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Effect of Different Approaches of Delivering Local Dental Anesthesia on Pain Perception in Children. A Double Blinded Randomized Controlled Clinical Trial

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Aim: To evaluate and compare the efficacy of warm local anesthesia (LA) (37 °C), buffered LA, and the use of an external cold and vibrating Buzzy device in reducing pain associated with maxillary infiltration injection in children in comparison to the conventional approach.

Material and methods: Eighty cooperative, systemically healthy children, aged 6–12 years were randomly selected from the Pediatric Dental Clinic at the Faculty of Dentistry, Mansoura University. A randomized controlled clinical trial design was used, wherein each child was randomly allocated to one of the following methods: Group A (conventional method) used 20% topical benzocaine gel. Group B received a warm LA of 37 °C. Group C received buffered LA, whereas 0.1 ml of 8.4% sodium bicarbonate was injected directly into the anesthetic carpule. Group D used a Buzzy device during injection. Sound, eye, and motor (SEM) and Wong Baker face pain rating (WBFPR) scales were used for evaluating the pain during LA injection. Data were collected, tabulated, and statistically analyzed at a 5% level of significance ($p \leq 0.05$). The four groups were compared with the ANOVA test (parametric) and the Kruskal-Wallis test (non-parametric). The Mann-Whitney test was used to compare two groups.

Results: The most significant finding to reduce injection pain was found in the buffered LA and Buzzy device groups, followed by warm LA, while the conventional method had the least impact on reducing pain.

Conclusion: Buffered LA, Buzzy device, and warm LA were more effective than conventional method in pain reduction during maxillary infiltration injection in children.

Keywords: Warm, buffered, Buzzy, pain, local anesthesia.

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Introduction

Local anesthesia has a key role in controlling pain during dental procedures, but most pediatric patients experience fear and anxiety regarding the pain caused by the injection. Hence, ensuring minimal discomfort and pain for children has consistently been a top priority in pediatric dentistry.[1] Applying a topical anesthetic agent before injection is the predominant method used to manage initial needle penetration pain. Several studies have successfully documented its effectiveness in alleviating the pain linked to LA injection.[2-4]

Various approaches have been developed to overcome the pain sensation of needle injection. Warming the local anathesia agent to body temperature (37°C) has been recommended to reduce pain during the injection of LA. [5] The physiological mechanism by which temperature reduces pain may involve a synergistic effect on the permeability of the Transient Receptor Potential Vanilloid-1 channels, which are heat-activated receptors. This effect enables the passage of anesthetic solution into the nociceptors, potentially contributing to pain reduction. [6]

Buffered LA to a pH value closer to the physiological pH is another approach that has been proven to reduce the pain perception associated with the administration of LA and decrease the onset time. With an increase in the pH of the solution, more free bases will be available to cross the nerve sheath, thereby reducing the onset time.[7]

Another non pharmacological approach to control injection pain involves using external cold and vibration, such as with the Buzzy device. Melzack and Wall [8] described its analgesic effect through the gate control theory of pain, wherein it modifies an individual's pain perception by transmitting non-pain signals (vibration or cold) while simultaneously masking the pain signals induced by the injection. [9]

Since assessment of pain reveals the severity of pain and estimates the effectiveness of potential interferences, many age-specific pain assessment tools and scales have been developed. As pain is a subjective experience, self-reporting techniques are acknowledged as the most accurate indicators of pain. Behavioral and physiological signs should be observed in conjunction with self-reports. Variations in the pain assessment techniques are useful to accurately estimate pain intensity in children. [10]

The most common self-reported pain measure scales are the Visual Analogue Scale (VAS), Wong-Baker Faces Pain Scale (WBFPS), Faces Pain Scale-Revised (FPS-R), and Facial Anxiety Scale (FAS).[11] Behavioral pain assessment is applicable for preverbal children and those unable to comprehend self-report scales, as it evaluates indicators such as crying, facial expressions, body posture and movement, and disruptions in daily routines. Common behavioral measures include the Face, Legs, and Arms Cry Consolability Scale (FLACC), the Sound, Eye, and Motor Scale (SEM), the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS), and the Non-Communicating Children's Pain Checklist-Revised (NCCPC-R). [12]

Effective administration of LA with minimal pain is crucial for dentists, especially when dealing with children, to achieve successful dental treatment, trust, cooperation, and a positive experience. [13] However, there is a paucity of studies comparing the efficacy of different approaches to reduce the injection pain of LA in children. Therefore, this study was conducted to evaluate and compare the effect of three different approaches during the injection of maxillary infiltration LA (warm LA, buffered LA, and Buzzy device) on pain perception in children, in comparison to the conventional method. The null hypothesis is that there is no significant difference between

the different approaches of LA administration (conventional, warm LA, buffered LA and and Buzzy device) in reducing dental injection pain in children.

Materials and methods

Study design

This study is a double-blinded randomized controlled clinical trial (RCT). The study design followed the Consolidated Standards of Reporting Trials (CONSORT) [14] guidelines, as shown in (Figure 1). The children who contributed to this study were randomly selected from the pediatric dental clinic, Faculty of Dentistry, Mansoura University, with the following specified criteria for inclusion and exclusion:

Inclusion criteria [15]

1. Children in need of maxillary LA for dental treatment.
2. Cooperative children who scored positive (score 3) or definitely positive (score 4) on Frankel's scale.[16]
3. Children who were systemically healthy and not taking any medications that could potentially affect their perception of pain.
4. Children with no known history of allergy to Mepivacaine LA.

Exclusion criteria [15]

1. Children who have medical conditions, neurosensory impairments, and psychiatric disorders.
2. Uncooperative children, who scored definitely negative (score 1) and negative (score 2) on Frankel's scale, including those with previous traumatic or negative dental experiences.
3. Children who are unable to understand the pain assessment methods.
4. Children experiencing emergencies or acute dental issues.
5. Children with periapical pathology at the site of injection.

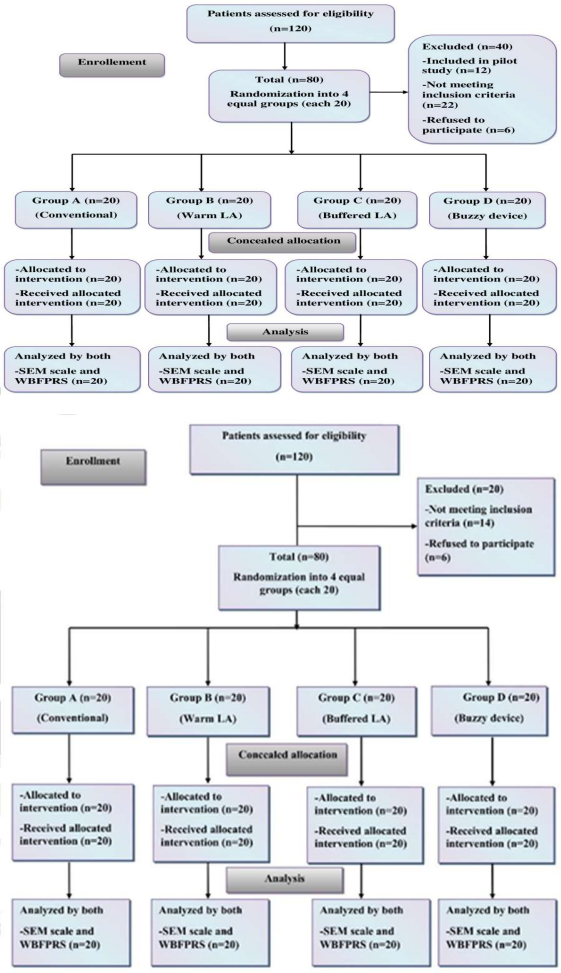

Figure 1: Flow chart of the study design

Sample size calculation

According to the results of a previous study [17], using G* Power Software Version 3.0.1.0., considering power = 95%, $\alpha = 0.05$, and effect size = 1.52, it was calculated that the minimum required sample size would be 13 cases in each group, which was increased to 20 in each group to compensate for a possible dropout of the patients and for more precise results. The total number of contributing children was 80.

Ethical considerations

This study was started after the approval of the research ethics committee, Faculty of Dentistry, Mansoura University, Egypt (Code M05040122). The present clinical trial was registered on

ClinicalTrials.gov under the number NCT05338983. Parents or guardians were provided with comprehensive explanations of the study and its procedures, and written consent was obtained from them prior to their participation in the research.

Randomization and allocation concealment

A randomized controlled trial design was used, wherein each child was randomly assigned, with the aid of an internet-based program (http://www.random.org), to receive a different approach for LA. The allocation concealment was maintained through the utilization of the sequentially numbered, opaque, sealed envelopes (SNOSE) [18] technique, prepared by an impartial individual prior to the commencement of the study. The sequence generation table remained sealed and safeguarded until the conclusion of the study. The eighty children were divided randomly into four equal groups (20 each). Group A used topical anesthetic gel only (conventional), Group B received warm LA, Group C received buffered LA, and Group D used a Buzzy device.

Blinding

The assessor, the children, and their parents or guardians were blinded to the method of reducing pain by local anesthetic injection (double-blinded study). To ensure blinding, all the steps of preparing warm and buffered LA were done by the principal investigator (operator) in a separate room in the dental clinic away from the assessor and the participating children. The Buzzy device was introduced to all the participants, and it was placed on the child's face without turning on its vibration, and the attached wings were at room temperature (unfrozen) during LA injection in the three groups (control, warm LA, and buffered LA). The device was only activated in the Buzzy group.[15, 19] The topical anesthetic gel was used in all four groups. The assessor role and attendance started at the time of the LA injection.

Methods

Pre-anesthetic Clinical Procedures

We asked the child to sit comfortably in the dental chair before conducting the examination and gathering all necessary information, including dental and medical histories. Taking a thorough history of the child's previous dental experiences from parents, listening carefully to the children, understanding their reasons for fear and anxiety, and establishing effective management strategies were essential considerations. All children's behavior was managed using the Tell, Show, Do (TSD) approach

For standardization, all clinical procedures were performed by a single operator (principal investigator) among the four groups, 20% Benzocaine topical anesthetic gel was applied at the site of injection in all four groups before LA injection, and the anesthetic solution was administered using a 30-gauge short dental needle over 60 seconds [20], with the mucosa of the maxillary primary molar dentition gently stretched during the procedure.

Group A (the conventional method) used topical anesthetic gel only: Following appropriate isolation and drying of the injection site, a topical anesthetic gel (20% benzocaine) was applied to the site of injection using a sterile cotton-tipped applicator for 60 seconds. Subsequently, the mepivacaine (2% HCL with epinephrine, 1:100,000) anesthetic solution was injected.

Group B (Warm LA): The carpule containing the anesthetic solution was placed inside a hermetically sealed plastic bag. This bag was then put into a baby bottle warmer, which had 300 ml of cold water at a temperature of 21 °C. The solution was heated in the warmer until it reached a temperature of 37 °C. After reaching this

temperature, the solution was ready for injection.

Group C (Buffered LA): 0.1 ml of 8.4% sodium bicarbonate solution (Otsuka, Egypt) was withdrawn from the 25 ml vial using a 1 ml insulin syringe and injected directly into the local anesthetic carpule. The carpule was then shaken five times to ensure proper mixing before the LA solution was injected.

Group D (Buzzy) external cold and vibration device: After seating the child in the dental chair, we introduced the Buzzy device by providing a simple explanation of how it operates. The device's wings were stored in the freezer. Once prepared, the frozen wings were attached to the device, and Buzzy was positioned externally above the cheek area, where the local anesthetic solution would be administered. With Buzzy held in place by hand, the button on the top of the device was activated, followed by the injection of the LA solution.

Pain assessment

In the present study, pain perception was measured by:

1. **The objective Sound, eye, and motor scale (SEM)** [21]: The assessor evaluated the children's responses during the injection by observing their sound, eye movements, and overall movement using the SEM scale. Scores on each category of the SEM scale ranged from 1 (indicating comfort) to 4 (indicating pain).
2. **The subjective Wong-Baker Face Pain Rating Scale (WBFPR)** [22]: Right after the LA was administered, the participants were asked by the same assessor to indicate the level of pain they felt during the injection by selecting one of five faces that most closely matched their experience. Each face was associated with a numerical value ranging from 0 to 10, as shown in (Figure 2).

Figure 2: Wong-Baker faces pain rating scale.

Piloting

Before starting the main study, all procedures and methods were tested on 12 children (other than 80 children in the main study) to assess the practicality of the interventions, the clarity of instructions based on a pre-prepared script, and as part of training for the principal investigator (dentist). The assessor (examiner) was trained to evaluate the children's responses during the injection using the SEM scale and to explain the WBFPR scale to assist the children in choosing one of six faces that best represented their experience. No changes were made to the pre-prepared script based on the observations made during piloting.

Intra-examiner Reliability

The pilot study aimed to assess the intra-examiner reliability before the main study using Intraclass correlation (ICC) [23] test to determine if the examiner would be able to produce equally reliable measurements. The assessor evaluated each child's behaviors during anesthetic injections and recorded the SEM pain scores. After one-week interval, these steps were repeated using videotape recordings of the same children to confirm that the results were accurate and reliable. ICC was used to test intra-examiner reliability. The pilot study's ICC score was 0.92, ensuring excellent agreement. After a one-week interval of the main study, 20% of the recordings of children's behavior during LA injection were used to check the intra-examiner reliability to confirm the accuracy and reliability of the results. The main

study's ICC scored 0.95, which ensured excellent agreement.

Statistical analysis

Data were collected, tabulated, and statistically analyzed using the Statistical Package of Social Science (SPSS) program for Windows (standard version 24). The normality of the data was tested with the Shapiro-Wilk test. Age data showed a normal distribution, while the rest of the data were not normally distributed. The four groups were compared with the ANOVA test (parametric) and the Kruskal-Wallis test (non-parametric). The in-between-groups comparison was tested by the Mann-Whitney test. Spearman correlation was used to correlate continuous data. For all the above-mentioned statistical tests, the threshold is fixed at the 5% level of significance ($p \leq 0.05$).

Results

I) Demographic data

There was no statistically significant difference in age and sex distribution among the four groups (p value > 0.05), as shown in (Table 1).

Table 1: Demographic data among the four groups.

Demographic data	Conventional Group(A) n=20	Warm LA Group(B) n=20	Buffered LA Group(C) n=20	Buzzy Group(D) n=20	P value
Age (years)					F=0.217
Mean ± SD	8.02±1.66	7.67±1.77	7.95±1.27	8.00±1.44	P=0.885
Min-Max	6-11	6-11	6-12	6-11	Ns
Gender (n,%)					χ^2 =6.98
Male	11 (55.0%)	12 (60.0%)	14 (70.0%)	6(30.0%)	P=0.072
Female	9 (45.0%)	8 (40.0%)	6 (30.0%)	14(70.0%)	Ns
F:ANOVA test, χ^2: Chi square test , Ns; non-significant (p>0.05)					

II) Evaluation of pain during local anesthesia injection based on the sound-eye-motor scale.

Based on sound score analysis, the warm LA, buffered LA, and Buzzy groups showed lower pain scores than the control group (conventional) with a statistically significant difference (p = 0.001), (p ≤ 0.001), (p = 0.001), respectively. There was no statistically significant difference in the reduction of pain between the warm LA group and each of the buffered LA group (p = 0.49) and the Buzzy group (p = 1). Both the Buzzy and buffered LA groups proved their efficacy in reducing injection pain with no statistically significant difference (p = 0.52), as shown in (Table 2).

Based on eye score analysis, the warm LA, buffered LA, and Buzzy groups recorded lower pain scores than the control group with a statistically significant difference (p = 0.009), (p = 0.001), and (p = 0.001), respectively. Buffered LA and buzzy groups showed lower eye pain scores than warm LA, with a statistically significant difference (p = 0.017). However, no statistically significant difference in reducing injection pain was found between the buffered LA and Buzzy groups (p = 0.863), as shown in (Table 3).

Table 2: The comparison of sound scores among the four groups regarding the SEM pain rating scale.

SEM score	Conventional Group (A) n=20	Warm LA Group (B) n=20	Buffered LA Group (C) n=20	Buzzy Group (D) n=20	P value
Sound					
Mean ± SD Median (Min-Max)	2.75±0.96 3 (1-4)	1.70±0.8 2 (1-4)	1.55±0.76 1 (1-3)	1.70±0.80 1.5 (1-3)	KW=18.4 P≤0.001*
	p1=0.001*, p2≤0.001*, p3=0.001*, p4=0.49, p5=1, p6=0.52				
1 (Comfort)	2 (10.0%)	9 (45.0%)	12 (60.0%)	10 (50.0%)	0.003*
2 (Mild discomfort)	6 (30.0%)	9 (45.0%)	5 (25.0%)	6 (30.0%)	
3 (Moderately painful)	7 (35.0%)	1 (5.0%)	3 (15.0%)	4 (20.0%)	
4 (Painful)	5 (25.0%)	1 (5.0%)	0 (0%)	0 (0%)	

KW: Kruskalwallis test. *statistically significant p ≤0.05.

Using Mann whitney test: p1: group A vs. group B , p2: group A vs. group C , p3: group A vs. group D

p4: group B vs. group C, p5: group B vs. group D , p6: group C vs. group D

Table 3: The comparison of eye scores among the four groups regarding the SEM pain rating scale.

SEM score	Conventional Group(A) n=20	Warm LA Group(B) n=20	Buffered LA Group(C) n=20	Buzzy Group(D) n=20	P value
Eye scores					
Mean ± SD	3.05±0.99	2.15±0.98	1.45±0.6	1.45±0.51	KW=29.6
Median(Min-Max)	3 (1-4)	2 (1-4)	1 (1-3)	1 (1-2)	P≤0.001*
	p1=0.009*, p2≤0.001*, p3≤0.001*, p4=0.017*, p5=0.017*, p6=0.863				
1	1 (5.0%)	6 (30.0%)	12 (60.0%)	11 (55.0%)	≤0.001*
2	6 (30.0%)	7 (35.0%)	7 (35.0%)	9 (45.0%)	
3	4 (20.0%)	5 (25.0%)	1 (5.0%)	0 (0%)	
4	9 (45.0%)	2 (10.0%)	0 (0%)	0 (0%)	

*Statistically significant p ≤0.05.

Based on motor score analysis, the warm LA, buffered LA, and Buzzy groups registered lower pain scores than the control group with a statistically significant difference (p = 0.043), (p = 0.007), and (p = 0.004), respectively. On the other hand, there was no statistically significant difference in reducing pain between the warm LA group and each of the buffered LA group (p = 0.626) and the Buzzy group (p = 0.502). Again, the motor reaction of children to injection pain in the buffered LA and Buzzy groups was comparable, with no statistically significant difference (p = 0.835), as shown in (Table 4).

Table 4: The comparison of motor scores among the four groups regarding the SEM pain rating scale.

SEM score	Conventionl Group(A) n=20	Warm LA Group(B) n=20	BufferedLA Group(C) n=20	Buzzy Group(D) n=20	P value
Motor scores					
Mean ± SD	2.50±1.0	1.85±0.81	1.70±0.57	1.65±0.49	KW=10.6
Median(Min-Max)	2 (1-4)	2 (1-3)	2 (1-3)	2 (1-2)	P=0.014*
	p1=0.043*, p2=0.007*, p3=0.004*, 4 =0.626, p5=0.502, p6=0.835				
1	3 (15.0%)	8 (40.0%)	7 (35.0%)	7 (35.0%)	0.003*
2	8 (40.0%)	7 (35.0%)	12 (60.0%)	13 (65.0%)	
3	5 (25.0%)	5 (25.0%)	1 (5.0%)	0 (0 %)	
4	4 (20.0%)	0 (0%)	0 (0%)	0 (0%)	

*Statistically significant p ≤0.05.

III) Pain evaluation based on the Wong-Baker Faces Pain Rating Scale.

The warm LA, buffered LA, and Buzzy groups showed lower pain scores than the control group with a statistically significant difference (P = 0.007), (P = 0.001), and (P = 0.001), respectively. The Buffered LA and Buzzy groups had lesser pain scores than warm LA with a statistically significant difference (P = 0.028) and (P = 0.014), respectively. On the other hand, the comparison between the Buffered LA and Buzzy groups did not show a statistically significant difference in reducing injection pain for children (P = 0.759), as shown in (Table5).

Table 5: WONG BAKER scores among the four groups.

WONG BAKER score	Conventionl Group(A) n=20	Warm LA Group (B) n=20	Buffered LA Group(C) n=20	Buzzy Group (D) n=20	P value
Mean ± SD	5.70±3.13	3.00±3.01	1.05±1.35	0.90±1.21	KW=33.6
Median (Min-Max)	4 (2-10)	3 (0-10)	0 (0-4)	0 (0-4)	P≤0.001*
	P1=0.007*, p2≤0.001*, p3≤0.001*,p4=0.028*,p5=0.014*,p6=0.759				
0 (No hurt)	0 (0%)	7 (35.0%)	11 (55.0%)	12 (60.0%)	≤0.001*
2 (Hurt)	4 (20.0%)	3 (15.0%)	7 (35.0%)	7 (35.0%)	
4 (Hurt little more)	7 (35.0%)	7 (35.0%)	2 (10.0%)	1 (5.0%)	
6 (Hurt even more)	3 (15.0%)	0 (0%)	0 (0%)	0 (0%)	
8 (Hurt a whole lot)	0 (0%)	2 (10.0%)	0 (0%)	0 (0%)	
10 (Hurt worst)	6 (30.0%)	1 (5.0%)	0 (0%)	0 (0%)	

*Statistically significant p ≤0.05.

IV) Correlation between SEM score and WONG BAKER score (Spearman correlation).

There was a statistically significant positive correlation between total SEM scores and WONG BAKER scores among the conventional group (r = 0.711, P ≤ 0.001), warm group (r = 0.903, P ≤ 0.001), and buffered LA group (r = 0.537, P = 0.015), while there was non-significance in the Buzzy group (r = 0.317, P = 0.173). An increased SEM score was associated with an increased WONG BAKER score, as shown in (Figures 3-6).

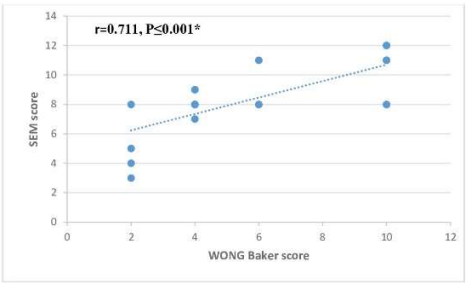

Figure (3): Scatter diagram for positive correlation between total SEM score and WONG BAKER score among conventional group.

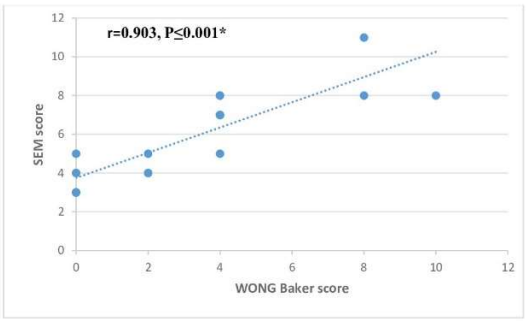

Figure (4): Scatter diagram for positive correlation between total SEM score and WONG BAKER score among Warm group.

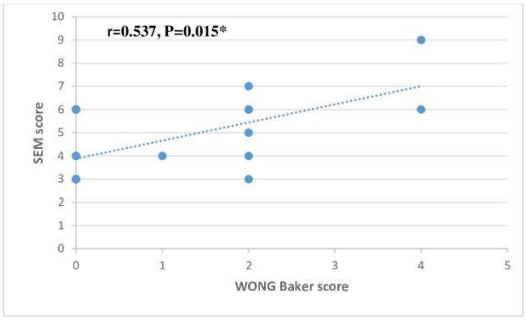

Figure 5: Scatter diagram for positive correlation between total SEM score and WONG BAKER score among Buffered LA group.

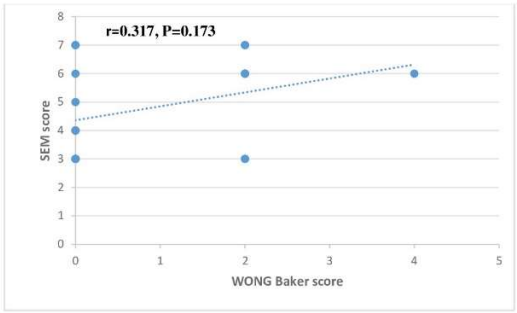

Figure 6: Scatter diagram for correlation between total SEM score and WONG BAKER score among Buzzy group.

Discussion

This study is a double-blinded randomized controlled clinical trial designed to assess and compare the impact of three different approaches (warm LA of 37°C, buffered LA, and the use of Buzzy device) on reducing dental injection pain among 6–12 years old children, in comparison to the conventional method. These methods are simple, noninvasive, and inexpensive for managing children experiencing dental injection pain.

The study involved children aged 6 to 12 years, a stage known as middle childhood, during which they begin to shape their attitudes toward dental care. This period is characterized by significant social, emotional, and cognitive transformations, fostering the growth of self-regulation and accountability in children.[23] Furthermore, this age group is competent to understand the concepts of pain and anxiety, making the self-reporting scales more reliable.

In the current study, children's pain was assessed by a well trained assessor, using two different scales : The WBFPR and the objective SEM scales. The use of WBFPR scale enables an immediate emotional response to dental treatment and allows the children to express their evaluation of pain without any verbal communication, which makes it suitable for young children. [24] It was

preferred by many studies. [24, 25] The use of SEM scale in the present study enables the assessment of patient's eyes, body movements, and verbal expressions of discomfort as a component response to pain, as well as the degree of intensity of pain sensation. [26]

In the present study, according to SEM and WBFPR scores, warm LA showed a reduction in injection pain in comparison to conventional method with a statistically significant difference. This result agrees with many studies. [27-28-29] They concluded that pre-warming the anesthetic solution reduces pain during LA administration in children.

On the other hand, this finding was not matched with Ram et al.[30] who compared warm and room-temperature anesthetics among 6-11 years old children during vestibular infiltration, interpapillary, and mandibular nerve block techniques. Their results showed no statistically significant differences in pain sensation during the injection of anesthetic solutions at both temperatures. This conflicting outcome could be attributed to numerous variables linked to the anesthetic technique, including anatomical location and infiltration or troncular technique. Dentist-related factors such as years of experience and injection speed, as well as patient-specific elements like previous experiences with anesthetic injections and subjective pain perception, may also contribute.

The results also showed that buffered LA was effective in reducing pain on injection when compared to the conventional method, with a statistically significant difference. This outcome aligns with the findings of Kurien et al.[31] , Afsal et al.[32] , and Dhaki et al.[33] .Contrary to this result, Chopra et al.[34] found that buffered lidocaine did not reduce pain for inferior alveolar nerve blocks in 30 children aged 6–12 years old. This finding contrasts with our own results. Possible reasons for this contrast can be explained by inherently greater pain with inferior alveolar nerve blocks than infiltrations, anesthesia [35], variations in injection sites, and different pain assessment methods.

In the present study, the WBFPR and SEM scales revealed a significant reduction in perceived pain, with a statistically significant difference among children when the Buzzy device was used compared to the conventional method. This finding is consistent with the results reported by Alanazi et al.[36] and Shetty et al.[37]. However, a contradictory result was recorded by Suohu et al.[38]. They reported that while the FLACC scale showed a significantly higher difference between the Buzzy group and the conventional anesthesia group in reducing pain during LA injection in children aged 5–10 years old, but there was no statistically significant difference in pulse rate, oxygen saturation levels, or WBFPR scores between the two groups. This incomparable finding could be attributed to the children's inability to comprehend and choose the most appropriate facial expression to indicate their pain during LA injection, as well as the absence of topical anesthetic gel use in both groups. Furthermore, Almeidaa et al.[39] recorded 100% acceptability of the Buzzy device by the children, and the majority (90%) would like to use it again. Anyhow, they did not find a difference between the Buzzy device and the conventional groups in alleviating pain during local anesthetic injection ($p < 0.05$). The disparity between our study's findings and theirs could be attributed to the small sample size of the pilot study's 20 participants (10 in each group). Moreover, the children in their study were treated by two undergraduate students whose dental experience might have differed (inter-operator variability).

In this study, no adverse effects were reported by any of the 80 children in any of the groups. Our observations and results led

us to reject the null hypothesis, concluding that warm LA, buffered LA, and Buzzy device approaches effectively reduced pain in children during LA administration when compared to the conventional method.

Limitations of the study

1. The results of the present study were obtained from cooperative children and may not be applicable to non-cooperative children.
2. Since the study only included maxillary buccal infiltration, these results cannot be generalized to more painful injections, such as IANB and palatal injections.

Conclusion

It is evident from the present results that the use of warm LA, buffered LA, and an external cold and vibration device (Buzzy) had a significant effect on reducing pain perception during maxillary infiltration injection among 6-12 years old children , in comparison to the conventional method. Buffered LA and Buzzy device were found to be the most effective methods, followed by warm LA, whereas the conventional method had the least impact on reducing injection pain.

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Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics

This study protocol was approved by the ethical committee of the faculty of dentistry-Mansoura university on: 22/12/2021, approval code: (M05040122).

Consent

Parents or guardians were provided with comprehensive explanations of the study and its procedures, and written informed consent was obtained from them prior to their participation in the research.

Conflicts of Interest

The authors declare no conflict of interest.

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