Original Article

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Efficacy of local anesthesia with cryotherapy on teeth with molar incisal hypomineralization: a randomized control trial

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Background: Tooth hypersensitivity presents a significant clinical challenge in managing molar-incisal hypomineralization (MIH), potentially compromising the effectiveness of restorative treatments. Cryotherapy has emerged as a promising approach to reduce pain and inflammation. This study aimed to evaluate and compare the effects of cryotherapy as an adjuvant to nerve blocks in reducing operative pain and sensitivity in patients.
Methods: A split-mouth randomized controlled trial was conducted in 28 patients with MIH of the right and left lower molars. ie, 56 teeth. Group (1) control group (n = 28) was administered an Inferior Alveolar Nerve block and group (2) was administered cryotherapy spray after the Inferior Alveolar Nerve block. The Visual Analog Scale (VAS) and Legs, Activity, Cry, Consolability (FLACC) scales were used to compare intraoperative pain. The Mann-Whitney U test was used to test the significance across the study groups, and the chi-square test was used to compare success rates between the two groups; a value of less than 0.05 was considered significant.
Results: For VAS scale, the mean value in Group A is 8.89 ± 0.79, whereas in Group B, the values are 4.71 ± 1.46. For the FLACC scale, Group A scores were 7.14 ± 1.04, and Group B scores were 4.48 ± 1.37. When intergroup values were compared, the FLACC and VAS scores were statistically significant at $P < 0.001$.
Conclusion: Within the limitations of this study, applying cryotherapy to tooth surfaces following an Inferior Alveolar Nerve block effectively reduces pain and sensitivity in teeth affected by MIH.

Keywords: Cryotherapy; Hypomineralization; Molar Incisor Hypomineralization.

INTRODUCTION

Molar incisor hypomineralization (MIH) is a qualitative enamel defect characterized by rapid post-eruptive breakdown of the enamel, which exposes the dentin [1,2]. Managing teeth impacted by MIH is difficult owing to their increased sensitivity and the challenge of administering local anesthesia to young patients. This is exacerbated by chronic subclinical inflammation resulting from bacterial infiltration into the exposed dentin, which alters nerve function and further complicates treatment [3,4]. Failure to achieve adequate local anesthesia may impair the quality of restorations, and this situation can exacerbate behavioral management issues in children who are already apprehensive about dental treatment. Under certain circumstances, a dental surgeon must administer a higher dose of a local anesthetic to compensate for a hyperresponsive tooth to achieve the intended result [5].

Several options have been proposed to overcome this

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difficulty. Some researchers have suggested buccal infiltration with articaine as an adjunct to the inferior alveolar nerve block to achieve more profound anesthesia [6]. Various techniques, including intra-ligamental, intraosseous, palatal, and lingual anesthesia, have been suggested as viable alternatives, with variable success rates. Researchers have suggested the use of nitrous oxide inhalation sedation to increase the pain threshold during dental treatment. Some preoperative management techniques, such as desensitizing toothpaste or application of fluoride varnish before the restorative appointment, have been suggested for quality pain control [7]. General anaesthesia is recommended as a last resort in situations where the prescribed treatment plan is extremely difficult to carry out and all other alternatives have failed [6,7].

Cryotherapy or Cold application is a well-known approach to pain management. This can be achieved by the direct application of ice, ice chips, melted ice water, ice massage, coolant sprays, whirlpools, ice baths, or prepackaged chemical ice packs at the required site [8]. It is postulated that the analgesic effect of cryotherapy is due to its ability to reduce nerve conduction velocity, which helps diminish pain perception. Cryotherapy is non-invasive and causes minimal patient discomfort, which is common in pediatric patients. In addition to alleviating pain, cryotherapy has anti-inflammatory properties and promotes rapid healing [9]. Recent literature has shown that cryotherapy is gaining importance in endodontics for pain management. [10,11]

A literature search finds no study regarding the effectiveness of cryotherapy on tooth surfaces after inferior alveolar nerve block (IANB) application in patients with MIH. Cryotherapy is likely to have an analgesic effect on tooth surfaces, which are sensitive even post-administration of local anesthesia. The primary aim of this study was to assess the effectiveness of cryotherapy on hypoplastic teeth after IANB injection in the mandibular first permanent molars. The null hypothesis asserts that there is no disparity in pain levels between the use of IANB with cryotherapy and IANB alone during the restoration of the first permanent mandibular molars affected by MIH.

METHODS

1. Study design and sampling

This double-blind, split-mouth, randomized clinical trial was conducted as per the Consolidated Standards of Reporting Trials guidelines (CONSORT). The study was reviewed and approved by the Ethics and Research Committee of Dental College (IECKDC/2023-02/001) and registered as a clinical research trial in India (CTRI/2024/04/066002). The study participants were patients visiting the Outpatient Department of the Department of Pediatric and Preventive Dentistry at a Dental College. Participants were enrolled via convenience sampling. All children and their parents/guardians were informed about the study, and signed informed consent was obtained from the parents. The estimated study period was six months; however, the study was completed ahead of time.

Sample size: Sample size was calculated based on a previous study on MIH by Dixit UB [5] By using the G Power Software with an alpha level of 5%, a beta level of 20%, Power equals 80%, and an effect size of 0.4. The minimum sample size required was 27 teeth per group. So, a total of 54 teeth of 27 subjects were included in this study.

1) Inclusion criteria

The study included healthy children aged 8–12 years who exhibited various levels of enamel breakdown and sensitivity in the lower first molars bilaterally, as assessed using the MIH TNI criteria 4 [12].

2) Exclusion criteria

Children with systemic diseases and those with a dental history of irreversible pulpitis, pulp exposure, abscess, sinus tract, or fistula of the first lower molars were excluded.

A split-mouth treatment approach was employed with

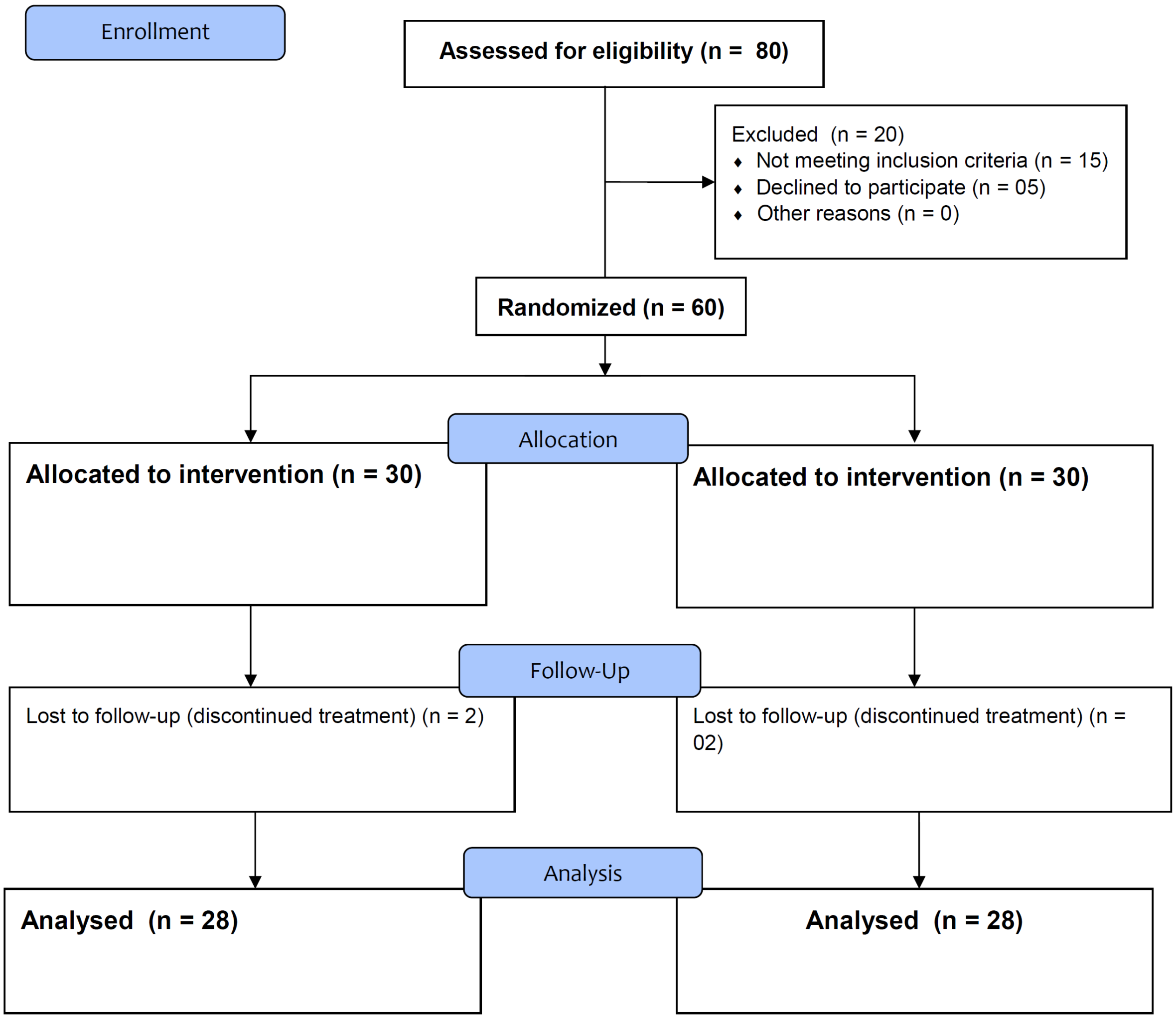

Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram. n, number.

simple randomization using a shuffled deck of cards to determine the treatment sequence for each tooth. Children who selected the even-numbered cards received treatment for the lower right tooth first, whereas those who selected the odd-numbered cards received treatment for the lower left first molar.

The CONSORT diagram (Figure 1) illustrates the allocation, randomization, follow-up, and final analysis, depicting the number of participants in each group based on the inclusion and exclusion criteria.

3) Procedure

Group 1 (control, n = 28): A standard IANB was performed using 2.5 mL of 2% lidocaine (1:200,000 adrenaline and the nerve block was administered with a 24-gauge 25-mm needle (Dispovan).

Group 2 (IANB + Endo frost, n = 28): A standard IANB was administered in the same way as in the control group, following which endo frost was sprayed on a cotton bud for 5 s, and the frosted cotton bud was applied for 10 s on tooth surfaces where there was enamel breakdown. Restorative procedures in both groups were done ten minutes after IANB to ensure that the patient experienced lip numbness. The protocol was standardized using the same operator, materials, techniques, restorations, and clinical settings. Any soft carious lesions were removed using a handheld instrument.

4) Evaluation

Pain was recorded during caries removal by a blinded

Table 1. Gender distribution of samples

Gender	Number of samples (N = 28)	Percentage of samples
Male	17	60.71%
Female	11	39.29%

N, number.

Table 2. The characteristics of Molar incisor hypomineralization distribution on the split-mouth design

MIH	Conventional IANB		IANB with cryotherapy		Significance (2 tailed)
	N = 28	%	N = 28	%	
MIH with hypersensitivity and < 1/3rd defect extension	7	58.3%	5	41.7%	0.692
MIH with hypersensitivity and 1/3rd-2/3rd defect extension	17	50.0%	17	50%	
MIH with hypersensitivity and > 2/3rd defect extension	4	40%	6	60%	

MIH, molar incisor hypomineralization.

Table 3. Pain value using VAS scale and FLACC scale across the conventional IANB and IANB with cryotherapy

Pain score	Conventional IANB				IANB with cryotherapy			
	Mean	Standard deviation	95% Confidence intervals		Mean	Standard deviation	95% Confidence intervals	
			Lower	Upper			Lower	Upper
VAS scale	6.89	0.79	6.59	7.20	4.71	1.46	4.15	5.28
FLACC scale	7.14	1.04	6.74	7.55	4.43	1.37	3.90	4.96

FLACC, Face, Legs, Activity, Cry, Consolability; IANB, inferior Alveolar nerve block; VAS, visual analogue scale.

observer who was blinded to the intervention during the restorative procedures. Two pain assessment scales (subjective and observational) were used.

1. Subjective pain assessment using the visual analog scale (VAS) consists of a 100 mm line with descriptors at each end. Patients mark their level of pain on the line, which is then measured and recorded.

2. Objective pain assessment by the Face, Legs, Activity, Cry, Consolability (FLACC) scale was recorded by a blinded observer. The scale consists of five criteria, each of which is assigned a score of 0, 1, or 2. The total score was obtained by summing the scores for each criterion.

2. Statistical analysis

Statistical analyses were performed using IBM SPSS v-22 (Statistical Package for the Social Sciences, IBM Co., Armonk, NY, USA). Shapiro-Wilk normality test shows that the data was not following a normal distribution. Therefore a Mann-Whitney U test was used to test the respective hypotheses i.e. test if the VAS and FLACC scales were significantly different across the study groups. The chi-square test was used to compare success rates between the two groups. A p-value of 0.05 level or less was considered significant.

RESULTS

Twenty-eight patients underwent restorative procedures on the right and left lower molars, accounting for 56 teeth with MIH.

Table 1 shows the sex distribution of the participants, whose ages ranged from 8 to 12 years with a mean age of 9 years. Of the 28 participants, 11 were females and 17 were males.

Table 2 displays the characteristics of MIH on the right and left sides of the subjects classified according to the MIH TNI index classification. The results indicate no significant difference between the types of MIH taken in this study, with a chi-square value of 0.733 and a p-value of 0.692 which is not statistically significant.

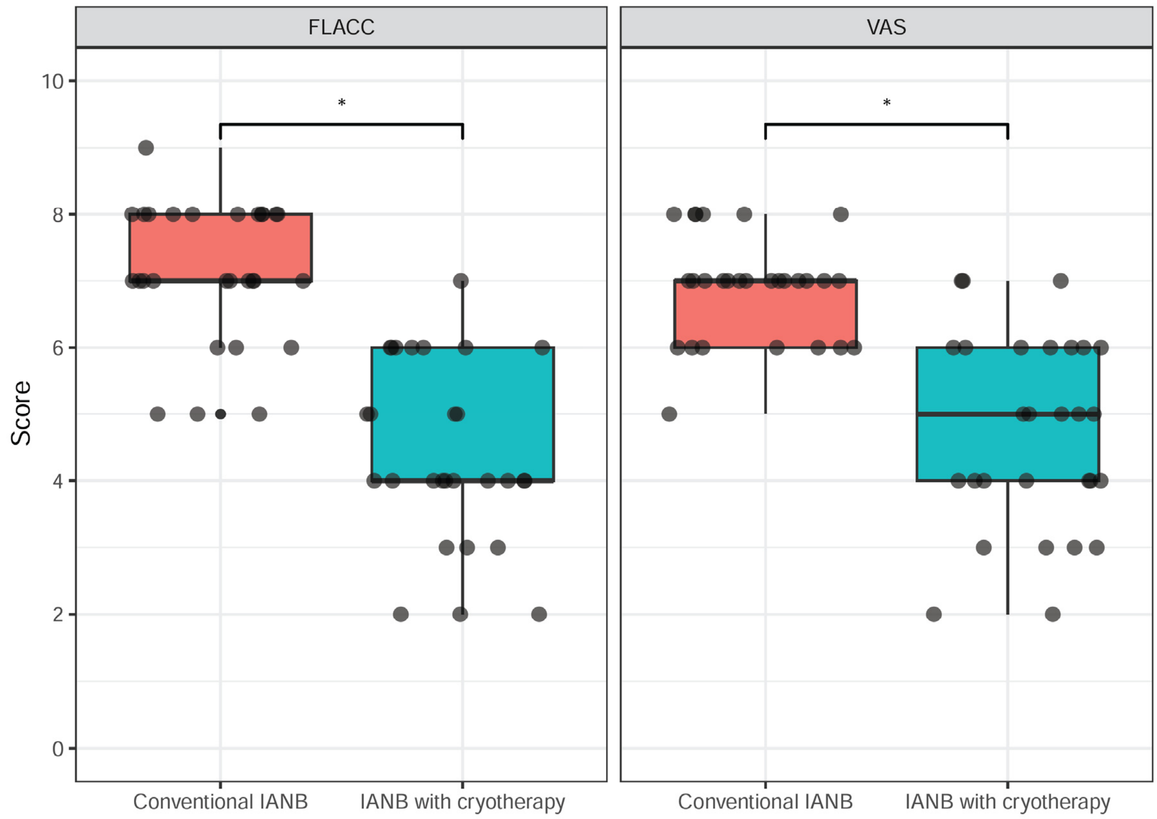

Fig. 2. This graph shows the pain values obtained using the FLACC and VAS in two groups. *(P < 0.05) is considered significant. FLACC, Face, Legs, Activity, Cry, Consolability; IANB, inferior Alveolar nerve block; VAS, visual analogue scale.

Table 4. Intergroup comparison of VAS scores

	Median	Percentile 25	Percentile 75	Mean rank	Z value	P-value
Conventional IANB	7.00	6.00	7.00	39.68	5.257	< 0.001*
IANB with cryotherapy	5.00	4.00	6.00	17.32		

*Significant at P < 0.05.
IANB, inferior Alveolar nerve block; VAS, visual analogue scale.

Table 5. Intergroup comparison of FLACC scores

	Median	Percentile 25 (Q1)	Percentile 75 (Q3)	Mean rank	Z value	P-value
Conventional IANB	7.00	7.00	8.00	40.77	5.711	< 0.001*
IANB with cryotherapy	4.00	4.00	6.00	16.23		

*Significant at P < 0.05.
FLACC, Face, Legs, Activity, Cry, Consolability; IANB, inferior Alveolar nerve block.

Figure 2 and Table 3 shows the pain values obtained using the VAS and FLACC. For the VAS, the mean value in Group A is 6.89 with a standard deviation of 0.79, whereas in Group B, the values were 4.71 with a standard deviation of 1.46. On the FLACC scale, Group A scores were 7.14 with a standard deviation of 1.04, and Group B scores were 4.48 with a standard deviation of 1.37. Upper and lower 95% confidence intervals (CIs) for the VAS and FLACC scales are shown.

Table 4 compares the VAS scores of Groups A and B. The results indicated a significant difference between the VAS scores of the groups, with a highly significant P-value of < 0.001.

Table 5 compares the FLACC scores of groups A and

B. The results demonstrated a higher mean pain score after conventional IANB than after cryotherapy with IANB. A significant difference in FLACC pain scores was observed between the groups ($P < 0.001$).

DISCUSSION

This study aimed to determine whether cryotherapy of the tooth after IANB reduces pain and discomfort during MIH treatment. The participants between 8-12 years of age were involved in this study, as post-eruptive enamel breakdown in MIH patients is most commonly observed within this age range. Before tooth restoration, An IANB was administered to all patients as it is an effective local anesthetic technique for lower permanent molars. Cryotherapy with Endofrost was used as an adjunct on the tooth surface as an intervention on one side in a split-mouth design among the subjects. A split-mouth design was chosen to reduce interindividual variability in pain scores, with each patient serving as their control [13]. In this study, the success of anesthesia was evaluated based on objective and subjective manifestations during cavity preparation. The VAS Scale employed in this study offers a simple method for subjectively quantifying pain and has been utilized in numerous prior studies to assess intraoperative pain in different individuals [14]. Additionally, the FLACC scale was employed as an objective method of pain assessment, known for its reliability and validity in evaluating pain in children and adolescents [15].

The subjects in this study exhibited enamel breakdown corresponding to grade 4 on the molar-incisor hypomineralization treatment need index (MIH-TNI). Compared with normal human enamel, teeth affected by MIH demonstrate decreased mineral quantity and quality, lower elastic modulus, higher protein content, and elevated carbon and carbonate concentrations. These factors contribute to post-eruptive enamel degradation and early exposure to the porous subsurface enamel or dentin [16]. The pain due to this type of dentin sensitivity is short, sharp, and well-localized, and ceases immediately after the removal of the stimulus. It is associated with exposed, open dentinal tubules and is mediated by A-delta fibres [17] Consequently, MIH-affected teeth exhibit high thermal conductivity and reduced thermal isolation characteristics, leading to chronic stress on the pulp-dentin complex. This chronic stress triggers an inflammatory response within the pulp and pH changes at the periapical tissue level, resulting in hypersensitive pulpal nerve tissue. Different stimuli can rapidly induce dentin fluid outflow, leading to pressure changes across the dentin that activate baroreceptors near the pulp and elicit immediate sharp pain. Clinically, it manifests as a hypersensitive tooth that is challenging to anesthetize, even with higher doses of local anesthetics [18].

Cryotherapy using endofrost can have an analgesic effect by reducing the local inflammatory response, slowing down nerve impulses, and minimizing postoperative edema. Endofrost, composed of a pressurized gas mixture of butane, propane, and isobutane, decreases the intra-pulpal temperature when applied to the tooth surface [19]. Studies have demonstrated that cooling teeth reduces pulpal blood supply and eliminates pain [20].

The cold application reduces nerve conduction velocity, particularly affecting myelinated Aδ nerve fibers in the dentin-pulp complex. Larger myelinated A fibers provide faster sensory input, resulting in a pain-relieving effect by temporarily closing the gate and impeding the transmission of unbearable impulses from unmyelinated C fibers [21]. Cryotherapy of tissues releases neuro-effective agents such as endorphins and modulates nociceptive transmission to the central nervous system, inducing an analgesic effect. Therefore, a combination of the reduced release of pain chemical mediators and inhibition of neural pain signal propagation due to cooling results in analgesia [22,23]. Algalfy and George [24] found decreased nerve conduction velocity at the cryotherapy application site, along with an increased pain threshold and tolerance. Our study consistently revealed a significant reduction in pain during cavity preparation when endofrost was applied to the tooth.

Studies have demonstrated that cryotherapy reduces inflammation by decreasing the pro-inflammatory cytokine TNF-α while increasing levels of anti-inflammatory cytokines such as IL-10 and IL-6 [8]. Additionally, cryotherapy is believed to diminish inflammatory edema by decreasing vascular permeability and reducing arterial and soft tissue blood flow to the affected areas [23,25-27].

Our preliminary study investigated the use of cold-application on hypomineralized tooth surfaces. Studies by Frank et al [28]. indicate that irreversible damage to pulp tissue occurs only when frozen at approximately -9°C. Furthermore, research on pulpal temperature using Endo Ice suggests that it reduces pulpal temperature by 7.1 to 8.5°C, indicating that it is safe for use on tooth surfaces. Furthermore, vital pulp cryotherapy has been reported in the literature for post-operative pain control and the management of pulpal hemorrhage [10,29,30]. Future studies should focus on the temperature changes in pulp tissues when using cryotherapy for teeth with enamel breakdown.

There are a few limitations to the study, the major being the small sample size, which was performed in a single center only. Therefore, the short- and long-term effects of cryotherapy on the tooth surface and pulp must be studied in detail.

In conclusion, this study shows that the application of cryotherapy to tooth surfaces after inferior alveolar nerve injection is effective in reducing pain and discomfort in teeth with MIH.

Based on the results of this study, multicenter studies with larger sample sizes and statistical correlations should be conducted to evaluate the effect of cryotherapy as an adjuvant to different nerve blocks in various types of MIH.

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Athira Aravind: Data curation, Validation, Writing – original draft, Writing – review & editing
Aswathi Sreedharan: Data curation, Methodology, Resources, Supervision
Athul Ramesh: Formal analysis, Resources, Software, Visualization, Writing – review & editing

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