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Effect of local anesthesia stored at different temperatures and its influence on pain perception in children: A randomized clinical trial

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Abstract

Background: Administration of local anesthesia (LA) is vital in invasive dental procedures, particularly in children as it invokes pain leading to uncooperative behavior and ensures future compliance. Inadequate anesthesia can lead to procedure failure, heightening fear and anxiety. Techniques to minimize pain include application of topical anesthesia, buffering with sodium bicarbonate, using fine needles, and delivery of LA agent slowly. The recent studies are focusing on effect of adjusting temperature of LA solution and its effects on pain. The observations showed there is decrease of pain during administration. **Aim:** To evaluate pain perception and onset of action on administration of local anesthetic solution (LA) at different temperatures. **Settings and Design:** The study has been conducted in patients attended the Department of Pediatric and Preventive Dentistry. It is randomized, control, three arm study. The research group comprises individuals in the age group of 6 to 12 years. **Material and Methods:** Group 1: Lignocaine at 45°C. Group 2: Lignocaine at 40°C. Group 3: Lignocaine stored at room temperature 25-30 °C. Pain was assessed using WONG-BAKERS FACES PAIN SCALE. Statistical analysis: One Way Anova tests and Post-Hoc Tukey Tests were used. **Results:** Pre-warmed and cooled local anesthetic solutions resulted in less pain on injection ($P < 0.001$, $P < 0.017$) and faster onset of action ($P = 0.062$, $P = 0.045$) when compared with conventional local anesthesia. **Conclusions:** Pre-warming and pre-cooling the anesthetic solution reduced pain on administration and during the procedures in children.

Keywords: Pain, Pre-cooled LA, warm LA

Introduction

Local anesthesia is defined as a temporary loss of sensation in circumscribed area of the body caused by a depression of excitation in nerve endings, or an inhibition of the conduction process in peripheral nerves [1]. Local anesthesia administration is the first and foremost approach for most of the procedures in dentistry which is painful [2]. To reduce the discomfort during local anesthesia administration, changing of the anesthetic solution temperature can be used. It is evident that heat induces vasodilation, while cold induces vasoconstriction [3].

Cold temperature has analgesic effects. In the field of neuroscience, cooling of lignocaine was set up to have beneficial effects like faster onset of action and increased duration of action [4]. Dabarakis et al. showed that mepivacaine at a temperature of 4°C had a longer duration of pulpal anesthesia for the maxillary first premolar

compared to mepivacaine at room temperature [5]. Warming anesthetic solution to body temperature has effectively reduced pain during injection for eye and plastic surgery and thus may have relevance in dentistry [6].

The Wong-Baker Faces Scale (WBFS) has been demonstrated in multiple pediatric settings for pain assessment [7]. This scale can be utilized directly and accurately in children aged three years and older. Its validity and reliability have been established through studies conducted in diverse settings and populations, encompassing individuals between the ages of 3-18 years [7]. Also, the Faces Scale was the most favored instrument by kids and parents among the different evaluation instruments. The aim of the present study was to evaluate pain perception and onset of action on administration of LA solution at different temperatures.

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Materials and methods:

A. Source of data:

The research was performed on patients visiting the Department of Pediatric and Preventive Dentistry.

Study design

It is double-blind, randomized; control study with a three-arm design conducted according to Consolidated Standards of Reporting Trials (CONSORT) guidelines. The participants included children aged 6-12 years, were chosen according to specific eligibility criteria.

Ethics

The study was approved by the Institutional Ethical Committee and the University of Health Sciences under protocol number IEC No: PMVIDS & RC/IEC/PEDO/PR/457-21. Informed statement of consent was obtained from parents/caregivers before child's participation in the research.

Inclusion criteria:

1. ASA class-1 patients aged 6-12 years
2. Child with positive or definitely positive behavior on the Frankl behavior rating scale (rating III or IV on the Frankl scale)
3. Children with no prior experience of dental anesthesia
4. Children require extractions in three quadrants with infiltrations.

Exclusion criteria

1. Children with a history of medically compromising conditions
2. Allergy to lignocaine
3. Abscess or swelling at the site of injection
4. Soft tissue lesion at the site of injection.

B. Method of collection of data and procedure

Materials

- Disposable 2ml syringes with a 27-gauge needle
- 2% Lidocaine local anesthetic solution
- Baby bottle warmer
- Refrigerator
- WONG BAKER faces pain scale

Procedure:

The study was conducted on 30 patients under aseptic conditions. This is a randomized, control, three arm study with split mouth technique.

For Group 1, (Lignocaine at 45°C) local anesthetic solution was placed in baby bottle warmer. Group 2, (Lignocaine at 4°C) local anesthetic solution was placed in the refrigerator and cooled. Group 3, Lignocaine at room temperature 25-30°C (control group). This study was carried out with the help of two researchers. The randomization was carried by the principal investigator, directing participants to choose between two colored balls, red representing warm and blue indicating cool. This choice determined the side for application and the type of modified local anesthetic solution (warm or cold) for the initial injection. Before anesthesia administration, the injection site was cleaned with sterile gauze, and a topical anesthetic gel was applied for one minute using a cotton pellet.

Temperature control of the anesthetic solution

A baby bottle warmer, similar to those used in previous reports, was employed. The anesthetic solution was placed in the warmer with 300 ml of water, and the anesthetic fluid reached a temperature of 45°C (107.6°F) within 3 minutes.

For cooling the anesthetic solution, it was refrigerated before injection. During the dental procedure, a 0.6ml volume of a local anesthetic solution, consisting of either warm or cold 2% lignocaine with 1:80,000 epinephrine, was meticulously deposited over 20 seconds using a 27-gauge needle into the height of the mucobuccal fold. The needle was skillfully positioned parallel to the long axis of the tooth, constituting the initial infiltration. Subsequently, a second infiltration ensued with the chosen local anesthetic solution in the second quadrant, followed by a third injection in the control group (group 3) solution in the opposing quadrant. Secondary investigator, who was blinded to the solution type, recorded the patients' pain scores using the Wong-Baker Faces Pain Scale after the administration for all the groups. The onset of anesthesia was assessed through both subjective and objective symptoms, along with gingival probing. The probing process commenced 3 minutes post-injection and was systematically

conducted every 15 seconds until the patient confirmed the absence of pain during probing. To uphold the trial's blind nature, the assigned interventions for each group were kept concealed from both the patients and the principal investigator.

The data collected for all the parameters was subjected to statistical analysis. The data was analyzed using the Statistical Package for Social Sciences (SPSS) to identify statistically significant values, with a p-value less than 0.05 one-way Anova tests and Post-hoc Tukey tests are used.

Results:

Initially, the study involved forty children aged between 6 and 12 years. However, due to drop-outs (denied after first or second treatment), resulting the total sample size to 30 (n=30).

Pain on administration (Tab. 1, 2) (Fig. 1)

The level of pain perceived according to the Wong-Bakers faces pain scale by the warm LA group was significantly lesser than that of the cold and room temperature LA group ($P < 0.001$) (Tab 1) (Fig 1). Intergroup comparisons revealed statistically significant differences in mean p values among the groups. Specifically, Group I versus Group II exhibited $p = 0.659$, Group I versus Group III showed a substantial difference $p = 0.001$ which is statistically significant, and Group II versus Group III displayed a notable distinction $p = 0.017$ (Tab 2).

Onset of anesthesia (Tab. 3, 4) (Fig. 2)

The mean times of the onset of anesthesia revealed a faster onset of action for both warm and cold LA solutions than the room temperature LA (Tab 3) (Fig 2). The intergroup comparisons unveiled distinct patterns in mean Q values and associated P values. Group I and Group II rendering a non-significant p-value of 0.990. Conversely, comparisons of Group I with Group III and Group II with Group III exhibited noticeable trends. The P values ($p = 0.062$) for Group I vs. Group III and ($p = 0.045$) for Group II vs. Group III, suggesting potential differences in the measured parameters between these groups.

Discussion:

In children, dental procedures can cause stress, anxiety, and pain. Approximately 20% of children have been shown to have dental fears and 21% exhibit negative behaviors in the dental settings [8]. Anxiety and pain often lead to children crying and screaming during dental procedures. Preventive anticipatory interventions could be useful in these kinds of stressful situations because they could break the cycle of unpleasant memories resulting from the painful experience, which in turn can intensify pain and anxiety [9]. Since its commercial launch in 1948, lignocaine has demonstrated a high degree of effectiveness and a low frequency of adverse effects [10, 11]. These attributes have been confirmed by clinical use and research, making lignocaine the "gold standard" to which all new local anesthetic solutions are compared. The success of mandibular block anesthesia has traditionally been determined by the presence of a feeling of "lip numbness" [12]. Soft tissue anesthesia cannot be reliably correlated with true pulpal anesthesia, so an objective method of measurement is required.

Studies have shown that warming LA solution before injection reduces pain. Nonetheless, alternate studies have proposed minimal or negligible impact. According to Arndt et al, there is no significant difference between LA at 37°C and that at room temperature 21°C. Bell et al (1996) and Alonso et al (1993), however, have shown benefit in warming the solution to 37°C and 42°C in prospective blinded randomized control studies [13]. Alonso et al. reported an inverse relationship between temperature and pain and reported that the highest mean pain level occurred at 10°C followed by 18°C, 37°C and 42°C [14]. With new policies of cooling LA at 4°C, particularly those containing adrenaline, there may indeed be an advantage to warming the solution to near body temperature.

There is a strong correlation between LA activity and pH, with LA activity increasing as pH rises (alkaline) and more particles become unionized [15]. Warming and buffering may reduce LA pain by shifting the dissociation constant so that a greater proportion of particles are uncharged [15]. During nerve conduction, uncharged particles can diffuse more readily into the nerve, inhibiting it more effectively and rapidly. It has been shown that increasing the anesthetic solution's

temperature prior to administration helps patients feel less discomfort. Although the cause of this is unknown, there are numerous theories. Warming the injection may either directly decrease stimulation since nerve terminals are cold-sensitive, or it may accelerate the onset of the block and prevent pain from spreading before the nociceptive impulses are fully perceived [16]. Another explanation is that the pKa value (dissociation constant) of local anesthetics are temperature dependent and when warmed, this pKa value decreases, allowing more of the active deionized form of the anesthetic to penetrate into the nerve membrane [17]. This form of the local anesthetic agent results in rapid anesthesia and minimizes pain during injection. According to study by Powell, pKa of lignocaine is 7.57 at 40°C and 7.92 at 25°C. Consequently, warming of lignocaine would possibly increase the onset and the quality of local anesthesia [18].

The present study had results much similar to that study conducted by Bainbridge et al, who compared the effect of local anesthetics at room temperature and body temperature for procedures on the cheek and chin and found that patients perceived drastically much less pain when injected with local anesthetic agents at body temperature [19]. The effects were additionally much similar to those reported by Rogers et al, who found in a study carried out with dental students aged 22 to 32 years, using the VAS measure, that the warmed dental injection was turned into substantially more comfortable than the ambient-temperature injection [20,21]. In accordance with the present study, Westblade in 1968 recommended that the onset and degree of anesthesia might decrease with cool solutions [22].

The findings have been contrary to a study conducted by Ulu et al, who compared warmed anesthetic solutions and solutions at room temperature in a split-mouth design on 46 adult patients requiring extraction of the third molar and found no statistically significant difference among the two groups [6]. A study carried by Ram et al also showed opposite results while comparing warm and room-temperature anesthetics for dental techniques and discovered no significant differences between the two [23]. A latest systematic review and meta-analysis by Hogan et al. concluded that greater research was

required to have conclusive evidence on the advantages of warming anesthetic solutions in dental procedures and its impact on children [24].

The present study used Wong Baker scale for subjective pain assessment in the present study since it has been reported to be effective in children 3–16 years of age and may be more easily understood than the visual analogue scale (VAS) scale [25]. This study is the first of its kind, examining the effects of warm and cold local anesthetics on pediatric patients. The results verified that the altered solutions were better in every aspect, including statistical and clinical ones.

Limitations

The study, assessing pain perception and onset of action during pediatric dental procedures with varied local anesthetic temperatures, offers valuable insights. Limitations include age group specificity (6 to 12 years) and subjective pain reporting. The research is conducted in a specific department, and the results may be influenced by local practices and patient demographics. Conducting multi-center studies could enhance the generalizability of the findings. Despite these constraints, the research provides crucial information for pediatric dentistry, underscoring the significance of temperature considerations in optimizing pain management during dental procedures.

Conclusion

The study crucially addresses pediatric dentistry's pain management, influencing young patients' behavior and future compliance. Utilizing the WONG-BAKERS FACES PAIN SCALE enhances pain assessment reliability. Findings propose practical, clinically applicable strategies involving temperature variations in local anesthetic solutions. The study's credibility and potential impact on pediatric pain management improvement are underscored by these strengths. In conclusion, warm and cold solutions significantly reduce pain during administration and dental procedures, demonstrating a faster onset of action in children compared to conventional room temperature anesthesia.

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Conflicts of interest

There are no conflicts of interest

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Figure Legends

Figures:

Fig.1 Intergroup comparison of PAIN PERCEPTION

Fig.2 Intergroup comparison of ONSET OF ANESTHESIA

Tables:

Tab.1 Intergroup comparison of PAIN PERCEPTION

Tab.2 Intergroup comparison using POST-HOC TUKEY test

Tab.3 Intergroup comparison of ONSET OF ANESTHESIA

Tab.4 Intergroup comparison using POST-HOC TUKEY test

Tables**Table 1**

GROUP	SAMPLES (n)	MEAN	SD	P VALUE
Warm LA	30	1.33	1.42	0.001*
Cold LA	30	1.66	1.58	
LA at Room temperature	30	2.73	1.43	

*significant

Table 2

GROUPS	MEAN	Q value	P value
Group I vs. Group II	M ₁ =1.33 M ₂ =1.67	1.23	p =0.659
Group I vs. Group III	M ₁ =1.33 M ₃ =2.73	5.17	p =0 .001
Group II vs. Group III	M ₂ = 1.67 M ₃ =2.73	3.94	p = 0 .017

Table 3

GROUP	SAMPLES	MEAN	SD	P VALUE
Warm LA	30	112.9	38.8	

Cold LA	30	111.5	39.5	0.028
LA at Room temperature	30	137.9	47.6	

Table 4

GROUPs	MEAN	Q value	P value
Group I vs. Group II	M ₁ =112.97 M ₂ =111.50	0.19	p = 0.990
Group I vs. Group III	M ₁ =112.97 M ₃ =137.93	3.24	p = 0.062
Group II vs. Group III	M ₂ = 111.5 M ₃ =137.93	3.43	p = 0.045