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Ultrasound-Guided Erector Spinae Plane Block versus Intravenous Nalbuphine for Postoperative Analgesia after video-assisted thoracoscopy in obese patients: A randomized controlled trial of safety and effectiveness

protocol of a study performed by

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the study was approved from the research ethical committee at the Faculty of Medicine, Zagazig University (IRB#5386/ 8-7-2025).

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Introduction

The prevention of respiratory complications is a significant issue after thoracic surgery and requires adequate postoperative pain management. Prevention and management of surgery-related pain is essential in VATS, due to high incidence of moderate to severe acute postoperative pain. Apart from non-steroid anti-inflammatory agents and intravenous opioids, local anesthetic infiltration of incision sites, preemptive analgesia methods, and regional anesthesia techniques play a role in multimodal analgesia **[1,2]**.

Guidelines for enhanced recovery after lung surgery recommend the use of regional analgesia and opioid-sparing analgesia to facilitate early mobilization and reduce the risk of pulmonary complications **[4]**.

Thoracic epidural analgesia (TEA) is recognized as the gold standard for acute postoperative pain relief after thoracotomy, multiple authors have suggested it is too invasive for VATS **[5]**.

The Paravertebral Block (PVB) is a widely utilized regional anesthesia technique for video-assisted thoracoscopic surgery (VATS). However, it is still regarded as an invasive procedure, raising concerns about its benefit-risk balance. As a neuraxial technique, it carries certain risks, including the potential for spinal hematoma and epidural abscess **[6,7]**.

In recent years, innovative chest wall blocks like **the Erector Spinae Plane Block (ESPB)** have been introduced to enhance pain relief while minimizing the risk of damaging nearby vital structures. The ultrasound landmarks for the ESPB are easier to locate and situated farther from the neuraxis and pleura compared to the epidural and paravertebral spaces. This characteristic makes it a potentially less invasive option and offers a simpler and safer alternative for pain management after video-assisted thoracoscopic surgery (VATS). Originally described for managing thoracic neuropathic pain, the ESPB has emerged as an effective regional anesthesia technique for preventing postoperative pain in VATS **[3]**.

In ESPB, a local anesthetic is reported to be administered at the level of T6 into the inter-fascial plane between the transverse process of the vertebra and the erector spinae muscles, widely spread cranially and caudally to provide anesthesia from T3 to T9 over the ipsilateral hemithorax. Studies have reported that ESPB affects both the ventral and dorsal rami and leading to blockage of both visceral and somatic pain **[3]**.

2. Patients and methods

2.1. Study population and setting:

This prospective, randomized, controlled clinical trial will be conducted at the thoracic surgery operation room, cardiothoracic surgery

building, Zagazig University Hospitals, from July 2025 to December 2025.

Our study included 102 patients who are planned for video-assisted thoracoscopy. Cases will randomly divided into two groups: Erector Spinae Plane Block (ESPB) and the control group, comprising 51 patients each. Inclusion criteria also include: American Society of Anesthesiologist (ASA) status of II and III, age between 21 years and 60 years, and BMI (body mass index) between 30 and 40 kg/ m^2. Patients who will be excluded from the present study included: BMI <30 or > 40 kg/ m^2, chronic pain with regular use of either opioids or gabapentinoids during the 2 weeks before surgery, history of thoracic surgery on the same side, anticipated high risk of conversion to thoracotomy, taking anticoagulation, suffering from any bleeding disorders, known allergy to local anesthetics, nalbuphine or fentanyl, active infection at the injection site, pre-existing neurological or psychiatric illness, severe cardiovascular disease, liver failure, renal failure (estimated glomerular filtration rate less than 15 ml min), and pregnancy.

Patients will be also excluded after randomization if they have converted to thoracotomy, severe intra- or postoperative blood loss >1000cc, required postoperative mechanical ventilation, or a technical difficulty in the ESPB performance.

2.2. Randomization and allocation

Patients will be randomized in a one-to-one ratio and assigned to either the **ESPB (group A) or control group (group B)** (Fig. 1). Randomization allocations will be kept in sealed opaque covers and only opened by the investigator immediately prior to the ESPB, which will be performed in a holding area before entry into the block rooms. All blocks will be performed by the same anesthetist using the linear probe of an Ultrasound machine (GE Vivid E95).

2.3. Preparation of patients

Prior to surgery, patients will be instructed to fast for eight hours. Standard non-invasive monitoring was started once patients entered the block room. Intravenous access will be then obtained, and 2mg of midazolam will be given as sedation to all patients.

2.4. Monitoring:

- Standard monitoring will be applied and maintained throughout the procedure, including 5-lead electrocardiogram, non-invasive blood pressure, pulse oximetry, end-tidal carbon dioxide.
- **Hemodynamic parameters:** Heart rate (HR) and the mean arterial blood pressure (MAP) will be recorded preoperatively (baseline data) and intraoperatively every 5 minutes for 15 minutes, then

every 15 minutes afterward till the end of surgery.

2.5. Standardized perioperative protocol (for both groups):

- Intravenous induction drugs include: fentanyl 2 microgram per kilogram, propofol 2 mg /kg, and cisatracurium 0.15mg /kg according to Lean Body Weight (LBW).
- Intubation and mechanical ventilation will be constituted to all patients using volume-controlled positive-pressure ventilation with a tidal volume of 4–6 ml/kg of ideal body weight (IBW) to maintain end-tidal carbon dioxide tension at 35–45 mm Hg.
- The lung isolation technique will be standardized for all patients with a left double-lumen endotracheal tube. The adequate position of the double-lumen tube was confirmed by fiberoptic bronchoscopy after intubation and in the lateral decubitus position. The IV fluid administration was limited to 6 mL/kg/h of crystalloids.
- Anesthesia was maintained with100% oxygen and 2% sevoflurane and propofol infusion as needed.
- Additional doses of cisatracurium (0.04 mg /kg) will be given every 20 minutes.
- Fentanyl doses of 25 mcg will be administered intravenously for any intraoperative increase in heart rate (HR) or mean arterial pressure (MAP) above 20% of baseline.
- At the beginning of the procedure, each patient will receive standard regimen for prevention of postoperative nausea and vomiting (PONV) comprising dexamethasone 4 mg IV and ondansetron 8 mg IV.
- **Recovery from general anesthesia:** At the end of the operation (Closure of the wound), sevoflurane will be discontinued, residual neuromuscular blockade will be reversed using neostigmine (0.05mg/kg) and atropine (0.02mg/kg) administered intravenously, and the patient will be extubated.
- **After full recovery**, when the verbal Numerical Rating Scale (VNRS) is ≥ 3, a rescue drug in the form of nalbuphine titration 5 mg intravenously will be given with a maximum dose of 60 mg per day.

2.6. Multimodal opioid-sparing analgesia technique will be performed only in group A and includes the following steps:

- ✓ **Ultrasound guided Erector Spinae Plane Block (ESPB):**

In group A only: after induction of general anesthesia, all patients will be placed in lateral position with the operated side upwards, an ESPB expert (at least 20 ESPB completed) performs the block as follows:

- Skin a sepsis with chlorhexidine, and sterile draping will be performed, and the ultrasound high frequency linear probe will be

sheathed.

- Scanning will be done in the longitudinal plane 3 cm parasagittal from the midline on the operated side, as defined by Forero et al. 2016. The tip of the T6 transverse process will be identified by progressively downgrading from C7. When the T6 transverse process is in the middle of the image and the pleura is visualized, the A22-gauge, 80mm needle (Stimulex D, B-Braun, Germany) is inserted in-plane and guided to the middle of the transverse process of T6 in a cephalad- caudad direction until the tip of the needle is placed into the fascial plane on the deep aspect of the erector spinae muscle.
- The confirmation of the correct location of the needle tip in the fascial plane deep to the erector spinae muscle is realized by injecting 1 to 2 mL of saline to view the elevation of the erector spinae muscle from the transverse process without distending the muscle. Finally, 20 ml of bupivacaine 0.25% with epinephrine 1/1000 concentration, 250 mg magnesium sulphate (mgso4) and 4 mg dexamethasone were injected.
    - ✓ Near the end of surgery, all patients will receive preemptive intravenous paracetamol (1000 mg), ketorolac (30 mg), and after full recovery a rescue opioid in the form of nalbuphine titration 5 mg intravenously will be given when the verbal Numerical Rating Scale (VNRS) is ≥ 3, with a maximum dose of 60 mg per day.
    - ✓ we will continue paracetamol (1000mg)/6 h and ketorolac 15 mg/8 for the first 24 hrs. postoperative.

2.7. Outcome measures of the study:

Our primary outcomes are recording total postoperative nalbuphine consumption during the first 24 hrs. postoperative and time to first rescue analgesia by registered nurses. While, the secondary outcomes include postoperative assessment of verbal Numerical Rating Scale (VNRS) at rest and at movement which is a self-report tool, most often used to measure pain intensity, where a person verbally rates their pain on a scale of 0 to 10. Zero represents "no pain," and 10 represents "the worst imaginable pain", opioid-related side effects specifically: Ramsay Sedation Scale **(table.1)** [(5)], pruritus (no itching=0, itching=1), respiratory depression (defined as respiratory rate<10/min or Spo2<90%) and simplified PONV impact scale for evaluation of PONV severity (no nausea or vomiting =0, nausea =1, Retching or mild vomiting =2, Two or more episodes of vomiting within a 30-minute period =3) [(6)] at the same time points during the first 24 hrs. postoperatively by registered nurses, in addition to patient satisfaction (completely satisfied or completely dissatisfied) [(7)].

Table 1: Ramsay Sedation Scale [(5)]

Sedation Level	Score
Patient is anxious and agitated or restless, or both	1
Patient is co-operative, oriented, and tranquil	2
Patient responds to commands only	3
Patient exhibits brisk response to light glabellar tap or loud auditory stimulus	4
Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus	5
Patient exhibits no response	6

2.7. Sample size calculation:

The sample will be calculated based on the comparison of medians between two independent groups; the expected median (IQR) in group 1 is 4 (3-6) and in group 2 is 5 (4-6) (**Durey et al., 2023)**, with a pooled interquartile range of approximately 2.5. The sample was 102 (51 participants) in each group at a 95% CI and a Power of the test 80%.

2.8. Statistical Analysis:

All data will be collected, tabulated, and statistically analyzed using SPSS 22.0 for Windows (SPSS Inc., Chicago, IL, USA) & MedCalc 13 for Windows (MedCalc Software bvba, Ostend, Belgium).

Data will be tested for normal distribution using the Shapiro-Wilk test. Qualitative data were represented as frequencies and relative percentages. Chi-square test ($\chi 2$) and Fisher's exact test will be used to calculate the difference between qualitative variables as indicated. Quantitative data will be expressed as mean ± SD (Standard deviation) for parametric and median and range for non-parametric data.

Independent t-test and Mann-Whitney test will be used to calculate the difference between quantitative variables in two groups for parametric and non-parametric variables, respectively.

All statistical comparisons are two-tailed, with a significance level of P-value ≤ 0.05 indicating significant, $p<0.001$ indicating a highly significant difference, while $P> 0.05$ indicates a non-significant difference.

2.8. Ethical Considerations:

Written consent was obtained from all patients and the study was approved from the research ethical committee at the Faculty of Medicine, Zagazig University (IRB#5386/ 8-7-2025). The work will be performed uniformly with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.