



A comparative evaluation of peppermint oil and lignocaine spray as topical anesthetic agents prior to local anesthesia in children: a randomized clinical trial

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Background: In pediatric dentistry, fear and anxiety are common among children. Local anesthetics (LA) are widely used to control pain and reduce discomfort in children during dental treatment. Topical anesthetics play a vital role in reducing pain and the unpleasant sensation of a needle puncture in children. Peppermint oil has been extensively used for various diseases. However, its anesthetic properties remain unknown. Peppermint oil, used in mouthwashes, toothpastes, and other topical preparations has analgesic, anesthetic, and antiseptic properties. This study aimed to compare and evaluate pain perception following the topical application of peppermint oil versus lignocaine spray before an intraoral injection in children, aged 8-13 years.

Method: Fifty-two children, aged between 8-13 years, who required local anesthesia for dental treatment were divided into two groups of 26 each by simple random sampling (Group 1: 0.2% peppermint oil and Group 2: lignocaine spray). In both groups, physiological measurements (e.g., heart rate) were recorded using pulse oximetry before, during, and after the procedure. Objective pain measurement (Sound Eye Motor (SEM) scale) during administration and subjective measurement (Wong-Baker Faces Pain Rating Scale (WBFPRS)) after LA administration were recorded. This was followed by the required treatment of the child.

Physiological parameters were compared between the two groups using an independent t-test for intergroup assessment and a paired t-test and repeated-measures ANOVA for intragroup comparisons. The Mann-Whitney U test was used to analyze the pain scores.

Results: Intragroup mean heart rates, before, during, and after treatment were statistically significantly different ($P < 0.05$). However, the intergroup mean pulse rates did not differ significantly between the two groups. The mean WBFPS score in the lignocaine spray group was 4.133 ± 2.06 was statistically different from that of the peppermint oil group (0.933 ± 1.03 ; $P < 0.001^*$). The mean SEM score was significantly lower in the peppermint oil group than that in the lignocaine spray group ($P = 0.006$). No negative effects were observed in this study.

Conclusion: 0.2% peppermint oil was effective in reducing pain perception.

Keywords: Analgesia; Children; Lignocaine Spray; Pain Perception; Peppermint Oil; Topical Anesthetics.

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INTRODUCTION

In pediatric dentistry, anticipatory anxiety is a common occurrence. A child expresses anxiety irrespective of

whether the treatment is invasive or non-invasive [1]. To practice pediatric dentistry successfully, effective pain management is essential. This is especially important for any invasive operation that calls for the use of local anesthetic (LA) [2]. Local anesthesia aims to alleviate pain

Received: January 17, 2024 • Revised: March 18, 2024 • Accepted: March 22, 2024

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related to dental treatment. However, it is often the procedure that causes the most pain and anxiety. The discomfort associated with dental injections is influenced by several factors. Methods, such as topical anesthesia, distraction, warming of the anesthetic solution, controlling the injection rate, buffering the anesthetic agent, counter-irritation, and local pre-cooling with refrigerant spray, have been tried to reduce the pain and discomfort of a dental injection [3].

Before a dental injection, topical anesthetics aims to minimize the prickling pain sensation caused by needle puncture. Hence, it has consistently been shown to be a crucial step before various dental operations, particularly for younger patients [4]. The topical application of an anesthetic drug to oral mucosa induces pharmacological activity, resulting in topical or superficial anesthesia. Topical anesthetics work by stopping signals from being sent by the sensory nerve terminal fibers. Only superficial tissues, up to a depth of two or three millimeters (ml), are affected. Interestingly, both psychological and physiological effects have been observed using topical anesthetics [5,6].

Lidocaine/lignocaine is the most extensively used topical anesthetic agent in pediatric dentistry. It is available as gels, patches, sprays, and solutions. As a topical anesthetics, lidocaine offers a larger safety margin, with rare instances of allergic responses. Studies have also reported that the unpleasant taste associated with topical lidocaine is concerning to young patients [7,8].

Plant extracts have been used for various medicinal purposes and their inclusion in dental materials has produced encouraging results. To date, limited dental research has been conducted on herbal anesthetics. Numerous plants have demonstrated anesthetic and analgesic properties [9]. Of these, mentha piperita (more commonly known as peppermint) is one of the “undiscovered plants” in dentistry. It is available as oil, leaves, leaf extract, and leaf water. Although this perennial herb originated in Mediterranean Europe, it is now grown worldwide. Peppermint oil is colorless or pale yellow in appearance and has a minor fresh menthol

scent. In addition to its cooling effect when used topically, peppermint oil offers other medicinal benefits including analgesic, anesthetic, antibacterial, antispasmodic, and cognitive-stimulating effects. It is used in mouthwashes, toothpastes, topical remedies, aromatherapy, and bath products [10].

To the best of our knowledge, no previous studies have investigated the topical anesthetic action of peppermint oil. This is the first study to compare and evaluate pain perception following topical application of peppermint oil versus lignocaine spray before dental injection in children, aged 8-13 years.

METHODS

1. Ethical approval and protocol registration

The Institutional Review Board and Ethics Committee of Dr. NTR University of Health Sciences approved the research protocol (IEC/NDCH/2022/SEPT/P-78). The experimental registration number in the Clinical Trials Registry of India is REF/2023/03/064843 [11].

2. Study design, setting, and duration

An equal allocation ratio was used in this randomized, parallel-group clinical experiment, comparing peppermint oil to lidocaine for topical anesthesia. The study involved children who visited the Department of Pediatric and Preventive Dentistry from June 2023 to December 2023 (6 months).

3. Sample size

G power analysis was used to estimate the sample size, with an effect size of 0.80, an alpha error of 0.05, and 80% power. Using a 1:1 allocation ratio, the sample size was determined as 52 in total (26 participants in each group).

4. Study materials

The comparative study included two groups:

GROUP 1: 0.2% peppermint oil prepared by dissolving

0.2 ml of peppermint oil in 99.8 ml of 5% ethanol. The oil was freshly prepared for each patient.

GROUP 2: 15% lignocaine spray (ICPA Health Product, India).

Following topical anesthesia, local anesthesia was administered to both groups of children using a dental syringe, with a 27-gauge long needle, and 2% lidocaine with 1:100,000 epinephrine.

5. Assessment

Heart rate was recorded as a physiological indicator using a pulse oximeter (ChoiceMMed MD300C2 Fingertip PulseOximeter). It is a non-invasive, objective method for assessing the physiological alterations caused by the subjective nature of anxiety. Heart rate was observed and recorded five minutes before, during, and five minutes after the dental injection.

The Wong-Baker Faces Pain Rating Scale (WBFPRS) was used to assess subjective pain. The WBFPRS (Home - Wong-Baker FACES Foundation, n.d.) panel was developed to help children communicate about their pain and is appropriate for use in children, aged 3 years and older (Wong & Baker, 1988). Pain experienced by the children was measured as follows. 0: Does not hurt. 2: Hurts a little bit. 4: Hurts a little more. 6: Hurts even more. 8: Hurts a whole lot. 10: Hurts the most. To self-report pain, children must be able to communicate [12].

The Sound Eye Motor (SEM) scale was used to objectively measure pain during dental injection. Objective pain was measured via sounds, eye signs, and motor movements. Each measure was allocated a score (range: 1 to 4, 1 = comfortable and 4 = severe pain). The total score (range: 3 to 12, 3 = comfortable, 12 = severe pain) was calculated as the sum of the 3 scores for sounds, eye signs, and motor movements [13].

6. Methodology

Convenience sampling was used to enroll participants. The objectives of the study were explained to all the children and their parents or guardians. Those who provided

informed consent and assent forms were enrolled.

Inclusion criteria:

1. Children, aged 8-13 years.
2. Children who exhibited positive (+) or negative (-) behaviors based on Wright's modification of the Frankl Behavior Rating scale [14].
3. Children who had never experienced local anesthesia administration.
4. Children who needed buccal infiltration for either tooth extraction or pulpectomy.

Exclusion criteria:

1. Children who definitely exhibited positive (++) or definitely negative (--) based on Wright's modification of the Frankl Behavior Rating Scale [14].
2. Children with diagnosed systemic diseases or acute infections.
3. Children with special care needs.
4. Children who were allergic to lignocaine and/or menthol.
5. Children seeking dental emergency treatment including dental trauma, acute pulpitis, dental abscess, cyst, pericoronitis, etc.

Using a computer-generated random sequence list, basic randomization was performed by an independent experienced postgraduate who supervised and coordinated the randomized allocation process. Sequentially numbered opaque sealed envelopes were prepared based on the random sequence list. Each patient selected one envelope for allocation concealment. All procedures in groups 1 and 2 were performed by a single experienced pediatric dentist. The participants and dental staff were not blinded. Due to the nature of the materials used, this study was an open trial. The primary and secondary outcomes were determined by an expert investigator who was not involved in this study. Data decoding was performed only after the results were analyzed, and the statistical analyst was blinded to both groups.

7. Treatment

Once the child was assigned to an intervention group,

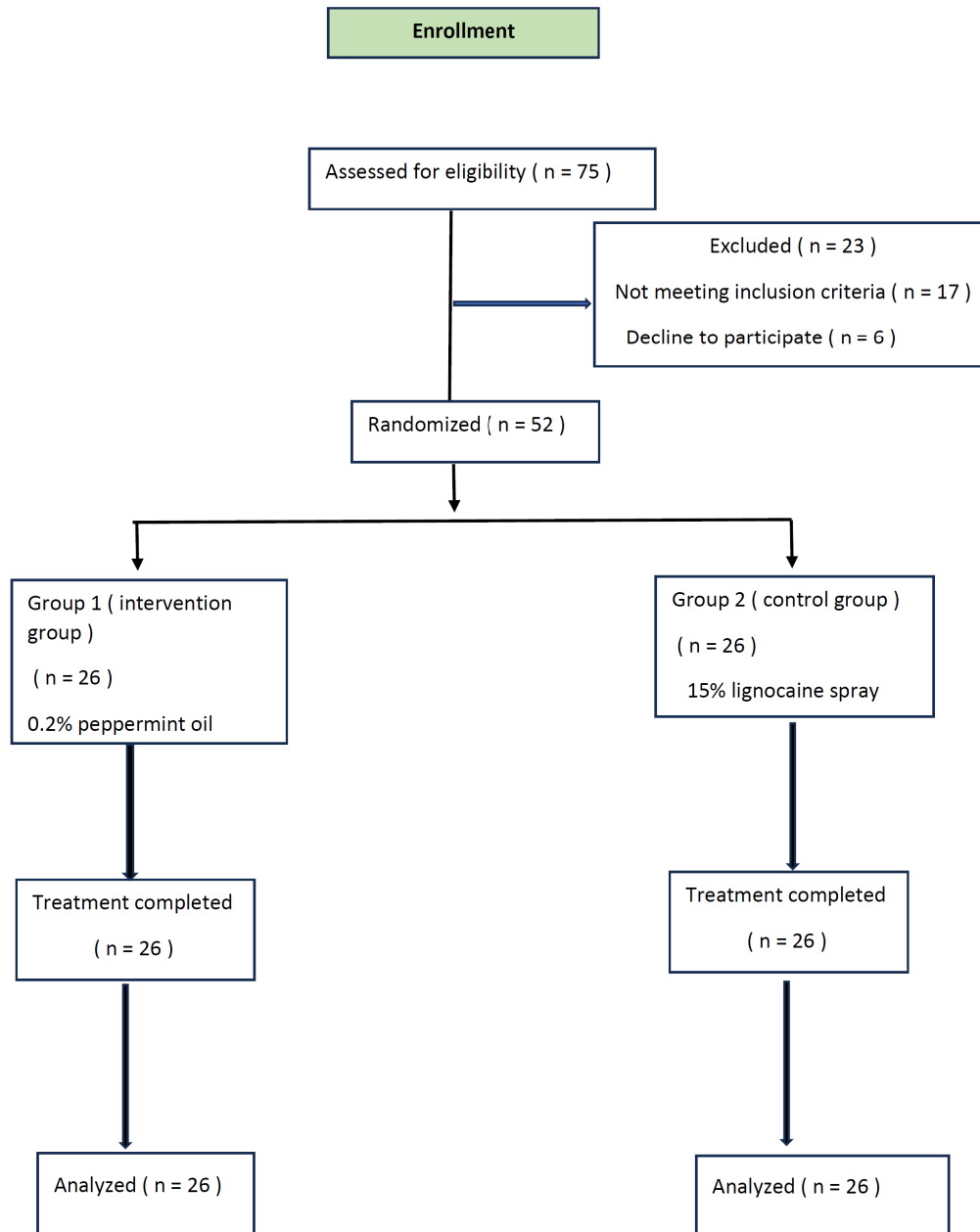


Fig. 1. Consolidated standards of reporting trials (CONSORT) flow diagram.

the topical anesthetic application site was isolated using cotton rolls. Additionally, a suction tip and sterile cotton gauze were used to keep the site dry. For children in group 1, 0.2% peppermint oil was applied at the height of the mucobuccal fold using a sterile cotton applicator tip using moderate pressure and rubbing motion. For children in group 2, lignocaine spray was activated at 1-2 cm distance from where buccal infiltration was to be performed. The application time was set at one. Following

topical anesthesia, 1 ml of 2% lignocaine with 1: 100 000 epinephrine (Lignox[®] 2% A, Warren, Navi Mumbai, India) was gently injected into the oral mucosa using a small, 1-inch (25 mm length), 27-gauge syringe following double aspiration. The co-investigator recorded heart rate changes at five minutes before, during, and five minutes following the injection. After profound anesthesia was administered, pulp therapy or extraction was performed. Using the SEM scale, trained personnel present in the

Table 1. Demographic details

Demographic details	Group 1 N(%)	Group 2 N(%)	P value
Gender			
Females	16 (61.5)	12 (46.20)	0.265 (NS)*
Males	10 (38.5)	14 (53.80)	
Age	9.733 ± 1.57	9.93 ± 1.86	0.754 (NS) [†]

*chi square test, [†]independent t test, N, number; NS, non significant.

Table 2. Comparison of pulse rates among the study group in different intervals

Groups	Before	During	After	P value
Group 1	95.02 ± 13.1	101 ± 15.2	95.88 ± 13.7	< 0.001*
Group 2	93.69 ± 14.7	99.0 ± 14.7	92.98 ± 11.65	0.008*

Repeated measures ANOVA P < 0.05* significant

Table 3. Intra group comparison of pulse rates among study groups

Groups	Intervals		P value
Group 1	Before	During	0.004*
		After	0.541 (NS)
	During	After	0.002*
Group 2	Before	During	0.005*
		After	0.079 (NS)
	During	After	0.003*

Paired t test P < 0.05* significant, NS, non significant.

dental clinic evaluated the patient's pain perception by observing the designated behaviors during needle puncture. Following the local anesthesia procedure, children were presented with the WBFPRS and asked to choose the facial expression that best represented their pain experience during the dental injection. The score selected by each patient was recorded.

8. Statistical analysis

Statistical Package for Social Sciences (SPSS), version 20, was used to tabulate and analyze the data. Chi-square and independent t-tests were used to compare demographic data between the two study groups. The Mann-Whitney U test was used to analyze pain scores. Physiological parameters were compared between the groups using an independent t-test for intergroup assessment and a paired t-test and repeated-measures ANOVA for intragroup comparisons. Statistical significance was set at P < 0.05.

RESULTS

Figure 1 shows the study flowchart. Of the 75 eligible children, 56 were recruited, randomized, allocated, and analyzed in this study.

The study included 52 children (28 female and 24 male). Of the participants, 38.5% (n = 10) were male and 61.5% (n = 16) were female in group 1 (intervention), while group 2 (control) consisted of 53.8% (n = 14) of male and 46.2% (n = 12) of female. No statistically significant difference (P = 0.143) was observed in sex distribution among the study groups (Table 1). Age distribution was also similar between the two groups (mean age: group 1 = 9.733 ± 1.57 years vs. group 2; 9.93 ± 1.86 years; P = 0.754) (Table 1).

Results from our one-way ANOVA analysis showed a significant difference in the intragroup comparison of heart rates at different intervals (Table 2). Moreover, the intragroup comparison of mean heart rates showed

Table 4. Inter group comparison of pulse rates at various intervals

Intervals	Groups	Mean ± SD	t value	P value
Before	Group 1	95.02 ± 13.06	0.262	0.795 (NS)
	Group 2	93.69 ± 14.70		
During	Group 1	101.0 ± 15.2	0.734	0.700 (NS)
	Group 2	99.0 ± 14.7		
After	Group 1	95.88 ± 13.76	0.945	0.539 (NS)
	Group 2	92.98 ± 11.65		

Independent t Test, NS, non significant; SD, standard deviation.

Table 5. Intergroup comparison of pain scales among study groups

Groups	Scales	Mean ± SD	U value	P value
SEM	Group 1	0.733 ± 0.79	49.5	0.006*
	Group 2	1.66 ± 0.81		
Wong baker	Group 1	0.933 ± 1.03	14.00	< 0.001*
	Group 2	4.133 ± 2.06		

SD, standard deviation; SEM, sound eye motor scale; Mann Whitney U test P < 0.05* significant

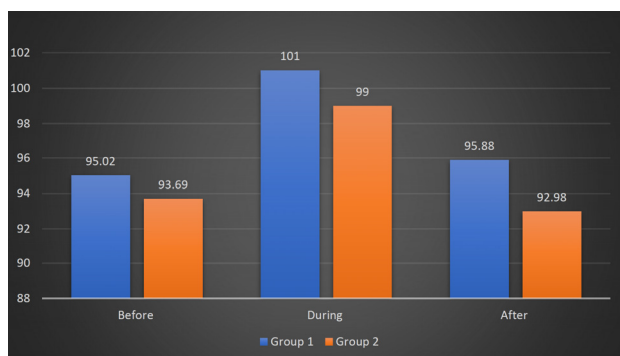


Fig. 2. Intergroup comparison of heart rates at various intervals

significant differences before, during, and after local anesthesia in both group 1 and group 2 (Table 3). In contrast, the intergroup comparisons of the mean heart rates did not differ significantly at various intervals (Table 4 and Fig. 2).

Results from the Mann-Whitney test showed that subjective pain as assessed by the children using the WBFPS was significantly different between the groups (P < 0.001). Furthermore, objective pain assessed using the SEM scale demonstrated a significant difference between the groups (P = 0.006). This finding revealed that children in the group using peppermint oil for topical anesthesia had lower pain scores than children in the control group (Table 5 and Fig. 3).

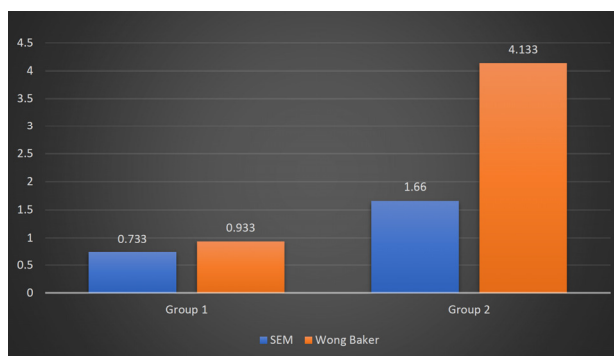


Fig. 3. Intergroup comparison of the pain scores. SEM, sound eye motor scale.

DISCUSSION

Children frequently refuse dental treatment due to anticipatory anxiety and the fear of pain [15]. Ironically, dental injection aims to provide local anesthesia to relieve treatment pain often causes the greatest anxiety and dread among patients. There are several ways to reduce the amount of pain and discomfort caused by injections [16]. In clinical pediatric dental practices, topical anesthetics are most often used to minimize the pain of local anesthetic administration [17].

Owing to concerns regarding the increased incidence of adverse reactions, such as overdosage, allergic

reactions, ulcerations, idiopathic swelling of soft tissues, anaphylaxis, and toxic reactions to topically applied local anesthetics are expected to occur, researchers have explored the use of herbal formulations as alternatives to synthetic topical anesthetics agents [18-22]. Shabbir et al. [23] reported that *Mentha piperita* has an astonishing number of biogenic effects that are applicable to medical and everyday domains. Peppermint is frequently used to treat nausea, irritable bowel syndrome, abdominal pain, colds, and cough in children. Peppermint oil has also been used to treat various conditions including pressure migraines, non-obstructive dyspepsia, infantile colic, and tension headaches. Both mint and its oil have antispasmodic properties that diminish fatigue and muscle agony. It has been noted that *Mentha piperita* concentrate works better than chlorhexidine-containing mouthwashes for suppression of biofilm growth, which is associated with dental caries and specifically, *Streptococcus mutans*. Powdered peppermint leaves were traditionally used to brighten teeth. Furthermore, peppermint can mask and reduce foul breath, provide freshness, and ward off the smell associated with bad breath.

The Cosmetic Ingredient Review (CIR) of the Cosmetic, Toiletry, and Fragrance Association states that peppermint oil concentrations in products should not exceed 3% in rinse-off formulations and 0.2% in leave-on formulations [24]. Therefore, 0.2% peppermint oil was used in this study. No side effects were observed. Peppermint essential oil is water-insoluble. Hence, in this study, ethanol was used as a solvent and a microbial preservative as is common in oral liquid medicines. Ethanol is the second most commonly used solvent in liquid formulations after water [25].

The German Commission E states that children under the age of 7 years should not be included in the current investigation because of the possibility of lung difficulties. Moreover, children with higher cognitive abilities (aged 7 years and over) were deemed more suitable [26].

Potentially, buccal infiltration offers a lower risk of tissue damage and requires less depth of needle

penetration than that of the inferior alveolar nerve block, when administering local anesthesia. In this study, only participants who required local anesthesia by buccal infiltration were selected. To improve topical anesthesia, appropriate isolation to enhance the adherence of the agent to oral mucosa for an extended period without dilution or removal by saliva, was ensured in this study. To prevent inter-examiner bias associated with the injection technique, the same individual administered all infiltrations in this study. To improve the tolerance and participation of pediatric patients, the reagent application time was limited to one minute.

Children's pain can be measured using three different methods: self-reported, physiological, and observational or behavioral. Ideally, a combination of these measures should be considered. For example, self-reported pain assessment and one or more of the other alternatives [27,28]. In this study, self-reported pain level (WBFPS), and behavioral (SEM scale) and physiological (heart rate) variables were measured. The WBFPS was selected for its ease of use and comprehensive scale, particularly for younger audiences. The SEM scale correlated the patient's pain level by assessing their eyes, body language, and vocal manifestations for discomfort. The mean heart rate was used as a proxy for physiological alterations in response to stress and anxiety.

In the intragroup comparison of heart rates, children demonstrated a significant increase in heart rates during local anesthesia administration, which may be due to the vasoconstrictor effect of local anesthesia [29] compared to the before and after intervals within each group. In contrast, the heart rates before and after local anesthesia were not significantly different, possibly because they fell within physiological limits. Our findings were consistent with the results reported by Mohite et al. [30]. In that study, the pulse rate decreased during needle penetration compared to the pulse rate before injection [30]. Our intergroup comparisons of heart rates were not significant, even though the mean heart rates were reduced. These results were also consistent with the findings of Mohite et al. [30], who found no discernible differences between

the lignocaine and herbal gel groups in their study. Similarly, Lucas Cerutti de Andrade et al. [31] demonstrated similar findings in their study, which examined the efficacy of a 20% benzocaine ointment versus *A. oleracea* as topical anesthetic agents, for the buccal mucosa.

The WBFPS of group 1 in the current study was lower than that of group 2. These results conflict with those of Raghavendra Havale et al. [32], who observed no statistically significant differences between betel leaf gel, ice, lignocaine gel, and clove oil gel. There was no statistically significant difference observed in the WBFPS following treatment with 15% lignocaine spray and 8% lignocaine gel, according to Sharma et al. [15]. Likewise, no statistically significant difference was reported in a similar study by Anantharaj et al. [33]. However, our results are in line with the findings of Pathan et al. [34], who demonstrated a statistically significant difference between lavender oil and benzocaine gel. Mandal et al. [35] also showed a statistically significant difference between 2% lidocaine gel and 20% benzocaine gel when comparing EMLA and 2% lignocaine gel. Additionally, Eslam et al. [36] also reported significant results.

In this study, the group 1 SEM scores were lower than those of group 2. These results conflicted with those of Anantharaj et al. [33], Parthan et al [34], Raghavendra Havale et al. [32], Mandal et al. [35], and Ibrahim et al. [36]. The difference may be attributed to the cooling effect and fresh menthol odor of peppermint oil.

Our findings suggest that children who had peppermint oil for topical anesthesia perceived less pain than children in the lignocaine spray group. The difference may be related to the cooling effect of menthol, the key constituent in peppermint oil.

Mechanism of action

The findings from this study suggest that peppermint oil provides topical anesthetic effects due to its menthol component, which provides a cooling sensation topically. The coolness from the menthol stimulates "cold" receptors and produces a tingling sensation and a feeling of coldness by blocking Ca^{++} currents in the neuronal

membranes. By increasing the frequency of "warm" receptor discharge, Ca^{++} solutions produce a diffuse feeling of warmth, whereas a reduction in the external Ca^{++} concentration causes an increase in the discharge of "cold" receptors. Evidence in the literature has also suggested that pain threshold is dependent on the modulation of Ca^{++} currents [37].

Limitations

First, owing to the physical state and application technique of the oil and spray, it was not possible to blind the participants or the clinician. Second, we did not compare other injection techniques other than buccal maxillary and mandibular infiltrations.

Conclusion

Pain perception was reduced in the 0.2% peppermint oil group compared to the lignocaine spray group. Thus, 0.2% peppermint oil may be considered as an alternative topical anesthetic agent for pediatric patients before buccal infiltrations.

Recommendations

Further research is needed to verify our results. In the future, studies should consider different concentrations of peppermint oil, larger sample sizes, and studies designed to compare the topical anesthetic effect of peppermint oil with other pain control methods.

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Sivakumar Nuvvula: Conceptualization, Writing - review & editing

DECLARATION OF INTERESTS: There are no conflicts of interest.

FUNDING: This study did not receive any financial support or sponsorship.

ACKNOWLEDGMENT: The authors thank Dr. Salma Shaik, M. Pharm, and Associate Professor at the Department of Pharmaceutical Chemistry, Narayana Pharmacy College, Nellore, Andhra Pradesh, India.

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