

STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN

TITLE: The Effect of Rubber Dam on Objective and Subjective Parameters of Stress During Dental Treatment in Children

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RCT: The study was approved by the Medical Ethics Committee of Izmir Katip Celebi University, under report No. 2024/0242

STUDY PROTOCOL:

This randomized, controlled, single-blinded study included 100 healthy, cooperative children (Frankl Scale, Rating 3-4) aged 6-12 years, classified as ASA I, with bilateral fully erupted mandibular first permanent molars requiring pit and fissure sealant procedures. The inclusion criteria were based on the International Caries Detection and Assessment System II, including deep and retentive pits and fissures, no restorations, and no evidence of carious lesions.

The study was planned as split mouth design: For each patient, one tooth was selected for rubber dam isolation, while the corresponding tooth from the opposite quadrant was chosen for cotton roll isolation. The Rubber dam application group divided also into two groups as topical EMLA application, and infiltration anesthesia application. Randomization was performed using manually generated sealed envelopes containing information about which isolation method and anesthesia technique would be used on which side of the jaw (right or left). Random numbers were written on separate papers, folded, and placed in opaque sealed envelopes. Each participant chose an envelope and was assigned the printed participant number. Each number identified the teeth included in the study, the isolation technique specified for each tooth, and the anesthesia method to be used during the rubber dam application.

After the cleaning procedure, following the randomization result and determination of which isolation method would be applied to which side of the patient's jaw, to ensure that the local anesthetics used would not affect the patient's cooperation, in the first session, the selected tooth was isolated with standard cotton rolls and high-volume suction for the pit and fissure sealing procedure on one side of the patient. Cotton rolls were placed in both the lingual and mucco-buccal side of the arch and the suction was positioned on the lingual side of the tooth. Cotton rolls were changed following enamel etching and, in every case, where they became excessively moisture throughout the treatment. The fissure sealant procedure was carried out following the manufacturer's instructions. Objective stress parameters (pulse rate, systolic blood pressure and diastolic blood pressure) for the children and the pulse rate of the operator were recorded at three different points. Systolic and diastolic blood pressure were measured using an automatic blood pressure monitor. Pulse rate was evaluated with a fingertip pulse oximeter. The operator's pulse rate was also recorded. Pain perception was assessed subjectively post-procedure using the Wong-Baker FACES Pain Rating Scale (WBFPRS) and Visual Analogue Scale (VAS). One week later, the patient was invited to a second appointment for the treatment of the corresponding tooth from the opposite side.

STATISTICAL ANALYSIS PLAN

All statistical analyses of the data were conducted using SPSS statistical software Version 21.0 (SPSS Inc., Chicago, IL, USA), with 0.05 selected as the level of significance (α). The normality test was conducted using Shapiro-Wilk and the Kolmogorov-Smirnov tests. Data were analyzed using Mann-Whitney U and independent samples t-tests. For within-group comparisons, Wilcoxon Signed Rank and the Friedman tests were employed.