Official Title: Evaluation of the Impact of Preoperative Anxiety on Postoperative Pain and Emergence Delirium in Patients Undergoing Pediatric Urogenital Surgery: A Prospective Observational Study

NCT Number: NCT07343388

Document Date: April 24, 2025

1. STUDY PROTOCOL

1.1. Objective and Study Design

This is a prospective, observational study designed to evaluate the impact of preoperative anxiety on postoperative early recovery parameters, pain intensity, and the development of emergence delirium in pediatric patients.

1.2. Ethical Approval and Consent

The study protocol was approved by the Clinical Research Ethics Committee of University of Health Sciences, Dr. Behcet Uz Children's Hospital (Date: April 24, 2025; Protocol No: GOA-155). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from the legal guardians of all participants prior to surgery.

1.3. Participant Selection

- **Inclusion Criteria:** Pediatric patients aged 2–7 years, classified as ASA (American Society of Anesthesiologists) physical status I–II, undergoing elective urogenital surgery under general anesthesia.
- **Exclusion Criteria:** Children with cognitive or mental developmental delays, diagnosed neurological or psychiatric disorders, chronic pain syndromes, or those undergoing emergency surgery. Cases involving experimental drugs or non-standard analgesia techniques were also excluded.

1.4. Anesthesia Management

A standardized general anesthesia protocol was applied to all participants:

- **Premedication:** No pharmacological premedication was administered.
- **Induction:** 0.1 mg/kg midazolam and 1 mcg/kg fentanyl. Airway was secured with a laryngeal mask airway (LMA) suitable for the child's weight.
- **Maintenance:** Inhalation anesthesia using sevoflurane and an air-oxygen mixture. Anesthesia depth was maintained at standard MAC values (1.0–1.2).
- **Postoperative Analgesia:** Standardized with 10 mg/kg paracetamol based on the surgical procedure and body weight.

1.5. Assessment and Data Collection

- **Preoperative Assessment:** Anxiety levels were assessed immediately before anesthesia induction using the Modified Yale Preoperative Anxiety Scale (mYPAS). Scores range from 23 to 100, with ge 30 indicating clinically significant anxiety.

- **Postoperative Assessment:** Conducted in the Post-Anesthesia Care Unit (PACU) at 0, 15, 30, 45, and 60 minutes:
    - **Pain Intensity:** Measured using the FLACC (Face, Legs, Activity, Cry, Consolability) scale (0–10).
    - **Emergence Delirium:** Monitored using the Pediatric Anesthesia Emergence Delirium (PAED) scale. Scores ge 10 indicated clinically significant delirium.
    - **Recovery Quality:** Evaluated using the Modified Aldrete Score (0–10).

2. STATISTICAL ANALYSIS PLAN (SAP)

2.1. Sample Size and Power Analysis

Sample size was determined based on the positive correlation coefficient (r = 0.479, P = 0.001) between preoperative anxiety and postoperative pain scores reported in the literature. With a Type I error rate (alpha) of 0.05 and a power (1-beta) of 0.95, the minimum required sample size was calculated as 51 patients. The study was completed with 114 patients to account for potential data loss and clinical variations.

2.2. Statistical Methodology

- **Data Distribution:** Assessed using the Shapiro-Wilk test.
- **Descriptive Statistics:** Continuous variables are presented as Mean pm Standard Deviation or Median (Interquartile Range). Categorical variables are presented as frequencies and percentages (n, %).
- **Comparative Analysis:** * Independent samples t-test, Pearson Chi-square, or Fisher's Exact tests were used for demographic and clinical comparisons.
    - The Mann-Whitney U test was applied for comparing PAED, FLACC, and Aldrete scores between groups (mYPAS < 30 vs. mYPAS ≥30).
- **Risk Analysis:** Raw Odds Ratios (OR) and 95% Confidence Intervals (CI) were calculated for clinical risk assessments at specific time points.
- **Regression Modeling:** Multivariate Logistic Regression analysis using the "Enter" method was performed to determine the independent effect of preoperative anxiety on outcomes. Models were adjusted for age, sex, ASA score, surgical history, and surgery type.
- **Significance Level:** $p < 0.05$ was considered statistically significant for all analyses.