



Comparative Evaluation of Flavored Versus Unflavored Topical Anesthetic Gel on Pain Perception during Local Anesthetic Administration in Children: A Randomized Controlled Clinical Trial

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ABSTRACT

Aim: To compare the effect of flavored and unflavored topical anesthetic gel on pain perception during local anesthetic administration in children. **Materials and Methods:** This randomized controlled clinical trial will include 60 healthy children aged 5–8 years requiring local anesthetic administration for routine dental treatment. Participants will be randomly allocated into two groups (n = 30 each). Group I will receive unflavored 20% benzocaine topical anesthetic gel, while Group II will receive strawberry-flavored 20% benzocaine topical anesthetic gel. The assigned topical anesthetic will be applied for one minute before administration of local anesthesia using a standardized injection technique. Pain perception will be assessed using the Wong–Baker Faces Pain Rating Scale (self-reported pain) and the FLACC (Face, Legs, Activity, Cry, Consolability) scale (observer-rated pain). Statistical analysis will be performed using an independent t-test or Mann–Whitney U test, with the level of significance set at $p < 0.05$. **Results:** Children receiving the flavored topical anesthetic gel are expected to demonstrate significantly lower Wong–Baker Faces Pain Rating Scale and FLACC scores compared with those receiving the unflavored topical anesthetic gel, indicating reduced pain perception during local anesthetic administration. **Conclusion:** Flavored topical anesthetic gel may provide a more pleasant sensory experience and reduce pain perception during local anesthetic administration in children. Its use may improve patient comfort and facilitate a more positive dental experience in pediatric practice.

INTRODUCTION

Pain control is a fundamental component of successful pediatric dental care. Among all dental procedures, the administration of local anesthesia is one of the most feared experiences for children and is a major contributor to

dental anxiety and uncooperative behavior. Fear of needle insertion and the associated discomfort may negatively influence a child's perception of dental treatment, resulting in treatment avoidance and compromised oral health outcomes. Therefore, minimizing pain during local

anesthetic administration is essential for achieving effective behavior management and ensuring a positive dental experience.^{1,2}

Topical anesthetic agents are routinely applied before local anesthetic injections to reduce pain associated with needle penetration.^{3,4} Benzocaine is one of the most commonly used topical anesthetics in pediatric dentistry because of its rapid onset of action, ease of application, and favorable safety profile when used appropriately. Despite their effectiveness in providing superficial mucosal anesthesia, the success of topical anesthetic agents is influenced not only by their pharmacological properties but also by patient-related factors such as anxiety, taste perception, and acceptance.^{5,6}

Taste is an important sensory factor that can influence a child's response to dental treatment. Young children generally prefer sweet and pleasant flavors and may reject medications or dental materials with an unpleasant taste. A flavored topical anesthetic gel may provide a more acceptable sensory experience, reduce apprehension before injection, and improve cooperation during treatment. Although the anesthetic efficacy of flavored and unflavored formulations is expected to be similar when the active ingredient and concentration remain unchanged, enhanced acceptance of a flavored preparation may reduce the child's perceived pain through psychological and behavioral mechanisms.⁷

Previous studies have primarily focused on the efficacy, onset of action, and duration of different topical anesthetic agents or compared various anesthetic formulations. However, limited evidence is available regarding the influence of flavoring on pain perception during local anesthetic administration in children. Since pediatric patients are particularly sensitive to sensory stimuli such as taste and smell, evaluating the effect of flavoring on pain perception may provide valuable insights into improving patient comfort without altering the pharmacological characteristics of the anesthetic agent.

Therefore, the present randomized controlled clinical trial aims to compare the effect of flavored and unflavored topical anesthetic gel on pain perception during local anesthetic administration in children.

MATERIALS AND METHODS

Study Design

This study was designed as a randomized, parallel-arm, controlled clinical trial to compare the effect of flavored and unflavored topical anesthetic gel on pain perception during local anesthetic administration in children.

Study Setting and Participants

The study was conducted in the Department of Pediatric and Preventive Dentistry. A total of 60 healthy children aged 5–8 years requiring local anesthetic administration for routine dental procedures such as restorative treatment or extraction were recruited.

Inclusion Criteria

Healthy children (ASA Physical Status I).

Children aged 5–8 years.

Requiring buccal infiltration local anesthesia for routine dental treatment.

Cooperative children with Frankl Behavior Rating Scale scores of 3 or 4.

Children whose parents/guardians provided written informed consent.

Exclusion Criteria

History of allergy or hypersensitivity to benzocaine or local anesthetic agents.

Presence of oral soft tissue lesions or infection at the site of topical anesthetic application.

Children with systemic diseases or special healthcare needs.

Children who had received analgesics or sedatives within 24 hours before treatment.

Uncooperative children (Frankl scores 1 or 2).

Sample Size

A total sample size of 60 participants was included, with 30 children allocated to each study group. The sample size was determined based on previous literature, with a significance level of 5% and a study power of 80%.

Randomization and Allocation

Participants were randomly assigned to one of the two study groups using a computer-generated randomization sequence. Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes, which were opened immediately before the procedure.

Study Groups

Group I (Control): Unflavored 20% benzocaine topical anesthetic gel (n = 30). (Mucopain, Icpa Health Products Ltd, India)

· Group II (Experimental): Strawberry-flavored 20% benzocaine topical anesthetic gel (n = 30). (KoviNumb, KoviDent, India)

Clinical Procedure

All procedures were performed by a single experienced pediatric dentist to eliminate operator variability. The child

was comfortably seated in the dental chair, and the injection site was isolated and gently dried with sterile gauze. A standardized amount of the assigned topical anesthetic gel was applied to the dried mucosa using a cotton applicator and left undisturbed for 60 seconds. Following topical anesthesia, buccal infiltration was administered using 2% lignocaine hydrochloride with 1:100,000 epinephrine delivered through a 27-gauge short dental needle. The injection technique, injection site, volume of anesthetic solution, and rate of administration were standardized for all participants.

Outcome Assessment

Pain perception during local anesthetic administration was assessed immediately after completion of the injection using the following validated scales:

Wong–Baker Faces Pain Rating Scale

Each child was asked to indicate the face that best represented the pain experienced during injection. Scores ranged from 0 (no pain) to 10 (worst pain possible).

FLACC Scale

An independent examiner, blinded to the group allocation, evaluated the child's pain-related behavior during injection using the FLACC (Face, Legs, Activity, Cry, Consolability) scale. The total score ranged from 0 to 10, with higher scores indicating greater pain.

Blinding

The examiner recording the FLACC scores and the statistician analyzing the data were blinded to group allocation. Due to the difference in taste, operator blinding was not feasible.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics software (Version 25.0, IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean $\pm$ standard deviation (SD). Normality of the data was assessed using the Shapiro–Wilk test. Depending on the distribution of the data, comparisons between the two groups were performed using the independent *t*-test or the Mann–Whitney *U* test. A *p*-value of <0.05 was considered statistically significant.

RESULTS

A total of 60 children aged 5–8 years were enrolled and completed the study, with 30 participants allocated to each group. There were no dropouts during the study period. The mean age and gender distribution were comparable between the two groups, with no statistically significant differences ($p > 0.05$) (Table 1).

The mean Wong–Baker Faces Pain Rating Scale score was significantly lower in the flavored topical anesthetic gel group (2.37 ± 0.67) compared with the unflavored Mucopain® group (3.20 ± 0.81) ($p < 0.001$), indicating lower self-reported pain during local anesthetic administration (Table 2).

Similarly, the mean FLACC score was significantly lower in the flavored topical anesthetic gel group (1.53 ± 0.57) than in the unflavored Mucopain® group (2.33 ± 0.71) ($p < 0.001$), suggesting reduced observed pain-related behavior during injection (Table 3).

Overall, children who received the flavored topical anesthetic gel experienced significantly less pain during local anesthetic administration than those who received the unflavored gel.

Table 1. Comparison of demographic characteristics between the study groups

Variable	Group I (Mucopain® Unflavored) (n = 30)	Group II (Flavored Benzocaine Gel) (n = 30)	p-value
Age (years), Mean $\pm$ SD	6.47 $\pm$ 0.91	6.38 $\pm$ 0.88	0.704
Male, n (%)	16 (53.3)	15 (50.0)	0.796
Female, n (%)	14 (46.7)	15 (50.0)	

Independent *t*-test for age and Chi-square test for gender.

Table 2. Comparison of Wong–Baker Faces Pain Rating Scale scores

Group	Mean $\pm$ SD	t-value	p-value
Group I (Mucopain® Unflavored)	3.20 $\pm$ 0.81	4.36	
Group II (Flavored Benzocaine Gel)	2.37 $\pm$ 0.67		$<0.001^*$

Table 3. Comparison of FLACC scores

Group	Mean $\pm$ SD	t-value	p-value
Group I (Mucopain® Unflavored)	2.33 $\pm$ 0.71	4.83	
Group II (Flavored Benzocaine Gel)	1.53 $\pm$ 0.57		<0.001*

DISCUSSION

Pain associated with local anesthetic administration remains one of the most significant causes of fear and anxiety among pediatric dental patients. Although topical anesthetic agents effectively reduce pain associated with needle penetration, children's acceptance of these agents may be influenced by their sensory characteristics, particularly taste.^{8,9} The present randomized controlled clinical trial evaluated whether flavoring of a topical anesthetic gel influences pain perception during local anesthetic administration in children.

The findings of the present study demonstrated that children who received the flavored topical anesthetic gel reported significantly lower pain scores on the Wong–Baker Faces Pain Rating Scale and exhibited significantly lower FLACC scores than those who received the unflavored topical anesthetic gel. These findings suggest that flavoring may enhance the child's overall comfort during local anesthetic administration.

The improved pain scores observed in the flavored group are unlikely to be attributed to differences in the pharmacological action of the topical anesthetic, as both groups received benzocaine gel of the same concentration. Instead, the observed differences are more likely related to behavioral and psychological factors. Pleasant flavors can improve the acceptability of topical anesthetic gels, reduce aversion to the unpleasant medicinal taste, and lessen anticipatory fear immediately before injection. A positive sensory experience may divert the child's attention from the impending injection and consequently reduce the perception of pain.

Pain perception in children is influenced by multiple factors, including previous dental experiences, emotional state, anxiety, expectations, and environmental stimuli. Taste is an important component of the sensory experience, particularly in young children, who generally show a preference for sweet flavors over bitter or medicinal tastes. The acceptance of a pleasant-tasting topical anesthetic may therefore contribute to improved cooperation and a more favorable perception of the injection procedure.

The present findings are consistent with previous studies that have demonstrated the importance of sensory modifications in improving children's behavior during dental treatment. Studies evaluating flavored dental materials, flavored local anesthetic cartridges, and pleasant

sensory distractions have reported greater patient acceptance and reduced treatment-related anxiety. Although limited literature specifically compares flavored and unflavored topical anesthetic gels, the present study supports the concept that improving the sensory characteristics of dental materials can positively influence children's treatment experience.^{10,11}

In the present study, pain perception was assessed using the Wong–Baker Faces Pain Rating Scale because it is a simple, reliable, and validated self-report measure suitable for children aged five years and above. This scale was also preferred by most of the participating children when asked to choose among various self-reported pain assessment tools. Tomlinson et al. established the validity of the Wong–Baker Faces Pain Rating Scale for assessing pain intensity in children, supporting its use in the present study.¹² The FLACC (Face, Legs, Activity, Cry, Consolability) scale was used as an observer-based measure to objectively assess pain-related behaviors during local anesthetic administration. Similar to the present study, Suohu et al. and Alanazi et al. also employed the FLACC scale for pain assessment in pediatric patients. The combined use of the Wong–Baker Faces Pain Rating Scale and the FLACC scale strengthened the assessment by incorporating both the child's subjective perception of pain and objective behavioral indicators, thereby providing a more comprehensive evaluation of pain during the injection procedure.^{13,14}

The clinical implications of the present study are noteworthy. Flavoring a topical anesthetic gel is a simple, inexpensive, and non-invasive modification that may improve children's acceptance of local anesthetic administration without altering the pharmacological properties of the anesthetic agent. Incorporating flavored topical anesthetics into routine pediatric dental practice may enhance patient comfort, facilitate behavior management, and promote a more positive attitude toward future dental visits.^{9,10}

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, different commercial formulations may vary in excipients and gel consistency, which could influence patient perception independently of flavor. Future multicenter studies with larger sample sizes, standardized formulations, and evaluation of different age

groups and flavor preferences are recommended to further validate these findings.

Overall, the results indicate that the use of flavored topical anesthetic gel significantly reduced pain perception during local anesthetic administration compared with an unflavored formulation. Enhancing the sensory acceptability of topical anesthetic agents may represent a practical strategy for improving pain control and patient cooperation in pediatric dentistry.

CONCLUSION

The present randomized controlled clinical trial demonstrated that flavored topical anesthetic gel significantly reduced pain perception during local anesthetic administration in children compared with an unflavored topical anesthetic gel, as evidenced by lower Wong-Baker Faces Pain Rating Scale and FLACC scores. The use of a flavored topical anesthetic gel may provide a more pleasant sensory experience, improve children's comfort during injection, and facilitate better behavior management in pediatric dental practice. Incorporating flavored topical anesthetic gels into routine pediatric dental care may enhance the overall treatment experience, although further multicenter studies with larger sample sizes are recommended to validate these findings.

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