

STUDY PROTOCOL

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Title: EVALUATION OF AROMATHERAPY AND COMPUTER-CONTROLLED LOCAL ANESTHETIC DELIVERY SYSTEMS ON DENTAL ANXIETY AND PAIN IN CHILDREN UNDERGOING TOOTH EXTRACTION

Sponsor

Istanbul University Scientific Research Projects Unit (BAP)

Background

Dental anxiety is a highly prevalent condition among children, characterized by excessive fear, physiological hyperarousal, and behavioral resistance during dental procedures. Reports indicate that 5–40% of children experience dental anxiety, which negatively impacts treatment compliance and increases perceived pain. Local anesthesia administration and tooth extraction are among the procedures most commonly associated with anxiety and discomfort in pediatric patients.

Non-pharmacological approaches such as aromatherapy have recently gained popularity as adjunctive methods to reduce preoperative dental anxiety. Lavender and sweet orange essential oils, in particular, demonstrate anxiolytic, sedative and mild analgesic properties. These oils exert their effects through modulation of neurotransmitters such as serotonin, dopamine and GABA, and have been shown to reduce heart rate, blood pressure, and behavioral manifestations of anxiety in children.

Computer-controlled local anesthetic delivery (CCLAD) systems, including SleeperOne®, provide a controlled injection rate and pressure, reducing discomfort caused by sudden tissue distension during traditional injections. CCLAD-assisted intraosseous anesthesia has been demonstrated to produce rapid, profound pulpal anesthesia with minimal soft-tissue numbness, reducing postoperative complications such as lip or cheek biting in young children.

Although numerous studies have evaluated aromatherapy and CCLAD separately, no study to date has examined the combined effect of aromatherapy and digital anesthesia on both dental anxiety and pain perception during tooth extraction in children. The current study aims to fill this gap.

Objectives

Primary Objective

To evaluate the effectiveness of aromatherapy and computer-controlled local anesthetic delivery (SleeperOne®) in reducing dental anxiety and pain among children undergoing mandibular primary molar extraction.

Secondary Objectives

- To compare pain levels during local anesthesia administration and tooth extraction using traditional versus digital anesthesia techniques.
- To assess changes in physiological parameters (heart rate, systolic and diastolic blood pressure, oxygen saturation) in relation to anxiety-reducing interventions.
- To determine whether aromatherapy enhances patient cooperation and reduces behavioral distress during dental procedures.

Study Design

This is a single-center, randomized controlled clinical trial conducted in the Department of Pediatric Dentistry at İstanbul University, Faculty of Dentistry. Children aged 6–12 requiring mandibular primary molar extraction will be recruited according to predetermined inclusion/exclusion criteria.

Participants will be randomly assigned to one of four groups:

Group 1: Conventional Local Anesthesia

In this group, local anesthesia will be administered using a standard dental syringe with the conventional infiltration technique. Before injection, 10% lidocaine topical anesthetic will be applied to the dried mucosa for approximately 1–2 minutes to reduce needle-related discomfort. Following topical anesthesia, the clinician will deliver infiltration anesthesia at a controlled pace to minimize tissue pressure and patient discomfort.

All injections will be performed using Ultracain DS Forte (4% articaine with 1:200,000 epinephrine), a commonly used and well-established local anesthetic agent in pediatric dentistry. After administration, a waiting period of approximately five minutes will allow adequate anesthetic diffusion before tooth extraction begins.

Group 2: Computer-Controlled Local Anesthetic Delivery System (CCLAD)

In this group, anesthesia will be performed using the SleeperOne® computerized intraosseous anesthesia device, which regulates injection speed and pressure automatically. This system enables precise delivery of the anesthetic solution and aims to reduce discomfort by maintaining a constant, controlled flow rate throughout the procedure. The device features a lightweight handpiece that allows pen-style grip for enhanced stability, improving clinician control and potentially lowering anxiety related to needle visibility. The intraosseous technique involves an initial mucosal anesthesia phase followed by controlled penetration through the cortical plate into the cancellous bone, enabling rapid onset pulpal anesthesia without extensive soft-tissue numbness. This approach represents an advanced alternative to traditional syringe injections and is evaluated for its potential to improve patient comfort, reduce perceived pain, and enhance cooperation during pediatric dental procedures.

Group 3: Aromatherapy + Conventional Local Anesthesia

In this group, children will receive aromatherapy prior to anesthesia. Lavender and sweet orange essential oils will be administered using a diffuser placed in the clinical environment, allowing gentle ambient inhalation without direct topical or oral exposure. This calming sensory intervention is designed to help reduce pre-procedural anxiety. Following aromatherapy, local anesthesia will be administered using the conventional syringe-based infiltration method. The procedure will follow the same steps described for Group 1, including topical anesthetic application and slow deposition of anesthetic solution. This group allows evaluation of whether aromatherapy enhances patient comfort when paired with a standard anesthetic technique.

Group 4: Aromatherapy + Computer-Controlled Local Anesthetic Delivery System (CCLAD)

In this group, aromatherapy with lavender and sweet orange essential oils will similarly be delivered via diffuser prior to the anesthetic procedure. After the aromatherapy exposure, local anesthesia will be administered using the computer-controlled SleeperOne® system, following the same intraosseous protocol described for Group 2. This combination aims to explore whether the anxiolytic benefits of aromatherapy complement the reduced-pain profile of digital anesthesia, potentially providing the most comfortable overall experience for pediatric patients undergoing tooth extraction.

Study Population

Inclusion Criteria

- Children aged 6–12 years
- Indicated for extraction of mandibular primary molars (without acute infection)
- No systemic disease
- Frankl Behavioral Rating Scale: Categories 2,3,4
- No analgesic or sedative intake within 24 hours
- Voluntary participation with parental informed consent

Exclusion Criteria

- Allergy to articaine, epinephrine, or essential oils
- Asthma, respiratory disorders, or upper respiratory infections
- Frankl Category 1 behavior
- Teeth with mobility, ankylosis, or advanced root resorption
- Inability to comply with aromatherapy inhalation

Aromatherapy Procedure

Aromatherapy with lavender and sweet orange essential oils will be administered via an electric diffuser in the clinical environment prior to anesthesia. Only inhalation exposure will be provided; no topical or oral application will be used.

Local Anesthesia Procedure

Before all anesthesia applications, topical anesthesia (10% lidocaine) will be applied to the dried mucosa for 1–2 minutes.

- **Groups 1 & 3:** Conventional infiltration anesthesia
- **Groups 2 & 4:** Computer-controlled digital intraosseous anesthesia (SleeperOne®)

Ultracain® DS Forte (4% articaine, epinephrine 1:200,000) will be used as the anesthetic agent in all groups.

Tooth extraction will be performed after verifying adequate anesthesia.

Outcome Measures

1. Anxiety Assessment

a. Physiological measurements:

- Systolic blood pressure
- Diastolic blood pressure
- Heart rate
- Oxygen saturation (SpO₂)

Measurements will be obtained using an blood pressure monitor and pulse oximeter at the following timepoints:

- Before intervention
- After aromatherapy (if applicable)

- After anesthesia
- After extraction

b. Facial Image Scale (FIS): Children will select a facial expression representing their emotional state at each timepoint.

2. Pain Assessment

a. Wong-Baker Faces Pain Rating Scale (WBS): Used to assess self-reported pain after anesthesia and after extraction.

b. FLACC Scale (Face, Legs, Activity, Cry, Consolability): Used by the clinician to evaluate behavioral pain responses after anesthesia and extraction.

Risks and Mitigation Strategies

Potential Risks

-Anxiety related to dental procedures: Children may experience procedural anxiety associated with local anesthesia administration or tooth extraction.

-Mild irritation or hypersensitivity to essential oils: Although rare, inhalation of lavender or sweet orange oils may trigger mild allergic reactions or respiratory discomfort in sensitive individuals.

-Pain or discomfort during or after extraction: Despite appropriate anesthesia, some children may report procedural discomfort.

-Physiological changes during vital sign assessment: Blood pressure or pulse measurements performed with blood pressure monitor and pulse oximeter may cause temporary unease in some children.

-Post-extraction soft-tissue injury: Accidental lip, cheek, or tongue biting may occur following local anesthesia.

Risk Mitigation Measures

- Implementation of behavior guidance techniques: Age-appropriate communication and behavioral support will be used to enhance cooperation and reduce anxiety.
- Comprehensive medical and allergy screening: A detailed medical history will be taken before treatment to identify potential allergies or contraindications related to anesthetic agents or essential oils.
- Atraumatic and standardized clinical procedures: All extractions will be performed under sterile conditions using minimally invasive, tissue-preserving techniques.
- Use of validated assessment tools: Anxiety and pain will be evaluated using validated pediatric scales to ensure reliable measurement.

Ethical Considerations

The study will follow the Declaration of Helsinki and Good Clinical Practice.

Parental informed consent will be obtained.

Participation is voluntary, and withdrawal is allowed at any time.