STUDY PROTOCOL

Study Title: "Comparison of the Analgesic Efficacy of Caudal and Quadratus Lumborum Blocks Using a Pain Monitor in Children Undergoing Lower Abdominal Surgery"

Study Objective and Importance (Primary Objective, Secondary Objectives), Expected Benefits and Risks:

The primary objective of this study is to compare the analgesic efficacy of Caudal and Quadratus Lumborum (QL) blocks using a pain monitor (Pain Monitor; PAM).

Secondary Objectives:

To evaluate the analgesic efficacy of Caudal and QL blocks in lower abdominal surgeries.

To compare the postoperative analgesia duration and analgesic requirements between the two groups.

To assess the side effects of Caudal and QL blocks to determine the most suitable method for children.

To evaluate the level of postoperative parental satisfaction.

We believe our study will contribute to postoperative analgesia management by investigating the use of a pain monitor for the objective measurement of pain, which is currently assessed subjectively in children.

Expected Benefits and Risks:
Benefits:

If the QL block provides superior analgesia compared to the caudal block, it could be more widely used for pain management in pediatric lower abdominal surgeries.

If the QL block significantly reduces analgesic requirements, it may decrease postoperative side effects such as nausea, vomiting, and urinary retention.

The use of the PAM monitor could provide more reliable pain monitoring, overcoming the limitations of subjective scoring, especially in young children.

This will be one of the few prospective randomized observational studies comparing QL and caudal blocks using a PAM monitor in pediatric lower abdominal surgery. The findings could offer recommendations for block selection in pediatric anesthesia practice and provide data on the reliability of the PAM monitor for pain assessment in children.

Risks:
As with all blocks, local anesthetic systemic toxicity (LAST) may occur if dosing adjustments are not correctly made.

Analgesia may be inadequate due to the technically more challenging ultrasonographic application of the QL block or insufficient spread.

Although very rare, complications such as dural puncture, bleeding, and infection can occur with caudal blocks. Similarly, with ultrasound use, there is a very rare risk of peritoneum or kidney injury with QL blocks.

Technical errors related to the PAM monitor may occur; motion artifacts could lead to false positive/negative results.

Satisfaction scoring may not be fully assessed by parents due to socio-cultural factors.

This study introduces an innovative approach to evaluating pain management in pediatric lower abdominal surgery while providing safety and efficacy data for the routine use of the QL block. When risks are controlled with methodological rigor, the potential clinical benefits (particularly analgesic sparing and objective pain monitoring) will be prominent.

Study Hypothesis:

H0: In patients aged 2 months to 6 years undergoing lower abdominal surgery, the quadratus lumborum block (QLB) provides more effective analgesia for pain management than caudal epidural block.

H1: QLB significantly reduces nociceptive responses measured objectively by the pain monitor (PAM), lowers postoperative FLACC (Face, Legs, Activity, Cry, Consolability) scores, increases parental satisfaction, delays the first analgesic requirement, and reduces total analgesic consumption.

Materials (Equipment) – Methods:

Children aged 2 months to 6 years with ASA I-II status undergoing lower abdominal surgeries (e.g., inguinal hernia, orchiopexy, hydrocele) performed by the pediatric surgery unit at Etlik City Hospital will be included. Patients will be randomized using the Research Randomizer program (https://www.randomizer.org/), and subsequently, QL or caudal blocks will be administered based on the assigned sequence. A total of 68 patients will be included in the study, with 34 patients in each group.

Demographic information, anesthesia, and surgical duration will be recorded. Informed consent will be obtained from parents/guardians preoperatively. Patients receiving routine oral premedication (0.5 mg/kg midazolam) in the preoperative area will be observed. In the operating room, after standard monitoring (SpO2, ECG, blood pressure) is established, the PAM monitor will be attached. For children under 3 years, a pediatric probe will be placed on the foot; for those 3 years and older, an adult probe will be placed on the hand. All observed patients will receive a standard anesthesia protocol (O2/air, sevoflurane, propofol, LMA, etc.). Under ultrasound guidance, a caudal block with 1 ml/kg of 0.125% bupivacaine (maximum volume 20 ml) or a bilateral QL block with 0.5 ml/kg of 0.25% bupivacaine (maximum volume 20 ml) will be

performed. Following routine awakening, the PAM monitor will be removed, data will be recorded, and patients will be monitored for up to 4 hours postoperatively. Any intraoperative additional analgesic or anesthetic requirements and their doses will be recorded. The anesthesiologists administering anesthesia and performing the blocks will be blinded to the study.

The PAM monitor used is routinely employed in our clinic for many patients and is not specific to this study. As indicated, the Medstorm pain probe and device belong to our Anesthesiology and Reanimation Clinic and are obtained from the pharmacy's consumables section. The probes used are deducted from the pharmacy's consumables stock; therefore, there is no additional cost. For this thesis titled "Comparison of the Analgesic Efficacy of Caudal and Quadratus Lumborum Blocks (QLB) Using a Pain Monitor in Children Undergoing Lower Abdominal Surgery," the PAIN MONITOR (PAM), which operates on the principle of skin conductivity and is used for analgesia assessment, will be observed.

The Painsensor is a pain probe that works on the principle of skin conductivity algometry, providing information about the patient's pain and wakefulness states within seconds. It is also used in other operating rooms of our hospital to assess block adequacy, wakefulness, and analgesic effect. Pain or stressful situations trigger the activation of sweat glands in the palms and soles of the feet. Consequently, the skin becomes moist, leading to better skin conductivity. The Painsensor detects peaks in skin conductivity. The device uses an algorithm to convert the number of peaks into a value between 0-10, called the Pain Index. This Pain Index reflects the body's pain or nociceptive response and reacts within 1-2 seconds. It assesses the effect of regional anesthesia on unmyelinated sympathetic skin nerves, is unaffected by changes in blood circulation or drugs affecting circulation, and is not influenced by the hypotensive effects of alpha-2 agonists or the circulatory effects of beta-blockers. It is a nociception response indicator usable for all age groups from 23 weeks of gestation. The reason for choosing this probe is that it only measures skin conductivity and is not affected by other variable factors like heart rate and blood pressure. For children under 3 years, a pediatric probe attached to the sole of the foot will be used; for children 3 years and older, an adult probe attached to the hand will be connected to the measurement device, and the patient will be monitored throughout the case.

Intraoperative PAM scores for all patients will be recorded at five time points: during LMA insertion, during block performance, during the first surgical incision, 20 minutes after the block, and during extubation.
Postoperative FLACC, PONV (Postoperative Nausea and Vomiting Score), STEWARD (Postoperative Recovery Scoring System), and PPPS (Pediatric Anesthesia Parental Satisfaction Score) will be assessed at 1, 2, and 4 hours postoperatively.

Rescue analgesia (IV paracetamol 15 mg/kg) will be administered if the FLACC score is ≥4. The time of first administration will be recorded.

Postoperative PONV scores, awakening scores, and complications will be recorded. Postoperative patient data will be obtained from anesthesia files.

Exclusion Criteria:

Severe systemic disease (ASA ≥III)

Infection at the block site

Coagulopathy (INR >1.4, platelets <100,000)

Local anesthetic allergy

Parental refusal

Children aged <2 months or >6 years

Sample Size: A power analysis conducted using G*Power 3.0.10 software determined that a total sample size of at least 68 (n1:34 – n2:34) is sufficient with 90% power and a 5% margin of error (alpha).

Test: t-tests - Means: Difference between two independent means (two groups)

Analysis: A priori: Compute required sample size

Input: Tail(s) = Two, Effect size d = 0.8, α err prob = 0.05, Power (1-β err prob) = 0.90, Allocation ratio N2/N1 = 1

Output: Noncentrality parameter δ = 3.298485, Critical t = 1.996564, Df = 66, Sample size group 1 = 34, Sample size group 2 = 34, Total sample size = 68, Actual power = 0.901502

Statistical Methods:

Descriptive Statistics: To describe participants' demographic characteristics (age, gender, etc.) and other variables.

Mean and Standard Deviation: To assess the average and distribution of continuous variables, such as pain levels.

Comparative Statistics: T-Test: To compare mean pain levels between the two independent groups (Caudal and Quadratus Lumborum blocks).

Correlation and Regression Analysis:

Pearson Correlation: To examine the relationship between pain levels and other variables (e.g., age, drug consumption).

Multiple Regression Analysis: To evaluate the effect of multiple independent variables (e.g., block type, age, gender) on the dependent variable (pain level).

The study does not involve providing any biased/misleading information to participants or completely concealing the study's purpose. All study information will be explained to participants comprehensibly, and consent will be obtained.
The research does not contain questions or practices that threaten the physical or mental health

of participants. It is an observational study aimed at monitoring the outcomes of regional blocks routinely applied for postoperative analgesia in the pediatric operating room.

Participants' personal rights and private information are protected. Personal data will not be recorded or shared with any institution.

The identities of participants will not be identified in the collected raw data/stored data. They will not be used anywhere.

The identities of participants will not be identified in the report content.

Study Termination Criteria:

Reasons Related to Patient Safety: Block failure (need for additional analgesia due to pain at surgical incision).

Technical Failure: Inability to perform the ultrasound-guided block due to anatomical reasons. Inability to obtain data from the pain monitor (device failure, artifact).

Protocol Violations: Randomization error or mixing of patient groups.

Outcome Assessment (Primary and Secondary Endpoints – Outcome Evaluation Criteria):

Primary Outcome:
Intraoperative PAM scores (during LMA insertion, during block performance, during the first surgical incision, 20 minutes post-block, during extubation). The QL block is expected to provide a significant decrease in PAM values compared to the caudal block.

Secondary Outcomes:

Lower FLACC scores in the QL group compared to the caudal group at postoperative hours 1, 2, and 4.

Later time to first analgesic requirement (IV paracetamol 15 mg/kg administered when FLACC ≥4) in the QL group compared to the caudal group.

Lower total consumption of rescue analgesic doses in the QL group.

The correlation between PAM and FLACC scores will be assessed.

Lower incidence of postoperative PONV (%) and antiemetic requirement in the QLB

group. Higher postoperative awakening score (Steward score) in the group receiving QLB.

Higher postoperative pediatric anesthesia parental satisfaction score (PPPS) in the group receiving QLB.

Block complications: Local anesthetic systemic toxicity (LAST), hematoma,

infection. **Outcome Evaluation Criteria:**

PAM scores, FLACC scores, Steward score, PPPS score, time to first analgesic, and amount (mg/kg).

PONV (0-none, 1-once, 2-twice, 3-three times or more).

Successful Block Criterion: No increase in PAM score after surgical incision (nociceptive response suppressed).

Failed Block: FLACC ≥4 or need for intraoperative supplemental analgesia (if block repetition is required, the patient will be excluded from analysis).

Steward awakening score: A score <4 indicates a need for additional observation; a score of 6 indicates readiness for discharge.

PPPS (Postoperative Pediatric Parental Satisfaction) will be measured using a Likert scale; each item is scored 1-5 (1=not satisfied at all, 5=very satisfied) (pain management, child's comfort, medical team's communication, clarity of post-discharge instructions, overall satisfaction; total score 5-25).

Clinical Implications:

If the superiority of the QL block is proven, it could be recommended as the standard regional block technique in pediatric lower abdominal surgeries.

If the PAM-FLACC correlation is high, objective pain monitors could be integrated into routine use in children.

INFORMED CONSTENT FORM

INFORMED CONSENT AND VOLUNTEER INFORMATION FORM
(Physician's Explanation)

We are conducting a study in the pediatric operating room of our hospital. The title of this study is "Comparison of the Analgesic Efficacy of Caudal and Quadratus Lumborum Blocks (QLB) Using a Pain Monitor in Children Undergoing Lower Abdominal Surgery."

In this study, no new medication will be administered to your child, no blood will be drawn, and no additional tests will be performed. This is a study comparing two different analgesic techniques used to prevent pain after your child's surgery. The study will last approximately six months, and a total of 68 patients will be included.

The potential benefits of this study include reducing postoperative pain, thereby increasing comfort, decreasing the need for analgesic medication, and consequently preventing nausea and

vomiting. We invite you to participate in this research. However, we must state that participation is entirely voluntary. Your decision to participate or not will be respected.

Before you decide, we wish to inform you about the study. Please read and understand this information. If you agree to participate after reviewing it, please sign this form.

After the regional block is administered to your child, a small adhesive sensor will be placed on the sole of the foot or the palm of the hand to measure pain levels. This sensor will be removed after your child wakes up from anesthesia. Subsequently, at the 1st, 2nd, and 4th hours postoperatively, we will ask you a few questions and assess the child's status.

If you agree to participate, your child will be evaluated by Dr. Dilara Yiğit or a physician she appoints, and the findings will be recorded.

You will not be charged any fees for participation in this study. You will also not receive any payment for participating.

Your child's medical information will be kept confidential. However, it may be reviewed by quality assurance personnel, ethics committees, or official authorities for auditing purposes, as required by regulations.

Your child will be informed about this research in an age-appropriate manner, and their assent will be sought for participation.

You have the right to refuse participation. Participation in this research is entirely voluntary. If you decline, it will not affect your child's medical care in any way. You also retain the right to withdraw your consent at any stage of the study without any penalty.

(Declaration of the Participant's Parent(s))
I have been informed by Dr. Dilara Yiğit about the above details regarding a medical research study to be conducted in the Department of Anesthesiology and Reanimation at Ankara Etlik City Hospital. Following this explanation, my child has been invited to participate as a subject in this study.

I trust that the confidentiality of information, which must be maintained between the physician and myself, will be respected with great care during this research. I have been sufficiently assured that the data will be meticulously protected when used for educational and scientific purposes.

I understand that I may withdraw my child from the study at any time without providing a reason. (However, I am aware that it is appropriate to inform the researchers in advance of my withdrawal to avoid inconveniencing them). Furthermore, the investigator may discontinue my child's participation in the study, provided it does not harm my child's medical condition.

I will not incur any financial responsibilities for the expenses related to the research. No payment will be made to me.

I have been assured that in the event of any health problem arising directly or indirectly from the

research procedures, all necessary medical intervention will be provided. (I will also not bear any financial burden for these medical interventions).

I understand that if my child encounters any health problem during the research, I can contact Dr. Dilara Yiğit at any time at the following numbers: 0312 797 00 00 (work) or 0533 471 92 02 (mobile), or at the address of the Ankara Etlik City Hospital, Department of Anesthesiology and Reanimation.

My child may choose not to participate in this research. I have not been subjected to any coercive behavior regarding my child's participation. I also understand that if I refuse participation, it will not adversely affect my child's medical care or my relationship with the physician.

I have fully understood all the explanations provided to me. After a period of independent consideration, I have decided to allow my child to participate as a subject in this research project. I accept this invitation with great satisfaction and voluntariness.

A copy of this signed form will be given to me.

Parent of the Participant:
Name, Surname:
Address:
Tel.
Signature

Witness:
Name, Surname:
Address:
Tel.
Signature:
Physician who obtained
consent: Name, Surname, Title:
Address:
Tel.
Signature

Date: ... / ... / ...