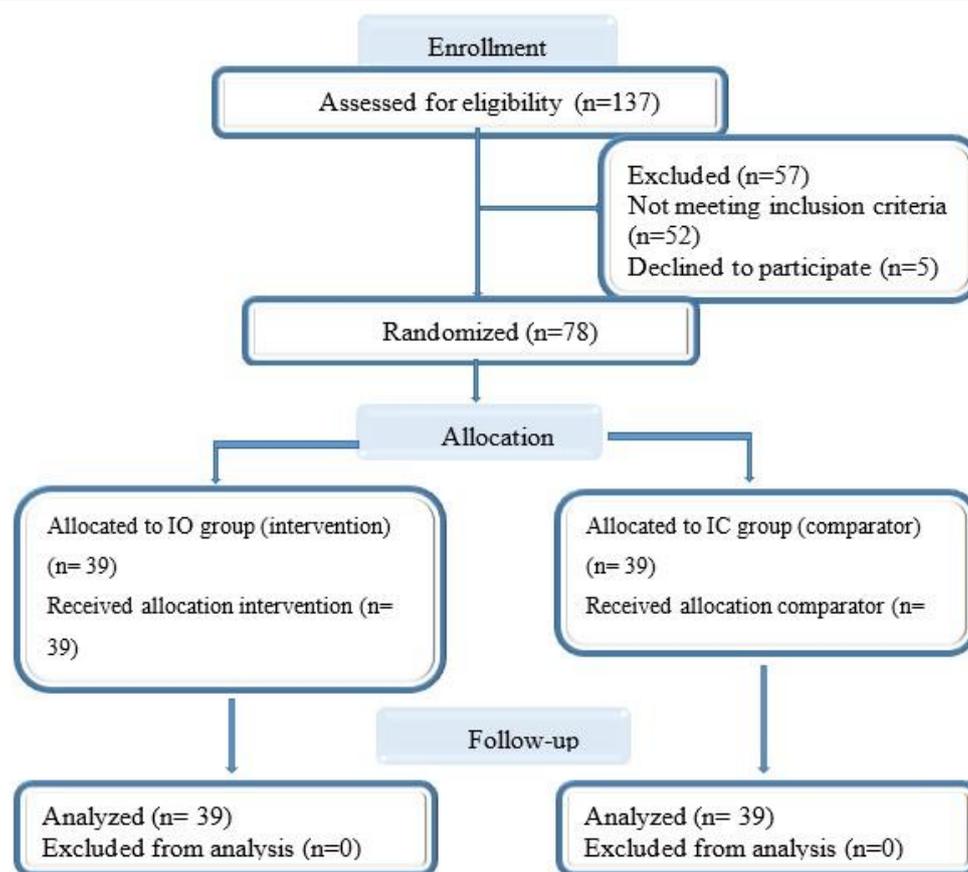


Figure (2): CONSORT flow diagram

Table (1): Summary of statistics of Demographic Data for IO Group and IC Group

Technique Follow-up	IO		IC		P value
	Mean	SD	Mean	SD	
Preoperative	8.3462 ^a	0.8458	8.3333 ^a	0.6370	0.9523
6 hours	3.9231 ^b	1.3834	4.0833 ^b	1.5857	0.7045
12 hours	1.6154 ^c	1.5512	1.6667 ^c	1.4039	0.9032
24 hours	0.4615 ^d	0.7606	0.6667 ^d	1.0901	0.4412
48 hours	0.1538 ^d	0.4641	0.2500 ^d	0.5316	0.4981
72 hours	0.0386 ^d	0.1961	0.1250 ^d	0.3378	0.2690
P value	P < 0.0001*		P < 0.0001		

Table (2): Mean and standard deviation and P value for VAS scores for the intergroup comparison between techniques within each follow-up and intragroup comparison within each technique between different follow-up periods.

Parameter		IO	IC	Total	
		N	20	16	36
Gender	Male	51.3%	41%	46.2%	
	Female	48.7%	59%	53.8%	
Age	Mean±SD	30.9±6.7	30.3±5.5	30.6±6.2	
Treated tooth	First molar	N	25	24	49
		%	64.1%	61.5%	62.8%
	Second molar	N	14	15	29
		%	35.9%	38.5%	37.2%

IV. DISCUSSION

The study aimed to assess whether intraoral (IO) cryotherapy was as effective as intracanal (IC) cryotherapy on postoperative pain reduction and analgesic intake in mandibular molar teeth with SIP and SAP.

Although there is conflicting evidence in the literature regarding the pulp state (vital or necrotic) and the prevalence and severity of postoperative pain, several studies proved a strong correlation between pulp vitality and the presence of preoperative signs and symptoms and the occurrence of postoperative pain^{18,19,20}. This can be explained by the fact that endodontic therapy that injures the periapical living tissue in teeth that have vital pulp stimulates the secretion of inflammatory and pain mediators, such as prostaglandins, leukotrienes, serotonin, histamine, and bradykinin at higher rate¹⁸. Asking the patient if they are experiencing any pain is the quickest way to determine their level of discomfort. However, a simple yes/no response is insufficient for evaluation. Patients can express their level of pain (in words or numbers) using pain scales²¹. Several endodontic researchers have utilized the modified VAS due to its validity and dependability²². Patients described it as simple, easy to comprehend and use.

All confounding factors that could affect our study were eliminated as much as possible by standardizing the endodontic steps done in both groups. The only variable was the cryotherapy technique. IC cryotherapy has proven efficacy in decreasing postoperative endodontic pain in several previous studies^{14,15,16}. That is why we considered it the gold standard against which other cryotherapy techniques should be compared. It worked by lowering the surface temperature of the external root, preventing edema and minimizing inflammatory responses periapically. It also slowed down peripheral nerve conduction but not C fibers²³.

The protocol for IC irrigation was a 5-minute final irrigation using 20 mL cold saline (2.5°C) at five successive times. This was the same amount and temperature of cold saline used in several in-vivo studies (15, 16, 24). Even though *Vera et al.*²⁴ relied on negative pressure irrigation using EndoVac, we decided to use a positive pressure irrigation technique similar to the one used in the first in-vivo

study on cryotherapy¹⁵ and various other studies after that^{16,25}. A 30-gauge needle with a side vent was used and placed as far as possible in the canal space, 2 mm less than the working length and not bound to avoid irrigant extrusion.

IO cryotherapy was chosen as an intervention as it is a simple and feasible technique that doesn't even have to be done chairside and the patient can apply it on his own. There is minimal error in such technique, and almost no side effects. If proven successful, this could generalize the use of cryotherapy as a postoperative pain management technique anywhere and at any time. Only two previous studies applied the technique following conventional endodontic treatment^{16,17}. Both RCTs are exactly similar except that *Yadav et al.*¹⁷ conducted their study on teeth with chronic irreversible pulpitis, while *Gundogdu & Arslan*¹⁶, similar to our study, conducted it on teeth with SAP. Both studies included 4 groups: no cryotherapy, IC cryotherapy, IO cryotherapy and extra-oral cryotherapy. We decided to conduct additional research on the IO cryotherapy technique after they recommended that more research be conducted on the subject. For IO cryotherapy, they wrapped small ice packs with sterile gauze, placing it on the vestibular surface of the treated tooth and keeping it there for thirty minutes. We intended to use the same technique but found it difficult to standardize the size of ice cubes and the wrapping of gauze. The previous study failed to mention the dimensions of the gauze layers. Therefore, we designed small ice packs with standard sizes to eliminate any variations. Also, the previous study failed to mention what was done when the ice started to melt. In the present study, as soon as the ice started to melt, the pack was replaced.

The results showed no statistically significant differences in either postoperative pain reduction or in analgesic intake between the IC and IO groups at all follow-up periods. Both IC and IO cryotherapy were successful in postoperative pain reduction. That was evident in intragroup comparisons where, in both groups, preoperative pain was significantly higher than pain levels at all other time intervals. Short-term postoperative pain is not considered a necessary component of long-term success. Cryotherapy has been proven

beneficial in reducing postoperative discomfort, but it is yet unclear if it will affect the long-term success of root canal procedures. Therefore, Cryotherapy treatments' effects on the long-term success of root canal procedures require further investigation.

V. CONCLUSION

Within the limitations of the present study, both cryotherapy techniques resulted in reduced postoperative pain levels. Moreover, analgesic intake was comparable and at a minimum in both techniques. However, Cryotherapy usage should, however, be the subject of more research.

Conflict of Interest:

The authors declare no conflict of interest.

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Ethics:

This study protocol was approved by the ethical committee of the faculty of dentistry-Cairo University on: 26/10/2021, approval number: 12 10 21.

VI. REFERENCES

1. Sathorn, C., Parashos, P. and Messer, H. (2008) 'The prevalence of postoperative pain and flare-up in single- and multiple-visit endodontic treatment: A systematic review', *Int Endod J.*, 41(2), 91–99.
2. Harrison, J.W., Craig Baumgartner, J. and Svec, T.A. (1983) 'Incidence of pain associated with clinical factors during and after root canal therapy. Part 1. Interappointment pain', *J Endod.*, 9(9), 384–387.
3. Siqueira, J.F. (2003) 'Microbial causes of endodontic flare-ups', *Int Endod J.*, 36(7), 453–463.
4. Francisco, S.S., Suzuki, C.L.S., Lima, A.P.D.S., Maciel, M.C.R. and Murrer, R.D. (2017) 'Clinical strategies for managing emergency endodontic pain', *Rsbo*, 13(3), 209.
5. Alves, V.D.O. (2010), Endodontic flare-ups: A prospective study. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod.* 2010;110(5):e68-e72.
6. Attar, S., Bowles, W.R., Baisden, M.K., Hodges, J.S. and McClanahan, S.B. (2008) Evaluation of Pretreatment Analgesia and Endodontic Treatment for Postoperative Endodontic Pain. *J Endod.*, 34(6):652-655.
7. Pochapski, M.T., Santos, F.A., De Andrade, E.D. and Sydney, G.B. (2009). Effect of pretreatment dexamethasone on postendodontic pain. *Oral Surg. Oral Med Oral Pathol Oral Radiol Endod.*,108(5):790-795.
8. Kullenberg, B., Ylipää, S., Söderlund, K. and Resch, S. (2006). Postoperative Cryotherapy After Total Knee Arthroplasty. A Prospective Study of 86 Patients. *J Arthroplasty*,21(8):1175-1179.
9. Nadler, S.F., Weingand, K. and Kruse, R.J. (2004) The physiologic basis and clinical applications of cryotherapy and thermotherapy for the pain practitioner. *Pain Physician*,7(3):395-399.
10. Takada, M. and Toi, M. (2019). Cryosurgery for primary breast cancers, its biological impact, and clinical outcomes. *Int J Clin Oncol.*, 24(6):608-613.
11. Filho, J., Silva, E., Camargo, I. and Gouveia, F. (2005) The influence of cryotherapy on reduction of swelling, pain and trismus after third-molar extraction. *Clin Pract.*, 136(6):774-778.
12. Fayyad, D.M., Abdelsalam, N. and Hashem. N. (2020). Cryotherapy: A New Paradigm of Treatment in Endodontics. *J Endod.*, 46(7):936-942.
13. Vera, J., Ochoa-Rivera, J., Vazquez-Carcaño, M., Romero, M., Arias and A., Sleiman, P. (2015). Effect of intracanal cryotherapy on reducing root surface temperature. *J Endod.*, 41(11):1884-1887.

14. Al-Nahlawi, T., Hatab, T.A., Alrazak, M.A. and Al-Abdullah, A. (2016) Effect of intracanal cryotherapy and negative irrigation technique on postendodontic pain. *J Contemp Dent Pract.*,17(12):990-996.
15. Keskin, C., Özdemir, Ö., Uzun, İ. and Güler B. (2017) Effect of intracanal cryotherapy on pain after single-visit root canal treatment. *Aust Endod J.*,43(2):85-90.
16. Gundogdu, E.C. and Arslan, H. (2018) Effects of Various Cryotherapy Applications on Postoperative Pain in Molar Teeth with Symptomatic Apical Periodontitis: A Preliminary Randomized Prospective Clinical Trial. *J Endod.*, 44(3):349-354.
17. Yadav, V., Shreya, Vandita, Samant, P.S. and Chauhan, R. (2021) Endodontic cryotherapy: A review of current status, potential sequelae, and call for action. *Dent Poster J.*,10(2):1-2.
18. Gotler, M., Bar-Gil, B. and Ashkenazi, M. (2012) Postoperative pain after root canal treatment: A prospective cohort study. *Int J Dent.* 2012.
19. Calhoun, R.L. and Landers, R.R. (1982) One-appointment endodontic therapy: a nationwide survey of endodontists. *J Endod.*, 8(1):35-40.
20. Udoeye, C.I. and Jafarzadeh, H. (2011) Pain during root canal treatment: An investigation of patient modifying factors. *J Contemp Dent Pract.* 2011;12(4):301-304.
21. Katz, J. and Melzack, R. Measurement of pain. (1999) *Surg Clin North Am.*, 79(2):231-252.
22. Polycarpou, N., Ng, Y.L., Canavan, D., Moles, D.R. and Gulabivala, K.(2005) Prevalence of persistent pain after endodontic treatment and factors affecting its occurrence in cases with complete radiographic healing. *Int Endod J.*, 38(3):169-178.
23. Ernst, E. and Fialka, V. (1994) Ice freezes pain: A review of the clinical effectiveness of analgesic cold therapy. *J Pain Symptom Manage.*: 9(1):56-59.
24. Vera, J., Ochoa, J., Romero, M., Vazquez-Carcano, M., Ramos-Gregorio, C. O., Aguilar, R. R., Cruz, A., Sleiman, P., & Arias, A. (2018). Intracanal Cryotherapy Reduces Postoperative Pain in Teeth with Symptomatic Apical Periodontitis: A Randomized Multicenter Clinical Trial. *J Endod.*, 44(1), 4–8.
25. Jain, A., Davis, D., Bahuguna, R., Agrawal, A., Singh, S., Ramachandran, R., & Varghese, A. (2018). Role of Cryotherapy in Reducing Postoperative Pain In Patients With Irreversible Pulpitis; An In-Vivo Study, *Int J Dent Med Sci Res.* 2018;2(10):43-49.