25.06.2024

RESEARCHPROTOCOL

Theeffectofbılateralerectorspınaplanblockperformedafterlumbarspınalstabılızatıonsurgeryon postoperatıve patıent recovery and paın

Contents

1. Introduction

Patients undergoing lumbar spinal stabilization surgery may experience severe postoperative pain lastingatleastthreedays.Analgesiaafterlumbarstabilizationsurgeryisbeneficialforearlyrecovery and is therefore necessary. However, traditional opioid-based analgesic techniques; It is associated with many undesirable effects, including nausea, vomiting, itching, and sedation. Inadequate postoperative pain control also has many side effects on physiological systems such as the cardiovascular, pulmonary, gastrointestinal, immunological, renal, and hematological systems. Furthermore,inadequatepostoperativepaincontrolincreaseshospitalstay,mortalityandmorbidity, prolongs patient ambulation time, increases patient costs, reduces patient satisfaction, and can lead to the development of chronic postoperative pain. Nonsteroidal anti-inflammatory drugs (NSAIDs), opioid analgesics, and local anesthetics are frequently preferred options for providing postoperative analgesia. In cases where these agents are insufficientto prevent pain, regionaltechniques areoften preferred to reduce the need for opioids. Erector spina plane block (ESPB), a component of multimodal analgesia andoneof the regional techniques, wasfirst used byForero et al. for analgesic purposes in thoracic neuropathic pain and later gained popularity. Although ESPB is frequently performed at the thoracic level, its use continues to increase today.

2. Objective

Theaimofourstudywasto reducethepainlevelsandanalgesicconsumptionofpatientsinthefirst 24 hours after surgery by applying bilateral ESPB postoperatively in patients undergoing lumbar spinal stabilization surgery, to ensure early ambulation of patients, to reduce unwanted side effects related to analgesics, and to reduce hospital stay durations.

3. Hypothesis

Bilateralerectorspinae plane block performed after lumbar spinal stabilization surgery reduces the needforpostoperativeanalgesicsandshortensthepatient'sambulationandhospitalstayduration.

4. StudyPhaseandNature

PhaseIVclinicaltrial-Prospectiverandomizedcontrolledsingle-blindclinicaltrial

5. StudyPopulation

Patientsundergoingelectivelumbarstabilizationsurgery

6. InclusionCriteria

- Patientswhovolunteertoparticipateinthestudy
- Patientsaged18-65years

• ASA(AmericanSocietyofAnesthesiologists)physicalstatusI,II,andIII

• Patientsundergoingelectivelumbarstabilizationsurgery

7. ExclusionCriteria

• Patientswhodidnotconsenttoparticipateinthestudy

• PatientswithASAphysicalstatusIVandV

• Useofanticoagulantmedications

• Allergytolocalanestheticdrugs

• Patientsundergoinglumbarstabilizationsurgeryatlevelthreeorhigher

• Patientswithahistoryofgastrointestinalbleeding

• Patientswithahistoryofpsychiatricillness(MajorDepression,Schizophrenia,BipolarAffective Disorder)

• Patientswithnarcoticand/oralcoholdependence

• Patientswithahistoryofcentraland/orperipheralneurologicaldisease

8. StudyCenter

AnesthesiologyandReanimationClinic,BursaHighSpecializationTrainingandResearchHospital, Health Sciences University

9. StudyDuration

6months

10. Material–Method

Patients included in the study will be divided into 2 groups of 24 each according to the randomized (closedenvelope)samplingmethod;ErectorSpinaPlaneBlock(ESPB,n=24)groupandControlgroup (CG, n=24). Patients who regularly take medication due to cardiovascular or other systemic diseases will continue their medication. Coagulation parameters will be checked before the operation, and those with normal parameters will be included in the study. Patients included in the study will be given information about NRS during the preoperative evaluation. The patients' age, height, weight, gender, additionaldiseases, ASA scores, operationand anesthesiaduration,operation level,and the level of block performed in the group that underwent ESP block will be recorded. Standard ECG, SpO2, non-invasive blood pressure (invasive blood pressure monitoring in necessary cases), and EtCO2 monitoring will be performed in the operating room and will be performed before induction, after induction, at 5, 10, 15, 30, 60, 90, 120, 180 minutes, and at the end of anesthesia.

The patients will be registered. After appropriate intravenous access is established in both groups, anesthesia induction will be achieved with 2 mg/kg propofol (Propofol®, FreseniusKabi, Melsungen, Germany), 1 µgr/kg fentanyl (Fentanyl Citrate®, Hospira, USA), and 0.6 mg/kg rocuronium(Esmeron®, Organon, Kloosterstraat, Netherlands). Anesthesia maintenance will be administered with a flow rate of2 l/min, a 50/50 O2/airmixture, and 2% sevoflurane (Sevorane®, Abbott,Chicago, USA). Patients will be randomly assigned to two separate groups using a sealed envelope method, regardlessoftheirdemographicandsurgicalcharacteristics.IntheESPBlockgroup,20mgtenoxicam (Tilcotil®, DEVA, Kapaklı, TEKİRDAĞ) and 1 g paracetamol (Parol®, ATABAY, Kurtköy, PENDİK, İSTANBUL) will be administered intravenously 30 minutes before the end of surgery. Before the 23 patients are awakened at the end of the operation, the research anesthesia team, following aseptic and antiseptic rules, will perform an in-plane approach with a linear probe (Hitachi Aloka Prosound F31) with adepthof 2-4 cm and a frequency of10-15 mHz, positionedapproximately 3 cm lateralto the spinous process, one level above the operative level, in the parasagittal plane, under USG guidance(HitachiAlokaProsoundF31).Aftervisualizingthetransverseprocess,a100mmlongblock needle (Stimuplex® D0.71x80mm, 22G, Braun, Germany) will be inserted through the skin, passing through the trapezius and erector spinae muscles. When the needle reaches the transverse process (approximately 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 transverse process of the vertebra to confirm the needle's position. After the fascia is seen to be open, ESPB will be performed by administering a total of 20 ml of local anestheticsolution,consistingof 10mlof0.5% bupivacaine (Buvasin, VEMPharmaceuticals,Turkey) and10mlof0.9% NaCl,into theerectorspinaearea.Thesameprocedureswillbeperformedonthe opposite side. The control group will receive 20 mg tenoxicam (Tilcotil®, DEVA, Kapaklı, TEKİRDAĞ) and 1 g paracetamol(Parol®, ATABAY, Kurtköy, PENDİK, ISTANBUL) intravenously 30 minutes before the end of surgery. After the surgery, patients will be decurarized with 2 mg/kg IV sugammadex (Bridion, MerckSharpDohme, New Jersey, USA), extubated, and taken to the recovery unit. After beingadmittedtotherecoveryroom,bothgroupswillbeassessedforNRSscores,andpatientswith an NRS score >5 will receive 50 mcg of fentanyl (TALİNAT®, VEM İlaç, Kapaklı/TEKİRDAĞ) for rescue analgesia.

A blinded investigator will assess patients' NRS scores, analgesic needs, names of analgesics administered,andnausea/vomitingat0,2,4,6,12,and24hourspostoperatively.Thetimeofthe

firstanalgesicadministration,ambulationtime,patientsatisfaction,andlengthofhospitalstaywill be recorded.

11. ResearchBudget

The costof24block needles and24 dosesof bupivacaine-based medication called buvasinfor one patienthasbeensubmittedwithapropharmaceuticalinvoice.Theexpenseswillbecoveredbythe researchers.

12. EthicsCommitteeApproval

Anapplicationhasbeensubmittedforethicscommitteeapproval.

13. Statistics

Statistical analyses of the obtained data will be performed using the IBM SPSS Statistics 21.0software 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 beused for variables that do not show normal distribution. For comparisons of consecutive measurements,theWilcoxonSignedRankstestwillbeusedforpairsofmeasurements,theFriedman 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 24 patients for each group (the group undergoing ESPB and the group not undergoing ESPB) to ensure a 95% confidence level with an alpha=0.05 error and a 0.99 effect size, for a total of 48 patients.

14. References

1. Yoshizaki M, Murata H, Ogami-Takamura K, Hara T. Bilateral erector spinae plane block using a programmedintermittentbolustechniqueforpainmanagementafterNussprocedure.JClinAnesth. 2019 Nov;57:51-52. doi: 10.1016/j.jclinane.2019.03.014. Epub 2019 Mar 7. PMID: 30852328.

2. ChinKJ,LewisS.Opioid-freeAnalgesiaforPosteriorSpinalFusionSurgeryUsingErectorSpinae Plane (ESP) Blocks in a Multimodal Anesthetic Regimen. Spine (Phila Pa 1976). 2019 Mar 15;44(6):E379-E383. doi: 10.1097/BRS.0000000000002855. PMID: 30180150.

3. ForeroM,RajarathinamM,AdhikarySD,ChinKJ.Erectorspinaeplaneblockforthemanagement of chronic shoulder pain: a case report. Can J Anaesth. 2018 Mar;65(3):288-293. English doi: 10.1007/s12630-017-1010-1. Epub 2017 Nov 13. PMID: 29134518

4. YörükoğluHU,İçliD,AksuC,CesurS,KuşA,GürkanY.Erectorspinaeblock forpostoperativepain management in lumbar disc hernia repair. J Anesth. 2021 Jun;35(3):420-425. doi: 10.1007/s00540-021-02920-0. Epub 2021 Mar 22. PMID: 33751203.

5. Bellantonio D, Bolondi G, Cultrera F, Lofrese G, Mongardi L, Gobbi L, Sica A, Bergamini C, Viola L, Tognù A, Tosatto L, Russo E, Santonastaso DP, Agnoletti V. Erector spinae plane block for perioperative pain management in neurosurgical lower-thoracic and lumbar spinal fusion: a single-centreprospectiverandomizedcontrolledcontrolledtrialBMCAnesthesiol.2023May30;23(1):187. doi: 10.1186/s12871-023-02130-z. PMID: 37254058; PMCID: PMC10227393.

6. NashibiM,TafrishinejadA,SafariF,AsgariS,SezariP,MottaghiK.Evaluationofultrasoundguided erector spinae plane blockefficacy onpost operative pain in lumbar spine surgery: a 53 randomized clinical trial. Pain. 2022 Jul;34(3):174-179. English doi: 10.14744/agri.2021.04864. PMID: 35792689.

7. Stewart JW,DicksonD,VanHalM,AryeeteyL,SunnaM,SchulzC,AlexanderJC,GasanovaI,Joshi GP. Ultrasound-guided erector spinae plane blocks for pain management after open lumbar laminectomy. Eur Spine J. 2023 Aug 12. doi: 10.1007/s00586-023-07881-4. Epub ahead of print. Erratum in: Eur Spine J. 2023 Nov 28;: PMID: 37572144.

8. GishiG,ÖksüzG.Effectofultrasound-guidedbilateralerectorspinaeplaneblockforpostoperative analgesiainpatientsundergoingmultilevelposteriorspinalinstrumentation.EurRevMedPharmacol Sci. 2023 Oct;27(20):9550-9558. doi: 10.26355/eurrev_202310_34128. PMID: 37916322.