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RESEARCH PROTOCOL

ULTRASOUND-GUIDED BILATERAL ERECTOR SPINACH PLANE BLOCK FOR POSTOPERATIVE PAIN IN PEDIATRIC TETHERED CORD SYNDROME SURGERY: A PROSPECTIVE, RANDOMIZED CONTROLLED STUDY

Contents

1.Giriş

Tethered cord syndrome is a developmental anomaly of neuroaxis characterized by stretching of the spinal cord. It is frequently seen and diagnosed in the pediatric age group due to the presence of many accompanying skin findings (meningocele, meningomyelocele, hypertrichosis, dermal sinus tract, subcutaneous lipoma, etc.). Surgical release of the tight and bound filum terminale is performed. Intraoperative neurophysiological monitoring (IONM) is used to preserve functional nerve tissue and prevent postoperative neurological deficits. Total intravenous anesthesia (TIVA-TCI) with propofol and remifentanil is used to ensure accurate measurements.

Postoperative pain is acute pain caused by surgical trauma and signal transmission in afferent neurons. Pediatric postoperative pain is associated with adverse behaviors, prolonged hospital stay,

and impaired functional recovery. Despite good progress in pain management, ineffective postoperative pain management in children remains a global problem. Regional anesthesia is increasingly used in pediatric patients to provide postoperative analgesia and support intraoperative anesthesia. Ultrasound-guided erector spinae plane block (ESPB) is a new approach. First introduced in 2016 by Forero et al., ESPB is a novel regional anesthesia technique that blocks branches of spinal nerves by injecting a local anesthetic into the fascial plane between the erector spinae muscle and the transverse process. Although new, ESPB has become quite popular due to its ease of application and reliability as a relatively superficial block. Initially, ESPB was defined for chronic pain from the thoracic region. Later, its indications expanded and it is now used in both acute and chronic pain conditions. Applications have also been reported in the lumbar, cervical, and sacral regions, respectively. In recent years, an increasing number of randomized controlled trials (RCTs) have reported that it provides effective postoperative analgesia for thoracic surgeries, nephrectomy, inguinal hernia repair, and laparoscopic cholecystectomy operations in children. In our study, we planned to evaluate the effect of bilateral ESPB on intraoperative anesthetic drug consumption and postoperative pain score and analgesia requirement in pediatric patients operated on due to tethered cord syndrome.

2. Objective

In our study, we aimed to reduce intraoperative anesthetic drug consumption and the level of pain in the first 24 hours postoperatively, the need for analgesics, and unwanted side effects related to analgesics by applying bilateral ESPB in pediatric patients operated on due to tethered cord syndrome.

3. Hypothesis

Bilateral ESPB reduces intraoperative anesthetic drug consumption and the need for postoperative analgesia in pediatric patients operated on due to tethered cord syndrome.

4. Study Phase and Nature

Low-risk scientific study - Prospective randomized controlled single-blind clinical trial

5. Study Population

Pediatric patients undergoing surgery for elective tethered cord syndrome

6. Inclusion Criteria

• Patients whose parents consented to participate in the study

• Patients aged 18 and under

• ASA (American Society of Anesthesiologists) physical status I, II, and III

• Pediatric patients undergoing elective tethered cord syndrome surgery

7. Exclusion Criteria

• Patients whose parents did not consent to participate in the study

• Patients with ASA physical status IV and V

• Use of anticoagulant medications

• Allergy to local anesthetic drugs

• Patients with a history of gastrointestinal bleeding

• Patients with infection in the area where the block is planned

8. Study Center

Health Sciences University Bursa High Specialization Training and Research Hospital Anesthesiology and Reanimation Clinic

9. Study Duration

1 year

10. Material – Method

Patients included in the study will be divided into 2 groups according to the randomized (closed envelope) sampling method; Erector Spina Plane Block (ESPB, n=34) group and Control group (CG, n=34). Patients who regularly take medication due to cardiovascular or other systemic diseases will continue their medication. Those whose coagulation parameters are checked before the operation and are normal will be included in the study.

The patients' age, height, weight, gender, additional diseases, ASA scores, operation and anesthesia duration, operation level, level of block performed in the group undergoing ESP block, and total anesthetic drug consumption will be recorded. Standard ECG, SpO2, non-invasive blood pressure (invasive blood pressure monitoring in necessary cases), EtCO2 and BIS monitoring will be applied in the operating room. After appropriate intravenous access is established in both groups of patients, anesthesia induction will be achieved with 2 mg/kg propofol (Propofol 2%®, FreseniusKabi, Melsungen, Germany), 1 µgr/kg fentanyl (Fentanyl Citrate®, Hospira, USA), and 0.6 mg/kg rocuronium (Esmeron®, Organon, Kloosterstraat, Netherlands). Following intubation, anesthesia maintenance will be administered with a 2 l/min flow rate of 50/50 O2/air mixture. Inhalation anesthetics will not be used, and no additional doses of muscle relaxants will be given. Neuromonitoring will be performed on all patients by the neurosurgical team following intubation. Patients will be turned to the prone position once they are stable. For total intravenous anesthesia in patients undergoing neuromonitoring-based anesthesia maintenance, propofol will be infused at an initial target plasma concentration of 2.5-4 µg.ml -1 (Medcaptain Shenzhen, Guangdong, CHINA, Elevated model FK/FD). Remifentanil (ULTIVA®, GlaxoSmithKline Parma, Italy) will be infused at a rate of 0.5-1 µg/kg/min. Infusions will be maintained to maintain a BIS of 40-60. Preoperative,

peroperative 5th, 10th, 15th, 30th, 60th, 90th, 120th, 180th minute, and post-extubation heart rate, supravascular pressure, intravascular pressure, SpO2, ETCO2, and BIS values will be recorded.

Patients will be randomly assigned to two separate groups using a sealed envelope method, regardless of their demographic and surgical characteristics. In the ESP Block group, with the patient in the prone position, the research anesthesia team, following aseptic and antiseptic rules, will insert a linear probe (Hitachi Aloka Prosound F31) with a depth of 2-4 cm and a frequency of 10-15 mHz, approximately 2-3 cm lateral to the spinous process, one level above the operative level, in the parasagittal plane, under USG guidance (Hitachi Aloka Prosound F31). After visualizing the transverse process using an in-plane approach, a 50 mm long block needle (Braun Stimuplex® D 0.22 Gax2 in.50mm, Braun, Germany) will be inserted through the skin, passing through the trapezius and erector spinae muscles. When the needle reaches the transverse process (approximately 2-3 cm deep), a test dose of 0.5-1 mL of 0.9% NaCl will be administered between the erector spinae fascia and the vertebral transverse process to confirm the needle's position. After the fascia is seen to be open, a local anesthetic volume of 0.5% bupivacaine (Buvasin, VEM Pharmaceuticals, Turkey) will be calculated as 2 ml per vertebral pressure, not exceeding a maximum dose of 2 mg/kg. This total volume will be diluted half and half with 0.9% NaCl solution to prepare a 0.25% bupivacaine concentration. The calculated local anesthetic solution will be administered to the erector spinae area for ESPB. The same procedures will be performed on the opposite side. No procedure will be performed on the control group. Both groups will receive 15 mg/kg Paracetamol (Parol®, ATABAY, Kurtköy, Pendik, Istanbul) intravenously 20 minutes before the end of surgery. After surgery, patients will be decurarized with 2 mg/kg IV sugammadex (Bridion, MerckSharpDohme, New Jersey, USA), extubated, and taken to the recovery unit. After being admitted to the recovery room, both groups will be assessed using the Wong-Baker FACES™ Pain Rating Scale for children under 5 years old and the FLACC: Pain Rating Scale for children 5 years and older, with pain scores at 0, 5, 10, 15, and 20 minutes. Patients with scores >5 will receive 0.5 mcg/kg fentanyl (TALİNAT®, VEM İlaç, Kapaklı/TEKİRDAĞ) for rescue analgesia. Paracetamol 15 mg/kg/6 hours will be administered intravenously for postoperative analgesia. A blinded investigator will assess patients' pain scores, analgesic requirements, names of analgesics administered, and nausea/vomiting at 30 minutes, 1, 2, 4, 6, 12, and 24 hours postoperatively. The time and dose of the first postoperative analgesic, and length of hospital stay will be recorded. 11. Research Budget

The cost of 34 block needles and 34 doses of the drug buvasin containing the active ingredient bupivacaine for one patient has been submitted with a propharmaceutical invoice. The expenses will be covered by the researchers.

12. Ethics Committee Approval

An application has been submitted for ethics committee approval.

13. Statistics

Statistical analyses of the obtained data will be performed using the IBM SPSS Statistics 21.0 software package. Descriptive statistics of the data will include mean, standard deviation, frequency, and percentage values. Chi-square and FischerExact tests will be used for the analysis of categorical variables. The normality assumption of continuous numerical variables will be checked separately in groups using the Shapiro-Wilk test. Analysis of variance (ANOVA) will be used for independent group

comparisons of numerical variables showing normal distribution. Kruskal-Wallis (KW) test will be used for variables that do not show normal distribution. For comparisons of consecutive measurements, the Wilcoxon Signed Ranks test will be used for pairs of measurements, the Friedman test for more than two measurements, and the Pearson correlation test will be used as a correlation test. The significance level will be set at $p<0.05$ in all analyses. The required sample size for the study was calculated as 68 (34+34) patients in total, including the group that underwent ESPB and the group that did not undergo ESPB, with an effect size of 0.70, 80% test power, and 95% confidence level. The relevant calculations were made in the G-Power 3.1.9.2 software package.

14. References

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