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Comparative Evaluation of Cryoanesthesia Combined with Active Distraction versus Topical Anesthesia for Reducing Pain and Anxiety during Local Anesthetic Administration in Children - A Randomized Controlled Clinical Trial

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Abstract

Background: Pain and anxiety during local anesthetic administration are common challenges in pediatric dentistry and may affect a child's cooperation. While topical anesthetics are routinely used to reduce injection pain, Cryoanesthesia and active distraction have shown promising results individually. Therefore, this study aimed to compare the effectiveness of Cryoanesthesia combined with active distraction versus topical anesthesia in reducing pain and anxiety during local anesthetic administration in children.

Materials and Methods: A randomized controlled clinical trial was conducted among 60 healthy children aged 6–10 years requiring local anesthetic administration

for routine dental treatment. Participants were randomly allocated into two groups (n = 30 each). Group I received Cryoanesthesia using a precooled ice stick applied to the injection site for 60 seconds followed by active distraction using a handheld stress ball during injection. Group II received 20% benzocaine topical anesthetic gel before local anesthetic administration. Anxiety was assessed using the Venham Picture Test (VPT) before and after injection. Pain perception was evaluated using the Wong–Baker Faces Pain Rating Scale immediately after injection, while the child's behavioral response during injection was assessed using the Sound, Eye, Motor (SEM) Scale. Statistical analysis was performed using the independent t-test, Mann–Whitney U test, and Chi-square test, with the level of significance set at $p < 0.05$.

Results: Children in the Cryoanesthesia with active distraction group exhibited significantly lower pain and anxiety scores than those in the topical anesthesia group. The mean Wong–Baker Faces Pain Rating Scale score was significantly lower in Group I than Group II (2.13 ± 0.78 vs. 3.47 ± 0.94; $p < 0.001$).

SEM scores also showed significantly better behavioral responses in Group I (1.83 ± 0.65 vs. 2.90 ± 0.80; $p < 0.001$). Post-injection VPT scores demonstrated a significant reduction in anxiety among children receiving the combined intervention compared with topical anesthesia alone ($p < 0.001$).

Conclusion: Cryoanesthesia combined with active distraction was significantly more effective than topical anesthesia alone in reducing pain perception, dental anxiety during local anesthetic administration in children. This simple, economical, and non-pharma cological technique can be recommended as an effective adjunct for pain and anxiety management in pediatric dental practice.

Keywords: Cryoanesthesia, Active Distraction, Local Anesthesia, Pediatric Dentistry

Introduction

Pain and fear associated with local anesthetic administration remain among the most challenging aspects of pediatric dental treatment.[1] The anticipation of needle insertion and the sensation of injection frequently provoke anxiety, resulting in uncooperative behavior and compromised treatment outcomes.[2]

Negative experiences during childhood may also contribute to long-term dental fear and avoidance of dental care. Therefore, effective pain and anxiety management during local anesthetic administration is an essential component of successful behavior guidance in pediatric dentistry.[3]

Topical anesthetic agents, particularly benzocaine gel, are routinely used to reduce the discomfort associated with needle penetration by providing superficial mucosal anesthesia. Although topical anesthesia decreases pain at the injection site, its effect is limited to the mucosal surface and does not completely eliminate discomfort associated with deeper tissue penetration or the deposition of anesthetic solution. Consequently, children may still experience pain and anxiety despite the use of topical anesthetics.[4]

Cryoanesthesia is a simple, inexpensive, and non-pharmacological technique that involves the application of cold to the injection site before local anesthetic administration.[5] cooling produces a transient anesthetic effect by decreasing nerve conduction velocity, increasing the pain threshold, and reducing the transmission of nociceptive stimuli.

The technique is easy to perform, requires minimal equipment, and has gained increasing attention as an adjunctive method for reducing injection pain in pediatric patients.[6]

Active distraction is another widely accepted behavioral guidance technique in pediatric dentistry. By engaging the child's attention in an unrelated activity, distraction reduces the perception of painful stimuli through cognitive modulation and limits the child's focus on the injection procedure.

Techniques such as squeezing a stress ball, interactive toys, or simple games encourage active participation and have been shown to improve cooperation while decreasing anxiety during dental procedures.[7]

Although several studies have independently evaluated the effectiveness of Cryoanesthesia and distraction techniques, limited evidence exists regarding the combined use of these interventions during local anesthetic administration in children. The simultaneous use of a physiological method (Cryoanesthesia) and a psychological method (active distraction) may provide superior pain control and anxiety reduction compared with the conventional use of topical anesthetic alone. Investigating this combined approach may offer clinicians a practical, cost-effective, and child-friendly strategy for improving the dental experience of pediatric patients.

Therefore, the present randomized controlled clinical trial was undertaken to compare the effectiveness of Cryoanesthesia combined with active distraction versus topical anesthesia in reducing pain perception, dental anxiety during local anesthetic administration in children.

Material and Method

Study Design

This study was designed as a parallel-arm, randomized controlled clinical trial conducted in the Department of Pediatric and Preventive Dentistry after obtaining approval from the Institutional Ethics Committee. The study was carried out in accordance with the Declaration of Helsinki, and written informed consent was obtained from the parents or legal guardians, while verbal assent was obtained from all participating children.

Sample Size

The sample size was calculated using G*Power software (Version 3.1) with a study power of 80%, an alpha error of 5%, and an effect size of 0.75 derived from previous studies evaluating pain during local anesthetic administration. A minimum of 27 participants per group was required. To compensate for possible dropouts, 30 children were included in each group, resulting in a total sample size of 60 participants.

Study Population

Sixty healthy children aged 6–10 years requiring local anesthetic administration for restorative or pulp therapy procedures in primary molars were recruited.

Inclusion Criteria

- Healthy children (ASA I).
- Age between 6 and 10 years.
- Children requiring buccal infiltration local anesthesia.
- Frankl Behavior Rating Score 3 or 4.
- Cooperative children with no previous unpleasant dental injection experience.

Exclusion Criteria

- Children with systemic illness or neurological disorders.
- History of allergy to lignocaine or benzocaine.

- Presence of soft tissue infection or ulceration at the injection site.
- Children receiving analgesics or sedatives within 24 hours before treatment.
- Children with cognitive or communication impairment.

Randomization

Participants were randomly allocated into two equal groups (n = 30 each) using a computer-generated randomization sequence. Allocation concealment was achieved using sequentially numbered opaque sealed envelopes opened immediately before the procedure.

Group I (Cryoanesthesia + Active Distraction)

The injection site was dried with sterile gauze. A sterile ice stick prepared from distilled water was applied to the mucosa for 60 seconds immediately before injection. During administration of local anesthesia, the child was instructed to squeeze a soft stress ball continuously until completion of the injection.

Group II (Topical Anesthesia)

The mucosa was isolated and dried. A thin layer of 20% benzocaine gel (Precaine-B gel) was applied at the injection site for 1 minute according to the manufacturer's instructions before administration of local anesthesia.

Local Anesthetic Administration

For all participants, local anesthesia was administered by the same experienced pediatric dentist using 2% lignocaine hydrochloride with 1: 80,000 epinephrine (Lidayn, Global Dent Aids Pvt Ltd, New Delhi, India) through a 27-gauge short dental needle (Dispovan, Hindustan Syringes and Medical Devices Limited, Faridabad, Haryana, India). Buccal infiltration was delivered at a slow and uniform rate to minimize operator-related variability.

Outcome Assessment

Anxiety Assessment

Dental anxiety was assessed using the Venham Picture Test (VPT). The child selected the picture that best represented his or her emotional state immediately before and immediately after local anesthetic administration. The total score ranged from 0 to 8, with higher scores indicating greater anxiety.

Subjective Pain Assessment

Immediately after completion of the injection, each child rated the perceived pain using the Wong–Baker Faces Pain Rating Scale, consisting of six facial expressions scored from 0 ("No hurt") to 10 ("Hurts worst").

Objective Pain Assessment

Behavior during local anesthetic administration was assessed by an independent blinded observer using the Sound, Eye, Motor (SEM) Scale, which evaluates vocalization, eye activity, and body movement during the injection procedure. Lower scores indicated better acceptance of treatment and reduced discomfort.

Statistical Analysis

The collected data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Data distribution was assessed using the Shapiro–Wilk test. Intergroup comparisons of normally distributed variables were performed using the independent Student's t-test, while non-parametric data were analyzed using the Mann–Whitney U test.

Within-group comparisons of VPT scores before and after injection were performed using the Wilcoxon signed-rank test. Categorical variables were analyzed using the Chi-square test. A p-value of <0.05 was considered statistically significant.

Results

A total of 60 children fulfilling the inclusion criteria completed the study, with 30 participants allocated to each group. No participant was lost to follow-up, and all data were included in the final analysis.

The demographic characteristics of the participants are presented in Table 1. The mean age of children in Group I (Cryoanesthesia + Active Distraction) was 8.12 ± 1.34 years, while that in Group II (Topical Anesthesia) was 8.05 ± 1.27 years. The difference was not statistically significant ($p = 0.842$). Similarly, the gender distribution between the two groups was comparable, with no statistically significant difference ($p = 0.796$), indicating successful randomization.

The comparison of anxiety levels measured using the Venham Picture Test (VPT) is shown in Table 2. Baseline VPT scores were comparable between the groups (4.30 ± 0.92 vs. 4.27 ± 0.95; p = 0.901). Following local anesthetic administration, both groups demonstrated a reduction in anxiety; however, the reduction was significantly greater in the Cryoanesthesia + Active Distraction group. The post-injection VPT score was significantly lower in Group I (1.63 ± 0.67) compared with Group II (2.93 ± 0.82) (p< 0.001).

The subjective pain perception assessed using the Wong–Baker Faces Pain Rating Scale is presented in Table 3. Children treated with Cryoanesthesia combined with active distraction reported significantly lower pain scores (2.13 ± 0.78) than those who received topical anesthesia (3.47 ± 0.94). The difference was highly statistically significant (t = 6.03, p< 0.001).

Behavioral responses during local anesthetic administration, evaluated using the Sound, Eye, Motor (SEM) Scale, are summarized in Table 4. Group I demonstrated significantly lower SEM scores (1.83 ± 0.65) than Group II (2.90 ± 0.80), indicating better cooperation and reduced behavioral manifestations of pain and anxiety during injection. The intergroup difference was statistically significant (t = 5.70, p< 0.001).

The overall comparison of the outcome measures is presented in Table 5. Children who received Cryoanesthesia combined with active distraction consistently demonstrated significantly lower anxiety, pain perception, and behavioral distress compared with those receiving topical anesthesia alone. These findings indicate that the combined intervention was more effective in improving the comfort and cooperation of pediatric patients during local anesthetic administration.

Table 1: Distribution of Participants According to Age and Gender.

Variable	Group I (Cryoanesthesia + Active Distraction) (n=30)	Group II (Topical Anesthesia) (n=30)	p-value
Age (years)	8.12 ± 1.34	8.05 ± 1.27	0.842
Male	17 (56.7%)	16 (53.3%)	0.796
Female	13 (43.3%)	14 (46.7%)	

Table 2: Comparison of Venham Picture Test (VPT) Scores

Time	Group I	Group II	p-value
Before Injection	4.30 ± 0.92	4.27 ± 0.95	0.901
After Injection	1.63 ± 0.67	2.93 ± 0.82	<0.001

Table 3: Comparison of Wong–Baker Faces Pain Rating Scale Scores.

Group	Mean ± SD	t-value	p-value
Cryoanesthesia +	2.13 ± 0.78	5.70	

Active Distraction			
Topical Anesthesia	1.83 ± 0.65		**<0.001**

Table 4: Comparison of Sound, Eye, Motor (SEM) Scores.

Group	Mean ± SD	t-value	p-value
Cryoanesthesia + Active Distraction	1.83 ± 0.65	5.70	
Topical Anesthesia	2.90 ± 0.80		<0.001

Table 5: Overall Comparison of Outcome Measures

Outcome Measure	Cryoanesthesia + Active Distraction	Topical Anesthesia	p-value
VPT (After Injection)	1.63 ± 0.67	2.93 ± 0.82	<0.001
Wong–Baker	2.13 ± 0.78	3.47 ± 0.	<0.00
SEM Score	1.83 ± 0.65	2.90 ± 0.80	<0.001

Discussion

The administration of local anesthesia is often regarded as one of the most anxiety-provoking procedures in pediatric dentistry. Fear of needles and anticipated pain can adversely affect a child's behavior, compromise treatment acceptance, and contribute to the development of long-term dental anxiety.[8] Therefore, identifying effective strategies to minimize pain and anxiety during injection remains a priority in pediatric dental practice. The present randomized controlled clinical trial compared the effectiveness of Cryoanesthesia combined with active distraction and conventional topical anesthesia in reducing pain perception, anxiety, and behavioral responses during local anesthetic administration in children.

The results of the present study demonstrated that children who received Cryoanesthesia combined with active distraction exhibited significantly lower anxiety levels, pain perception, and behavioral distress than those who received topical anesthesia alone.

These findings suggest that combining physiological and psychological pain control techniques provides greater comfort during local anesthetic administration than relying solely on topical anesthetic agents.

The Venham Picture Test (VPT) was used to assess dental anxiety because it is a simple and validated self-report measure suitable for young children. Both study groups demonstrated a reduction in anxiety following treatment; however, the reduction was significantly greater in the Cryoanesthesia with active distraction group.

This finding may be attributed to the synergistic effect of cold-induced analgesia and cognitive distraction. Cryoanesthesia temporarily decreases nerve conduction velocity and raises the pain threshold, while active distraction diverts the child's attention away from the injection, thereby reducing the perception of fear and discomfort. The combined effect appears to produce superior anxiety control compared with topical anesthesia alone.[9]

Pain perception assessed using the Wong–Baker Faces Pain Rating Scale was significantly lower among children receiving Cryoanesthesia combined with active distraction than those receiving topical anesthesia alone. In the present study, the Wong–Baker Faces Pain Rating Scale was selected because it is a simple, child-friendly,

and reliable instrument for assessing pain intensity in pediatric patients. Naik et al.

reported that the Wong–Baker Faces Pain Rating Scale demonstrated the highest inter-rater reliability among three commonly used pediatric pain assessment tools, suggesting that it is one of the most reliable instruments for clinical use in children requiring dental treatment.[10]

The significantly lower Wong–Baker scores observed in the present study indicate that the combined intervention effectively reduced pain perception during local anesthetic administration. Topical anesthetic agents primarily anesthetize the superficial mucosal layer and have limited influence on discomfort associated with deeper tissue penetration or anesthetic solution deposition.[11]

In contrast, Cryoanesthesia decreases nociceptor activity and slows peripheral nerve conduction, while active distraction, achieved by squeezing a stress ball, diverts the child's attention away from the injection, thereby reducing the overall perception of pain.

Behavioral responses evaluated using the Sound, Eye, Motor (SEM) Scale further supported the effectiveness of the combined intervention. Children in the Cryoanesthesia with active distraction group demonstrated fewer vocalizations, reduced eye movements, and minimal body movements during injection compared with the topical anesthesia group. Improved behavioral responses indicate better acceptance of dental treatment and enhanced cooperation, which are essential for successful pediatric dental procedures.

The findings of the present study are consistent with those of Aminabadi et al., who evaluated the efficacy of distraction and counter stimulation during local anesthetic administration and reported that children in the distraction group exhibited significantly lower pain perception and better cooperation.

Similarly, the present study demonstrated that combining Cryoanesthesia with active distraction resulted in significantly lower pain, anxiety, and behavioral distress than topical anesthesia alone, suggesting that the combined approach provides superior pain control during local anesthetic administration in children.[12]

From a clinical perspective, Cryoanesthesia combined with active distraction offers several advantages. The technique is inexpensive, easy to perform, non-invasive, and does not require specialized equipment. It can be readily incorporated into routine pediatric dental practice without increasing treatment complexity or cost. Consequently, this approach may improve the overall dental experience, increase patient cooperation, and enhance the quality of care delivered to children.

The present study has certain limitations. The sample size was relatively small and included children from a single institution, which may limit the generalizability of the findings. In addition, only Buccal infiltration anesthesia in cooperative children was evaluated. The effectiveness of the combined intervention during other injection techniques, different age groups, or among highly anxious children requires further investigation. Future multicenter randomized clinical trials with larger sample sizes and long-term follow-up are recommended to validate these findings and establish standardized clinical protocols.

Overall, the present study demonstrated that combining Cryoanesthesia with active distraction is a more effective strategy than topical anesthesia alone for reducing pain, anxiety, and adverse behavioral responses during local anesthetic administration in pediatric patients.

Conclusion

Within the limitations of the present randomized controlled clinical trial, it can be concluded that Cryoanesthesia combined with active distraction is significantly more effective than conventional topical anesthesia in reducing pain perception, dental anxiety, and adverse behavioral responses during local anesthetic administration in children. Participants receiving the combined intervention demonstrated significantly lower Venham Picture Test (VPT), Wong–Baker Faces Pain Rating Scale, and Sound, Eye, Motor (SEM) Scale scores compared with those receiving topical anesthesia alone.

The combined use of Cryoanesthesia and active distraction represents a simple, safe, cost-effective, and non-invasive technique that can be easily incorporated into routine pediatric dental practice. Its use has the potential to improve child cooperation, enhance patient comfort, and promote a more positive dental experience during local anesthetic administration.

Further multicenter randomized clinical trials with larger sample sizes are recommended to validate these findings and support its widespread clinical application.

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