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RESEARCH ARTICLE
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The effect of pH-buffering on lignocaine's anesthetic properties during Inferior alveolar nerve block in children: A randomised controlled trial

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ABSTRACT

Introduction: Pain management during local anesthesia administration is a critical aspect of pediatric dentistry, as procedures like Inferior alveolar nerve block (IANB) are often associated with significant discomfort. Buffered local anesthetics, which adjust the pH of the solution to a more physiological range, have been proposed as a method to reduce pain and accelerate the onset of anesthesia.

Aim: This study aimed to evaluate the efficacy of pH-buffered lignocaine compared to standard lignocaine in terms of pain perception, onset time, and efficacy during dental procedures in children.

Materials and Methods: A prospective randomized controlled trial was conducted with 30 children aged 6–10 years who required bilateral inferior alveolar nerve blocks. Participants were randomly assigned to receive either 2% lignocaine with epinephrine or buffered lignocaine prepared by mixing sodium bicarbonate with lignocaine in a 1:10 ratio. Pain perception was assessed using the Wong-Baker Faces Pain Scale and SEM scale, while onset and efficacy of anesthesia were evaluated through subjective (numbness) and objective (gingival probing) measures. Statistical analysis was performed using SPSS software.

Results: Buffered lignocaine demonstrated significantly lower Wong-Baker pain scores (2.54 ± 1.35) compared to standard lignocaine (3.20 ± 1.05; p=0.007). The onset of anesthesia was faster with buffered lignocaine (60.00 ± 10.38 seconds) compared to standard lignocaine (73.63 ± 13.45 seconds;

p=0.012). Efficacy measures also favoured buffered lignocaine, showing faster achievement of maximum anesthetic effect (75.00 ± 15.35 seconds vs. 85.63 ± 12.37 seconds; p=0.018).

Conclusion: Buffered lignocaine is a more effective alternative to standard lignocaine for pediatric dental procedures, offering reduced pain and faster onset of anesthesia. Further studies are recommended to optimize preparation methods and storage conditions for buffered anesthetic solutions.

Keywords: buffered local anesthesia, painless pediatric dentistry, adrenochrome

1. Introduction

Pain is one of the most common fears associated with dental procedures. For many patients, the mere thought of needles trigger anxiety and discomfort. Pain management is an extremely important step for treatment in pediatric dentistry [1]. IANB and palatal infiltration are considered as the most painful steps for local anesthesia administration [2]. Local anesthesia is defined as the transient loss of sensation in a specific area of body by the depression of nerve ending excitation or inhibition of conduction in the peripheral nerves.[3] Although local anesthetic injections cause pain and anxiety in children, they are an integral part of dental treatment for comfortable, cooperative, and pain-free dental treatment [4]. Two of the primary reasons linked to the pain during local anesthetic administration are site and speed of injection. Secondary reasons being the tissue pH, size of the needle used, choice of anesthesia agent, technique of the dental professional [5].

The pH of local anesthetic solutions ranges from 3 to 6.5. This acidity is known to be the reason of discomfort during injection and delay the onset of anesthesia [6]. The higher acidity of local anesthetics with vasoconstrictor also slows the onset of the anesthetic while it transforms from its ionized to non-ionized form in order to penetrate the lipid membrane of the nerve sheath [7]. In pediatric dentistry, the effect of adjusting the pH of local anesthetics with epinephrine is of interest as a way to reduce pain and time to onset of anesthesia [8].

2. Aim

To evaluate the efficacy of pH buffering of a local anesthetic drug, on the pain, discomfort and onset of local anesthesia injection during dental procedures.

3. Materials and methods

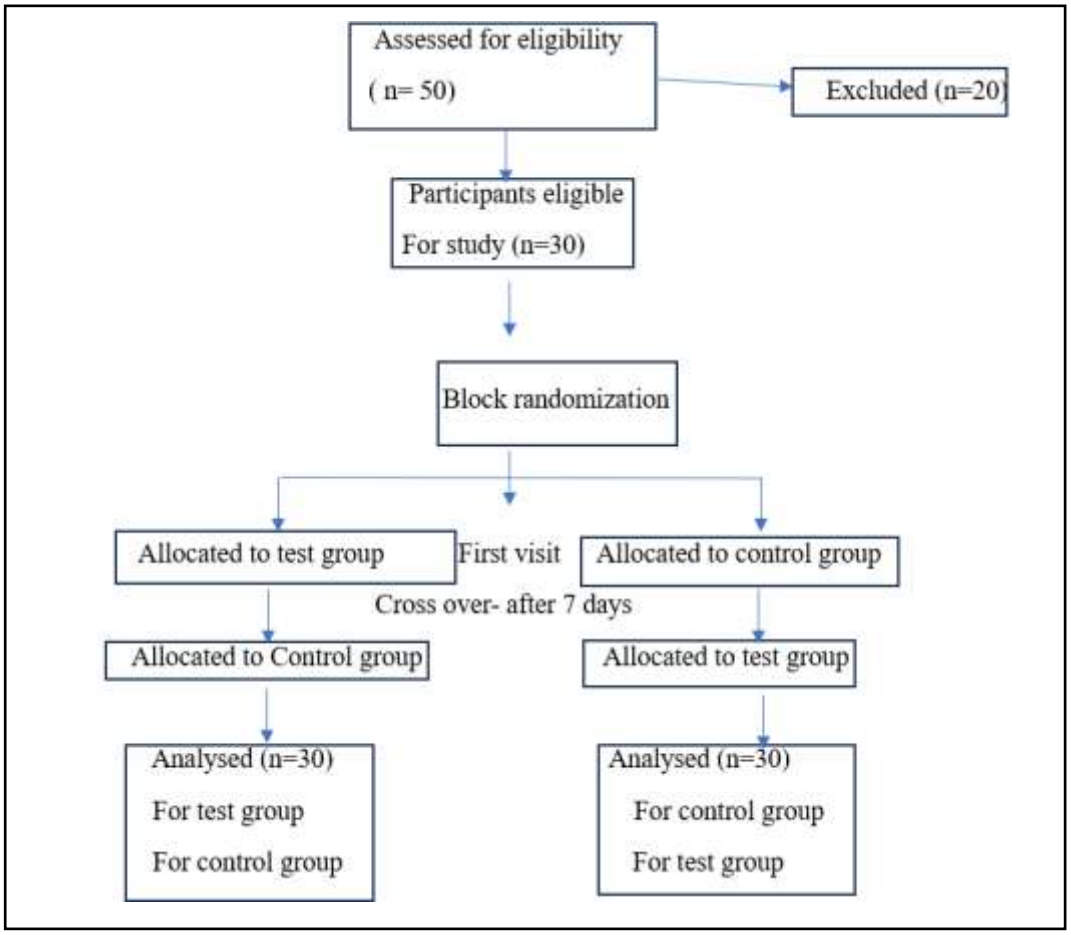
This prospective randomised controlled trial was done in the Department of pediatric and preventive dentistry, College of dental sciences and research centre. All procedures performed in the study were conducted in accordance with the ethics standards given in the 1964 Declaration of Helsinki, as revised in 2013. The Institutional Ethical Committee approval for the study was obtained (CDSRC/IEC/2024/31) and was done in accordance with the consolidated standards of reporting trials. The study was registered under Clinical Trial Registration of India with CTRI number (**CTRI/2025/03/082187**). An informed consent was taken from all the participants. The sample size was calculated using the following formula:

$$n = \frac{z2 \times P \times (1-P)}{E2}$$

With a confidence level of 95% and probability of 0.05, sample of 30 healthy children were recruited for the study.

The patients between 6 and 10 years of age who: 1) had not undergone any prior dental treatment; 2) require bilateral IANB and, 3) exhibited Frankl's behaviour rating grade three or four were included

and patients who: 1) were allergic to local anesthesia; 2) had a history of a medically-compromised condition or, 3) had already undergone dental treatment for any other tooth were excluded.



Subjects were randomly allocated in a ratio of 1:1 via balanced Latin square design into 2 groups: Group 1-Test group and Group 2- Control group. Each patient was randomly assigned to receive either 2% lignocaine with 1:200,000 epinephrine or buffered lignocaine, for the first visit; the other two local anesthetic solutions were administered in the second and third visit randomly. Buffered lignocaine was freshly prepared by mixing sodium bicarbonate with lignocaine solution in a 1:10 ratio by volume. A 30 ml vial of commercially available 2% lignocaine hydrochloride with 1:200,000 epinephrine and 3 ml of 8.4% bicarbonate (Neon Laboratories Ltd.) were mixed into the vial to make the final preparation. The pH of the commercially available solution was found to be 4.33, while the pH of the buffered solution was 7.32. Either solution, at a volume of 1.8 ml, was dispensed in a disposable 2 ml syringe with a 27-gauge needle, which was used for all inferior alveolar nerve block injections.

For assessment of primary outcome that is pain perception- assessed by SEM scale (Figure 1) and Wong- baker faces pain rating scale (Figure 2) and for assessment of secondary outcomes, the time of onset and efficacy of analgesia were determined.

Observations	1. Comfort	2. Mild Discomfort	3. Moderately Painful	4. Painful
Sounds	No sounds indicating pain	Nonspecific sounds; possibly indicating pain	Specific verbal complaints, e.g., "ow", raising voice	Verbal complaints indicating intense pain, e.g., screaming, sobbing
Eyes	No eye signs of discomfort	Eyes wide, showing concern, but no tears	Watery eyes and/or flinching eyes	Crying, tears running down face
Motor	Hands relaxed; no apparent body tenseness	Hands show some distress or tension, grasping chair due to discomfort, muscular tension	Random movements of arms or body without aggressive intention to make physical contact, grimace, twitch	Movements of hands trying to make aggressive physical contact, e.g., punching, pulling head away

Figure:1 Sounds, eyes and motor scale

Figure:2 Wong baker faces pain rating scale

3.1 Assessment of pain perception

On the day of the appointment, every patient was reassessed for inclusion and exclusion criteria. After seating the patient on the dental chair, topical anesthetic agent (Procaine-B 20% Benzocaine) was applied over the injection site one minute before the injection. The first researcher then administered the local anesthetic solution using the standardized inferior alveolar nerve block (IANB) technique. The first operator was handed the loaded syringe (2 ml disposable syringe with 27-gauge needle) and was unaware of the type of local anesthesia that he was administering. The trained assistant who was pre-calibrated and blinded to the type of solution recorded the SEM scale during anesthetic deposition from a distance of 1.5 meters.

Using a standardized Wong-Baker Faces pain scale (WBFPS), pain perception was also judged subjectively by the patient who was also blind to the type of anesthetic agent. The child was asked to point at the face as per his experience. Subsequently, the number corresponding to the face selection was recorded.

3.2 Assessment of efficacy of anesthesia

Efficacy of anesthesia was assessed both objectively and subjectively. The subjective sign was assessed by repeatedly asking the child about numbness on the tongue, corner of the mouth, and lip every 30 seconds; this was repeated until the child experienced complete numbness. The objective sign was assessed by gingival probing as explained above for the onset of anesthesia; this was repeated until the child experienced the complete absence of pain.

3.3 Assessment of onset of anesthesia

The onset of anesthesia was measured in seconds by an objective sign (gingival probing). Probing was carried out with a blunt-ended Williams's periodontal probe by gently probing on the gingival, which was initiated 30 seconds after injection and checked every 15 seconds using a stopwatch until the child patient experienced the absence of pain.

The data were recorded and subjected to statistical analysis using the statistical package for the social sciences (SPSS) 20.0 software.

4. Results

The analysis was conducted using SPSS 20.0 software to ensure accurate computation and interpretation of the results.
The statistical analysis performed in this study included the following tests:
1. Independent t-test: This test was used to compare the means of pain perception scores (Wong-Baker Faces Pain Scale and SEM scale), onset of anesthesia, and maximum efficacy time between the two groups (buffered lignocaine and standard lignocaine).
2. p-value Calculation: A p-value threshold of <0.05 was set to determine statistical significance. Results with p-values below this threshold were considered significant, indicating a meaningful difference between the groups.

4.1 Pain Perception

- Wong-Baker Faces Pain Scale: Buffered lignocaine demonstrated significantly lower pain scores (2.54 ± 1.35) compared to standard lignocaine (3.20 ± 1.05), with a p-value of 0.007.
- SEM Scale: While buffered lignocaine showed slightly lower scores (1.80 ± 0.35) than standard lignocaine (2.10 ± 0.45), the difference was not statistically significant (p=0.102).

4.2 Onset of Anesthesia

- Buffered lignocaine achieved a faster onset time (60.00 ± 10.38 seconds) compared to standard lignocaine (73.63 ± 13.45 seconds), with a statistically significant p-value of 0.012.

4.3 Maximum Efficacy Time

- Buffered lignocaine showed quicker achievement of maximum efficacy (75.00 ± 15.345 seconds) versus standard lignocaine (85.63 ± 12.37 seconds), with a statistically significant p-value of 0.018.

4.4 Subjective and Objective Signs

- Subjective Evaluation: Buffered lignocaine resulted in faster numbness onset as reported by patients.
- Objective Evaluation: Gingival probing revealed faster maximum efficacy for buffered lignocaine (77.4 ± 12.45 seconds) compared to standard lignocaine (86.4 ± 15.50 seconds), with a significant p-value of 0.022.

Table 1 Pain perception score

Group	Wong Baker Faces Pain Scale	SEM scale	p-value
Group 1	2.54 ± 1.35	1.80±0.35	0.007*
Group 2	3.20 ± 1.05	2.10±0.45	0.102

(p-value < 0.05)

Table 2- Onset of anesthesia (Seconds)

Group	Onset of anesthesia	p-value
Group 1	60.00 ± 10.38	0.012*
Group 2	73.63 ± 13.45	0.230

(p-value < 0.05)

Table 3 Maximum efficacy time (Seconds)

Group	Time for maximum efficacy	p-value
Group 1	75.00 ± 15.345	0.018*
Group 2	85.63 ± 12.37	0.341

(p-value < 0.05)

Table 4 Subjective sign evaluation (gingival probing)

Group	Maximum efficacy	p-value
Group 1	77.4 ± 12.45	0.022
Group 2	86.4 ± 15.50	0.602

(p-value < 0.05)

5. Discussion

In pediatric dental practice, managing pain is crucial during local anesthesia administration. Along with pain management patients do experience the discomfort and unpleasant sensation, especially during inferior alveolar nerve block.[4] One explanation for the discomfort associated with the administration of local anesthesia is the acidic nature of commercially available local anesthetics, which generally have a pH of approximately 4.5. This acidity is intentionally adjusted to extend the shelf life of the anesthetic. Within the cartridge, the molecules primarily exist in a water-soluble, ionized state (RNH+). For effective penetration of the anesthetic through the nerve sheath, it is essential for the substance to be in its unionized free base form; this requires the dissociation of the H+ ion from the ionized molecule [9]. Given that the physiological pH is approximately 7.4, an increase in H+ ions within the tissues may induce pain by activating nociceptors, including acid-sensing ion channels (ASICs). [10].

There exists a robust theory explaining that when sodium bicarbonate ($NaHCO_3$) is combined with anesthetic agents, a reaction occurs between $NaHCO_3$ and hydrochloric acid (HCl) in the local anesthetic, resulting in the formation of water (H_2O) and carbon dioxide (CO_2).[8]. It has been reported that carbon dioxide (CO_2) can provide independent anesthetic effects that enhance the action of anesthetics by sevenfold. After injection, CO_2 quickly diffuses out of solution and increases the efficacy of lidocaine by directly depressing the axons, which alters the charge of the nerve.[3].

Buffering the local anesthetic solution can lead to reduced pain during administration by minimizing the activation of acid-sensing nociceptors. Furthermore, utilizing alkalinized agents facilitates a quicker transition of the solution from its ionized to unionized form. This process enhances nerve penetration and results in a more rapid onset of the anesthetic effect. [3,8].

The buffer agent used in all this study was sodium bicarbonate. The buffered anaesthetic solution was always prepared immediately before injection, manually. The most frequent buffer concentration is 8.4%, which was used in our study. Final pH of the buffer anaesthetic solution which ranged between 6.5 and 7.59.

The inferior alveolar nerve block is often regarded as one of the most challenging and discomforting procedures in pediatric dentistry, highlighting the need for innovative approaches to reduce pain and anxiety in young patients. [2] The present study employed this procedure to compare the pain perception and efficacy of local analgesia. However, because pain is extremely difficult to quantify in children, two different scales were used for pain assessment. The Wong-Baker Faces pain scale was utilized for subjective pain measurement and demonstrated good construct validity as a self-report tool [12]. In contrast, the SEM [11] is an objective scale that assesses pain or discomfort by considering the child's responses to stimulation.

In the present study, pain perception recorded with the help of the self-reported score (Wong-Baker scale) were different for all formulations, and the patients showed a preference for buffered lignocaine. The difference between lignocaine and buffered lignocaine was statistically significant. However, the SEM scale score recorded for pain perception between lignocaine and buffered lignocaine was not statistically significant.

The result of this study showed that Wong-Baker and SEM scores were lower for buffered lignocaine than lignocaine; this could be attributed to the decreased tissue irritation from the more physiologic pH of the buffered solution. Alternatively, because buffering increases the concentration of uncharged

lignocaine particles, the faster onset of nerve blockade may help explain the decreased sensation of pain.

Pain score obtained from both scales for buffered lignocaine was lesser compared to lignocaine, even though the difference was not significant

In the current study, the time to onset after administering a local anesthetic agent was found to be statistically significant between lignocaine and buffered lignocaine. However, Whitcomb et al. [13] and Hobeich et al. [14] did not demonstrate a faster onset with buffering for the inferior alveolar nerve block and maxillary infiltrations, respectively. Additionally, Chow et al. [15] discovered that alkalinizing a local anesthetic did not accelerate the onset of a regional upper limb nerve blockade.

In the present study, we assessed the efficacy of different local anesthetics, specifically lignocaine and buffered lignocaine, using both subjective signs (such as numbness in the lip, tongue, and corner of the mouth) and objective signs (pain during probing). The results suggest that buffered lignocaine is a more effective local anesthetic.

Taking into consideration altered chemistry of local anesthetic solution, physical and chemical stability of buffered local anesthetics should also be kept in mind.

Pascuet et al. [16] in 2009 stated both 1% and 2% buffered lidocaine diluted (10:1) with 8.4% sodium bicarbonate were chemically stable for 28 days when packaged in polypropylene syringes and stored at 5°C with protection from light. Buffered lidocaine solutions containing epinephrine (1:100 000) remained stable for only 7 days when stored in polypropylene syringes at 5°C with protection from light.

Figure:3 and Figure:4 Change of colour of the local anesthetic solution from clear to pink.

Further observation of the colour stability of buffered lignocaine was the colour of the solution changed to pink after 40 days (Figure 3 and 4). The explanation for this can be adrenochrome is that is produced when epinephrine undergoes oxidation, often in the presence of air or certain oxidizing agents. Sodium bicarbonate raises the pH of the solution, making it more alkaline. Adrenaline is stable in an acidic environment but becomes prone to oxidation in an alkaline pH. Oxidation of adrenaline leads to the formation of adrenochrome, which gives the solution a pinkish, brown or reddish tint.

Reaction with oxygen and light: Alkaline conditions speed up the oxidation of adrenaline when exposed to oxygen. This oxidation can also be influenced by light, heat and metal ions present in the solution. Therefore, it is suggested to buffer the solution immediately before use. For storage, store the buffered solution in airtight, dark containers in regulated temperature.

Some other procedural, behavioural, and pharmacological strategies have been proposed to alleviate pain and discomfort during pediatric dental treatment. These include

1) Topical Anesthetics
2) Distraction Techniques
3) Needle Selection and Technique- Smaller-gauge needles and slow, steady injection techniques significantly reduce pain.
4) Warming the Solution
5) Precooling the site of injection

By combining these methods, we can create a more positive experience for our pediatric patients. A study by Chopra R et al. reported no difference in pain perception between lignocaine and buffered lignocaine. Malamed et al. [3] and Kashyap et al. [17] both studies reported that injections with alkalinized 2% lignocaine were more comfortable when used for the inferior alveolar nerve block. Dhake et al. [2] in his 2022 study, it was concluded that using buffered articaine for maxillary primary molar extraction resulted in less pain during injection, a faster onset of anesthesia, and reduced discomfort during extraction. Gandhi et al. [5] in in 2022, it was reported that warm and buffered local anesthetics (LAs) were more effective in reducing intraoperative discomfort than conventional LAs. Preheated LAs resulted in the least pain, followed by buffered LAs, while conventional LAs caused the most pain. Afsal et al. [18] in 2019 the study concluded that buffered lignocaine is the least painful agent for injection in patients aged 5 to 10 years. Furthermore, a statistically significant difference was observed in the local anesthetic efficacy among lignocaine, buffered lignocaine, and articaine. Buffered lignocaine emerged as the most efficacious anesthetic agent; however, both articaine and lignocaine demonstrated comparable effectiveness.

6. Conclusion

For patients aged 6-10 years buffered lignocaine was found to be less painful agent during injection. Its ability to provide faster onset, reduced injection pain, and improved patient comfort makes it an ideal choice, especially in pediatric dentistry where patient cooperation is essential. By adopting buffered lignocaine, we can significantly improve the quality of care we provide to our young patients.

7. Limitations

The limitations of the study include, the relatively small sample size, limiting the generalizability of the findings. Pain perception in children is subjective and can vary with emotional state, which may affect the reliability of self-reported pain scores. Additionally, the freshly prepared buffered lignocaine solution lacks long-term stability. The study focused only on immediate outcomes like pain perception, onset time, and efficacy during the procedure, without evaluating long-term outcomes (e.g., post-operative pain, delayed reactions, or overall treatment experience).

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9. Conflict of interest

There was no conflict of interest between the authors and the study protocols and the conclusion has been accepted unanimously.

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