STUDY PROTOCOL AND STATISTICAL ANALYSIS PLAN
Official Title of the StudyEffect of Bilateral Lumbar Erector Spinae Plane Block on Postoperative Analgesia in LumbarSpinal Surgery

ClinicalTrials.gov Identifier (NCT Number)
Not yet assigned (Retrospective registration)

Document Information
- **Document Type:** Study Protocol and Statistical Analysis Plan
- **Document Date:** 24 August 2021
- **Protocol Version:** Version 1.0

Study Sponsor / Institution
Afyonkarahisar Health Sciences University

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Study Site
Afyonkarahisar Health Sciences University Hospital

Statement for Retrospective Registration
This protocol and statistical analysis plan were finalized prior to participant enrollment.
The study was completed before registration on ClinicalTrials.gov.
This document is submitted to support retrospective registration and verification of the study design.

Evaluation of the Effect of Bilateral Lumbar Erector Spinae Plane Block on Postoperative Analgesia in Lumbar Spinal Surgery

1. Introduction

Lumbar spinal surgery is frequently associated with significant postoperative pain due to extensive tissue manipulation and muscular dissection. Effective postoperative analgesia is essential to ensure early mobilization, reduce opioid consumption, and improve overall patient satisfaction.

The Erector Spinae Plane (ESP) block is an ultrasound-guided interfascial block increasingly utilized for postoperative analgesia in thoracic and lumbar procedures. Bilateral lumbar ESP block has been shown to provide extensive somatic and visceral analgesia with a favorable safety profile. However, evidence regarding its efficacy in lumbar spinal surgery remains limited.

This study aims to evaluate the effect of bilateral lumbar ESP block on postoperative pain management, opioid consumption, and recovery parameters following lumbar spinal surgery.

2. Aim

The primary aim of this randomized controlled study is to determine whether bilateral lumbar ESP block improves postoperative analgesia compared with standard analgesic practices in patients undergoing lumbar spinal surgery.

Secondary aims:

- To compare postoperative opioid consumption
- To evaluate mobilization time and length of hospital stay
- To assess patient satisfaction and block-related complications

3. Hypothesis

- **H0 (Null Hypothesis):** Bilateral lumbar ESP block does not significantly reduce postoperative pain scores or opioid consumption compared with standard analgesia.
- **H1 (Alternative Hypothesis):** Bilateral lumbar ESP block significantly reduces postoperative pain scores and opioid consumption compared with standard analgesia.

4. Study Type

This study is a prospective, randomized, controlled, and single-blind clinical interventional trial. The study is designed as a clinical efficacy comparison evaluating the effectiveness of a regional anesthesia technique added to routine clinical practice

5. Study Population

Patients aged 18–80 years undergoing elective lumbar spinal surgery (e.g., discectomy, laminectomy) at Afyonkarahisar Health Sciences University Hospital.

6. Inclusion Criteria

Patients aged 18 and over, 80 and under
American Society of Anesthesiologists Patient Classification Score (ASA) between I and III
Patients who can cooperate and give consent
No chronic analgesic or opioid use
No mental or psychiatric disorders
No alcohol or illicit drug use
Patients scheduled for elective spinal surgery

7. Exclusion Criteria

Patients who withdrew from participation at any time during the study
Foreign nationals who could not be contacted
Patients with an ASA score of IV or higher
Patients scheduled for emergency surgery
Pregnant women and breastfeeding mothers
Bleeding diathesis
Drug allergy
Anticoagulant use
Local/systemic infection
Serious arrhythmia

8. Withdrawal Criteria

- Patient request for withdrawal
- Noncompliance with study procedures
- Incomplete postoperative data

9. Study Location

Afyonkarahisar Health Sciences University Department of Anesthesiology and Reanimation

10. Study Duration

8 months

11. Materials and Methods

This study is a prospective, randomized, controlled trial comparing bilateral ESP block with standard analgesia in lumbar spinal surgery.

a. Standard Anesthesia

- **Induction:** Propofol (1–2 mg/kg), fentanyl (1–2 mcg/kg), rocuronium (0.6 mg/kg)
- **Maintenance:** Sevoflurane in oxygen–air mixture
- Standard IV fluid replacement
- Hemodynamic monitoring per ASA guidelines

b. Block Technique (Group 1 – ESP Block)

- **Timing:** Preoperative, after induction of anesthesia
- **Position:** Prone
- **Level:** Bilateral ESP block at L2–L4
- **Technique:** Ultrasound-guided, in-plane
- **Injectate:** 20 mL of 0.25% bupivacaine per side
- Negative aspiration performed before injection
- Spread of local anesthetic visualized under ultrasound

c. Study Groups

Group 1 (ESP Group):

Bilateral lumbar ESP block + standard multimodal analgesia

Group 2 (Control Group):

Only standard multimodal analgesia (no block)

d. Postoperative Analgesia Protocol

Both groups will receive:

- IV paracetamol (1 g every 8 hours)
- IV tenoksikam (20 mg every 12 hours)

Rescue analgesia:

- When the VAS score exceeds 4, an additional 40 mg of tramadol will be administered.

e. Pain Assessment

Pain will be assessed using VAS (0–10):

- At PACU admission
- Postoperative 2nd, 4th, 8th, 12th, and 24th hours

VAS scores between 0–3 represent mild pain.

Additional recorded outcomes:

- Total opioid consumption
- Time to first mobilization
- Length of hospital stay
- Nausea, vomiting, hypotension, motor block
- Block-related adverse events

12. Study Budget

No external funding is used.

All interventions and medications are standard clinical practice.

13. Ethics Approval

The study will begin after receiving approval from:

Afyonkarahisar Health Sciences University Clinical Research Ethics Committee

(Decision number: AFSU 2021/10-448 Ethics Committee Code 2011-KAEK-2)

Written informed consent will be obtained from all participants.

14. Statistical Analysis

Sample size estimation was performed using the G*Power 3.1.9.2 software.

Using an effect size of 0.5, a significance level of $\alpha = 0.05$, and a power of 80%, the required total sample size was calculated as 102 participants.

Study data were analyzed using IBM SPSS Statistics version 22.

Data were expressed as proportions, median (min–max), or mean ± SD.

The normality of distribution was evaluated using:

Visual methods (histograms)

Analytical tests (Kolmogorov–Smirnov test)

For comparison of continuous variables:

Student's t-test was used for normally distributed data

Mann–Whitney U test was used for non-normally distributed data

For categorical variables, the chi-square test was applied.

A p-value < 0.05 was considered statistically significant.

Primary outcomes:

Postoperative VAS scores

Opioid consumption at 24 hours

Secondary outcomes:

Mobilization time

Length of hospital stay

Adverse events