

Official Title: The Effect of Dental Anxiety on the Success of Mandibular Anesthesia in Mandibular Molar Teeth with Symptomatic Irreversible Pulpitis: A Prospective Clinical Study

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Null Hypothesis (H₀): Dental anxiety does not affect the success of mandibular anesthesia in the treatment of symptomatic irreversible pulpitis in mandibular molar teeth.

Study arms: A prospective clinical trial with two parallel intervention arms. Participants will be divided into two groups based on their Modified Dental Anxiety Scale (MDAS) scores:

- Group 1 (Low Anxiety Group): MDAS score < 10
- Group 2 (Moderate to High Anxiety Group): MDAS score ≥ 11 (including those with dental phobia if MDAS > 19)

Sample Size Calculation: Using G*Power 3.1.9.7 software, based on an effect size of 0.8, $\alpha = 0.05$, and power = 0.80, the required sample size was determined as **26 patients per group**, totaling **52 participants**. The actual power achieved was 81%.

Materials and Methods:

Inclusion Criteria:

- Systemically healthy adults aged 18–65
- Mandibular molar teeth with symptomatic irreversible pulpitis requiring root canal treatment
- Radiographic evidence of closed apex and absence of periapical pathology
- Periodontal probing depth ≤ 3 mm
- Tooth mobility < 0.5 mm
- Pain score of 55–170 mm on the Heft-Parker Visual Analog Scale (HP-VAS) (i.e., moderate or severe pain)
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- **Exclusion Criteria:**
 - Systemic disease
 - Teeth with open apex, periapical lesion, internal or external resorption
 - Periodontal probing depth > 3 mm
 - Tooth mobility > 0.5 mm
 - HP-VAS score < 55 mm (no or mild pain)
 - Pregnant patients or those with allergy to articaine

Procedure:

- All treatments and measurements will be conducted between 09:00 and 12:00 to minimize circadian and cortisol fluctuations.
- Patients will avoid food intake for at least 2 hours before treatment and abstain from caffeine, alcohol, tobacco, and intense exercise within 24 hours.
- Patients will rest in the dental chair for 5 minutes, then their demographic data will be recorded.
- MDAS will be administered to assess anxiety level.
- HP-VAS will be used to assess pre-treatment pain level.
- Pulse rate, SpO₂, and salivary cortisol levels will be recorded pre- and post-anesthesia.

Anesthesia Protocol:

- All procedures are performed by a single operator in a one-unit room.
- Topical anesthesia: 10% lidocaine spray (Locanest) applied for 60 seconds.
- IANB (Inferior Alveolar Nerve Block):
 - 1.8 ml of 4% articaine hydrochloride with 1:100,000 epinephrine (Ultracaine DS Forte) via 27G needle
- Buccal and lingual infiltration:
 - Additional 1.8 ml injection performed 5 minutes after IANB
- Block Failure Definition:
 - If deep lip numbness is not achieved within 15 minutes, the block is considered failed and the participant is withdrawn from the study.

Outcome Evaluation:

- During treatment, if the patient feels pain, they raise their hand, and the pain is marked on the HP-VAS.
- If required, supplemental anesthesia (PDL or intrapulpal) will be administered and recorded.
- Successful anesthesia: No or mild discomfort
- Failed anesthesia: Moderate or severe pain
- Cold test will be performed 15 minutes after IANB. If positive, additional anesthesia will be given.

Biological Sampling:

- Saliva samples will be collected 15 minutes before and after anesthesia.
- Samples will be stored at -80°C until analysis.
- Special sterile, single-use Sali-Tubes (SLV-4158, DRG, Germany) will be used.

Statistical Analysis:

All statistical analyses will be performed using SPSS Statistics 20 software (IBM Corp., Armonk, NY) at a 5% significance level. If the data are normally distributed, Student's t-test will be used to compare preoperative pain levels, salivary cortisol, SpO₂, and pulse rate across different anxiety levels. Chi-square test will be used to analyze the relationship between anxiety levels and the success rate of anesthesia.