Original Article

Evaluating the pain at site, onset of action, duration and anesthetic efficacy of conventional, buffered lidocaine, and precooled lidocaine with intraoral cryotherapy application in patients with symptomatic irreversible pulpitis: A clinical study

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Abstract

Aim: Injection pain and incomplete anesthesia can lead to procedural failure, causing fear and anxiety among patients. The aim of the study was to compare and evaluate pain at the site, the onset of action, duration, anesthetic efficacy, and success rates of conventional, buffered, and precooled 2% lidocaine of an inferior alveolar nerve block (IANB) in symptomatic irreversible pulpitis (SIP).

Materials and Methodology: In this double-blind, randomized clinical trial, 45 patients with deep carious lesions having moderate-to-severe pain in the mandibular first molar teeth were selected. Patients were randomized into one of the following groups: Group I-Conventional lidocaine (Control), Group II-Buffered lidocaine (Experimental), and Group III-Precooled lidocaine with intraoral cryotherapy (Experimental). All patients received an IANB followed by which the pain at the site, onset of action, duration, anesthetic efficacy, and success rate were compared and evaluated.

Statistical Analysis: Kruskal–Wallis and Chi-square tests were used for statistical analysis.

Results: Data were statistically analyzed and there was a significant reduction in pain at the site with faster onset of action and higher anesthetic efficacy in buffered lidocaine followed by precooled lidocaine. The success rate for conventional IANB is 38.9%, for buffered lidocaine, 86.2%, and for precooled lidocaine, 78.9%.

Conclusions: In patients with a mandibular molar presenting with SIP, block anesthesia with buffered lidocaine showed the best results and a superior success rate, followed by precooled lidocaine, with the least efficacy seen in the conventional lidocaine group.

Keywords: Anesthetic efficacy; cryotherapy; inferior alveolar nerve block; precooled lidocaine; symptomatic irreversible pulpitis

INTRODUCTION

The effectiveness of clinicians who perform routine endodontic procedures is highly dependent on the efficacy

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Date of submission : 02.09.2024
Review completed : 30.09.2024
Date of acceptance : 13.10.2024
Published : 10.12.2024

Access this article online

Quick Response Code:

Website: https://journals.lww.com/jcde

DOI: 10.4103/JCDE.JCDE_625_24

How to cite this article: Karunakar P, Solomon RV, Kumar BS, Reddy SS. Evaluating the pain at site, onset of action, duration and anesthetic efficacy of conventional, buffered lidocaine, and precooled lidocaine with intraoral cryotherapy application in patients with symptomatic irreversible pulpitis: A clinical study. J Conserv Dent Endod 2024;27:1228-33.

of the local anesthesia used.[1] However, successful pulpal anesthesia can be challenging due to several factors. The reasons for failure of anesthesia may be multifactorial such as acidic pH of inflamed tissues, altered resting potentials, presence of sodium channels resistant to tetrodotoxin, and stimulation of nociceptors. Patient-related factors include anxiety, psychological distress, anatomical variations, inflammation or infection, altered sensory perception, and potential interactions with the medications.[2]

The pain experienced during local anesthetic (LA) administration is influenced by factors such as injection speed, pressure, pH, temperature, and volume of the solution. Managing these variables helps reduce patient discomfort. A key factor in increased pain is the lower pH of solutions containing epinephrine. Lidocaine, a weak base, is unstable at its natural pH of 7.9, so it is prepared in an acidic solution to enhance solubility and shelf life. Epinephrine, added to prolong the effect and reduce toxicity, lowers the pH of the lidocaine solution (3.3–5.5).[3] This acidic environment may contribute to increased pain at the injection site.

To tackle these challenges, several approaches have been introduced, including premedication with nonsteroidal anti-inflammatory drugs, application of topical anesthesia, and additional local infiltration.[4] Novel approaches and methods are continually proposed to improve the reliability and effectiveness of local anesthesia, such as precooling with intraoral cryotherapy or using buffered anesthesia.

In buffered anesthesia, lidocaine with epinephrine is mixed with sodium bicarbonate (8.4%) in 10:1 or 9:1 ratio which adjusts the pH closer to the neutral level (~7.4) of human tissues. Cryotherapy, or applying cold to a localized area, effectively blocks nerve impulses and enhances local anesthetic efficacy.[5,6] Using refrigerated lidocaine at 4°C–6°C can lead to rapid onset and higher duration of action, especially when nerve block anesthesia is employed for molar teeth. In addition, precooling the injection site with ice sticks can significantly reduce injection discomfort.[7]

To anesthetize lower posterior molar teeth, the inferior alveolar nerve block (IANB) technique is widely and routinely practiced.[8] The failure rates as evidenced in various literature studies in anesthetizing mandibular molars using IANB for teeth with irreversible pulpitis range from 44% to 81%.[9]

This study aims to compare and evaluate pain at the site, onset of action, duration, efficacy, and success rates of conventional, buffered, and precooled 2% lidocaine. The null hypothesis indicates no markable differences in pain at the site, onset of action, duration, and anesthetic efficacy between conventional, buffered, and precooled 2% lidocaine in IANB for patients with symptomatic irreversible pulpitis (SIP).

MATERIALS AND METHODOLOGY

This clinical trial has been formulated as a prospective, double-blind randomized clinical trial with an equal allocation ratio of 1:1:1. The research adhered to the Consolidated Standards of Reporting Trials. The study was approved by the institutional review board (PMVIDS and RC/IEC/CONS/PR/570-23) and registered with the Clinical Trials Registry of India (CTRI/2024/08/071805). Each patient was explained in detail about the procedure followed by which voluntary written consent was obtained.

Inclusion

Patients visiting the outpatient Department of Conservative Dentistry and Endodontics at Panineeya Institute of Dental Sciences and Research Center Hyderabad, Telangana, India, with deep carious lesions having moderate-to-severe (visual analog scale [VAS] >5), aged 18–45, American Society of Anesthesiologists I or II, with SIP in the mandibular molar was included.

Exclusion

Exclusion criteria included known hypersensitivity to lidocaine or sodium bicarbonate, recent cardiac surgery, pregnancy or lactation, premedication, necrotic teeth with associated sinus tracts, advanced periodontitis, poor oral hygiene, the presence of dental fractures, and large periapical radiolucency (>2 mm).

SIP with apical periodontitis was diagnosed based on comprehensive case history, clinical and radiographic evaluations, and a positive electric pulp test (EPT, Parkell gentle pulse pulp vitality tester, USA). Out of 80 initially assessed patients, 45 were selected for the trial. All 45 patients had given their consent to be a part of the study and met the inclusion criteria parameters [Figure 1].

For better study analysis and outcome, a double-blind investigation was done with both the second investigator and patients unaware of their group assignments. Study participants were allotted into three random groups. Group I being the control and Group II and Group III being the experimental groups.

This grouping was performed at random by employing a computer software (Randomizer. at) that generated allotment numbers with allocation 1:1:1. Patients were instructed to rate their pain using a 10-point VAS rating from 1 to 10 gradation of pain at three stages: baselines scores were taken, after the injection, and during endodontic treatment. They were informed about the procedure and asked to record their pain. All study participants underwent a patch test, where they received intradermal anesthesia with their assigned anesthetic solution and were observed for an hour.

Group I: Conventional local anesthesia (Control)-A standard IANB was employed with 27-guage, 1.5-inch needle using 1.8 mL of 2% lignocaine with 1:80,000 epinephrine was given slowly over 2 min, targeting the mandibular foramen through the coronoid notch.[10]

Group II: Buffered local anesthesia (Experimental)-To prepare a buffered solution, 3 mL solution was removed from a 30-mL vial bottle of 2% lignocaine with 1:80,000 epinephrine (Lignox 2% A INDOCO, Mumbai, India) using a single-use syringe. To this, 3 mL solution of 8.4% sodium bicarbonate was added with a sterile syringe to achieve a 1:10 dilution. After shaking until clear, the freshly prepared solution was used for IANB following the same technique as the conventional group.[11]

Group III: Precooled local anesthesia (Experimental)-An ice stick was held at the injection site for 15 s. IANB was administered with 1.8 mL of refrigerated 2% lidocaine with 1:80000 epinephrine (4°C–6°C). Both the ice sticks and cold lidocaine were used immediately after refrigeration to maintain temperature consistency.

LA solutions were administered by the first operator, who managed the randomization and ensured allocation concealment. The second operator, blinded to group assignments, assessed pain at the injection site using VAS and performed an EPT every minute until two consecutive negative responses confirmed the onset of anesthesia.

The second operator also conducted the endodontic treatment, recorded VAS scores for pain, and confirmed tooth vitality by observing bleeding from the pulp chamber and root canals. Pain scores during the procedure were recorded using VAS. Anesthesia was deemed successful if minimal or no pain was experienced. After completion of the therapy, patients were also assessed for the duration of the anesthesia.

Statistical methods

The data collected was entered in the Microsoft Excel sheet by the examiner. The mean, standard deviation, and percentages were calculated. Data were analyzed using IBM SPSS 23 version 2.0 software (IBM SPSS, IBM Corp., Armonk, NY, USA).

Statistical tests

Kruskal–Wallis test is used for the comparison of pain, duration, efficacy, and onset between the three groups. Pair-wise comparison was done by using *post hoc* analysis. Chi-square test is used for the comparison of success rates between groups. $P \leq 0.05$ was considered statistically significant. Simple bar chats are used for data presentation.

RESULTS

The results demonstrate that all three local anesthetic agents effectively alleviated pain. Based on the inter-group comparison, there was a statistical difference between all three groups. The buffered group reported less pain on site [Graph 1]; long duration of action [Graph 2], followed by the precooled group which was not statistically significant [Table 1]. However, there is a statistical difference in terms of the onset of action. The buffered group showed higher efficacy with a success rate of 84.2%, followed by the precooled group with a success rate of 72.0%, least with the conventional group with a success rate of 38.6% which was statistically significant [Table 2].

DISCUSSION

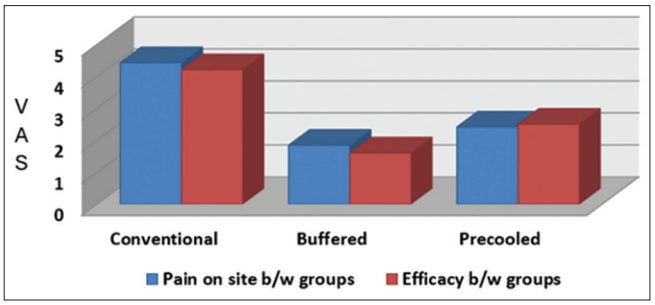
In this clinical study, the effectiveness of IANB for pain relief in SIP was assessed using conventional, buffered, and precooled 2% lidocaine, leading to the rejection of the null hypothesis.

Anesthetizing mandibular molars with SIP is challenging, with IANB failure rates between 20% and 70%. The pH enhances effective anesthesia by neutralizing tissue acidity, allowing more local anesthetic to remain nonionized, and facilitating better nerve membrane penetration for improved pain control. Achieving effective pulpal anesthesia in acutely inflamed teeth can be challenging, as inflammation reduces the efficacy of the anesthetic by up to eight times. Initially, it was thought that acidosis from inflammation caused ion trapping of anesthetic molecules, but it is now understood that inflammation activates nociceptors and sensitizes nerve

Table 1: Mean comparison of pain, onset of action, efficacy and duration between conventional, buffered and precooled lidocaine

Groups	*n*	Mean±SD			
		Pain b/w groups	Onset of action in seconds b/w groups	Efficacy b/w groups	Duration in minutes b/w groups
Conventional	15	4.42±0.8	139.6±68	4.2±0.7	193.3±14.4
Buffered	15	1.84±0.7	61.1±8.7	1.6±0.6	313.8±36.4
Precooled	15	2.41±0.6	79.6±19	2.5±0.9	278±39.3
Test Statistic		39.043	42.619	36.009	36.412
P		<0.001*	<0.001*	<0.001*	<0.001*
		Pairwise comparison – ***post hoc*** analysis			
Conventional	Buffered	<0.001*	<0.001*	<0.001*	<0.001*
	Precooled	<0.001*	<01*	<0.001*	<0.001*
Buffered	Precooled	0.359	0.034*	0.092	0.250

Kruskal Wallis test; *$P \leq 0.05$ considerable statistically significant



Graph 1: Comparison of pain and efficacy between conventional, buffered, and precooled lidocaine

Table 2 : Comparison of success rate between groups

Groups	No		Yes		Chi-square value	*P*
	n	%	*n*	%		
Conventional	10	63.2	5	36.8	1.462	0.03*
Buffered	3	15.8	12	84.2		
Precooled	5	21.1	10	72.0		

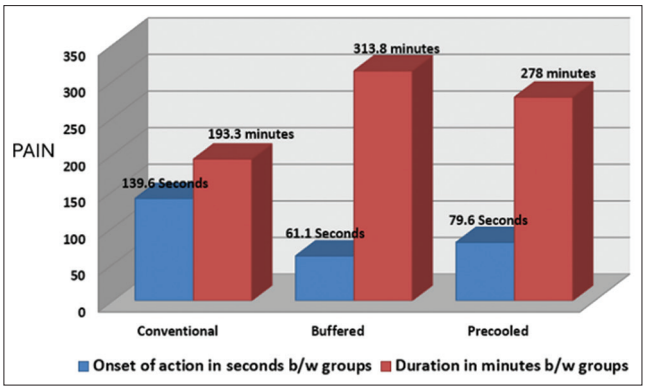
Chi-Square test; *$P \leq 0.05$ considered statistically significant

endings. Contributing factors for the failure of IANB include anatomical variations, accessory innervation, psychological aspects, and resistant sodium channels. Adjusting the pH and temperature of the anesthetic solution may improve effectiveness and reduce injection discomfort.[12]

Pain and discomfort were assessed using the VAS for its reliability and ease of use.[13] Topical ice was applied for 15 s to prevent cold-induced reactions. Pulpal anesthesia was confirmed with the EPT, indicated by two consecutive maximum EPT readings with no response.[14] The effectiveness of the anesthesia was evaluated based on patient feedback during access opening and root canal procedures. Commercial anesthetic solutions are prepared acidic to extend shelf life, but this can contribute to reduced clinical effectiveness.[15]

Buffering local anesthetics accelerates their effectiveness by increasing the proportion of nonionized, active anesthetics that can cross the nerve membrane more efficiently.[16] This leads to a faster onset of anesthesia and reduces the pain and discomfort usually associated with injections which was observed from the results of the current study. The buffering process involves mixing sodium bicarbonate with the anesthetic solution to adjust its pH closer to that of natural tissues. This phenomenon enhances the diffusion of the anesthetic through the nerve membrane, resulting in a quicker anesthetic effect.

Buffering also produces carbon dioxide (CO_2), which lowers the pH within the nerve sheath and further enhances the anesthetic's effectiveness, potentially providing faster pain relief.[17] CO_2 diffuses through the nerve sheath more quickly than the anesthetic. The results demonstrate that the buffered local anesthetic group reported less pain at



Graph 2: Comparison of onset of action and duration between conventional, buffered, and precooled lidocaine

the injection site, higher efficacy, and a longer duration of action than the precooled group, though the difference was not statistically significant. However, for onset of action, the buffered group exhibited a quicker onset of action among all tested groups which was statistically significant, achieving a success rate of 84.2% which correlates with findings from previous studies emphasizing the efficacy of buffered anesthetics in enhancing pain management outcomes.[18]

However, it is essential to use buffered anesthetics soon after their preparation, as they can become unstable and may precipitate if left for too long due to excessive alkalinity. Studies conducted such as those by Condouris and Shakalis[18] have shown that CO_2 significantly enhances nerve conduction blockade in isolated rat sciatic nerve models, and Momsen *et al*. found that buffered lidocaine with adrenaline remains stable for up to 24 h after preparation, hence prompt use is generally recommended to maintain the solution's efficacy.[19,20]

The increased effectiveness of anesthesia observed in the precooled group can be attributed to Setnikar's research[21] on lignocaine's ionization. Setnikar found that cryotherapy slightly raises the ionization constant (pKa) of lignocaine, which enhances the proportion of cationic to base forms. Since the cationic form is the active anesthetic component, this shift increases its potency. In addition, lower temperatures improve the binding of the anesthetic to nerve membrane proteins, leading to more effective and long-lasting anesthesia. Cooling also alters the conformation of membrane proteins that control sodium channel permeability, thereby boosting anesthetic potency.[22] The precooled group showed less pain onsite, quicker onset of action, higher efficacy, and long duration of action when compared to the conventional group. It was also observed that the success rate of the precooled group was lesser than the buffered group but higher than the conventional group.

The use of cryotherapy along with precooled local anesthetic significantly reduces injection pain compared to the control

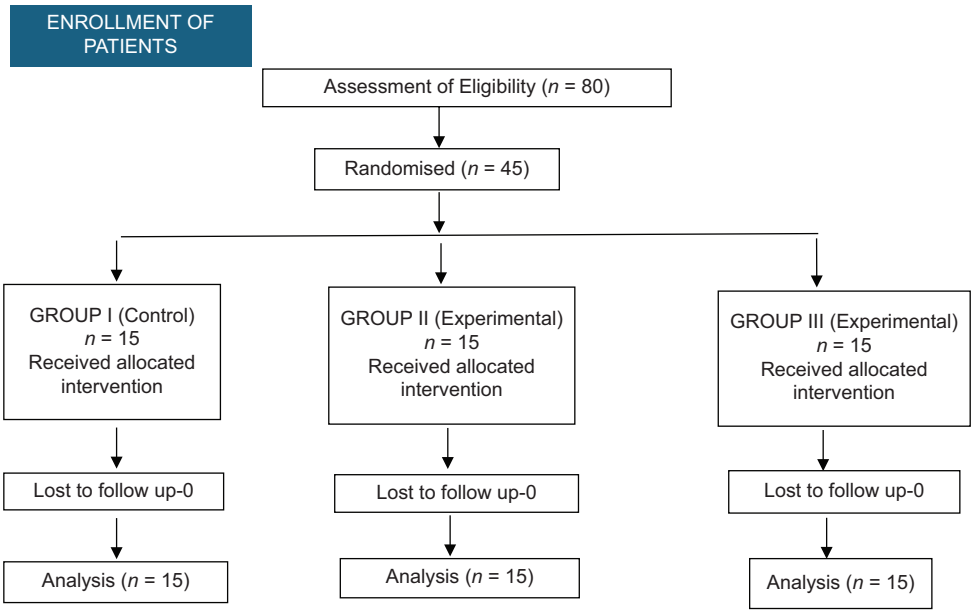


Figure 1: Flow diagram

group. Cold temperatures naturally provide analgesia, and temperatures below 7°C can deactivate A-delta nerve fibers, which are responsible for sharp pain during injections.[23,24] Furthermore, the onset of anesthesia was quicker in the precooled group. Typically, anesthetic molecules need time to diffuse through connective tissues and reach the nerve trunk.[25] A limitation of this study in the buffered group is the use of only one sodium bicarbonate concentration (8.4%). Future research should investigate varying concentrations to evaluate their impact on anesthetic efficacy.

CONCLUSIONS

Anxiety and fear in dental practice often arise from local anesthesia (LA) injections. This study shows that simple, cost-effective methods such as buffered or precooled LA can significantly improve patient comfort during endodontic treatments. Further research should explore the effects of precooled LA at various temperatures and the effectiveness of buffered lidocaine in different scenarios.

Despite limitations, the study confirms that conventional, buffered, and precooled local anesthetics effectively relieve pain in SIP. Buffered anesthetics showed the highest efficacy (84.2%), followed by precooled (72.0%) and conventional (36.8%). Similar research in the future can provide a better correlation to the current findings.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

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