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Comparison Of The Analgesic Effect Of Ultrasound-Guided Erector Spinae Plane Block And Ultrasound-Guided Retrolaminar Block In Patients Undergoing Video Assisted Thoracoscopic Surgery: A Prospective, Randomized Study.

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Study Title

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Introduction:

Video-assisted thoracoscopic surgery (VATS) is increasingly being used to manage primary lung cancer and helps reduce postoperative pain. However, it is a fact that pain following VATS can be severe and long-lasting. According to Takahiro Homma *et al.*, 18.8% of patients who undergo VATS present with persistent pain 2 months after surgery (1–3).The provision of pain relief is a significant consideration, and thoracic epidural analgesia is often regarded to be the gold standard. (4) However, epidural analgesia is not always ideal, and other practical regional methods of analgesia after VATS have been proposed as Erector Spinae Plane Block (ESPB) or retrolaminar block (RLB) . (5)

The retrolaminar block (RLB), which was first introduced by Pfeiffer et al.(6), is a modified paravertebral block that administers local anesthetic between the lamina of the thoracic vertebra and the erector spinal muscles, using landmark technique or under ultrasound guidance. (6) Previous clinical study by Wang, Q., Wei, S., Li, S. *et al.* reported that RLB provides a good analgesic effect after VATS but was inferior to paravertebral block(PVB)(7).

Erector spinae plane block (ESPB) is a relatively new interfascial block procedure first described for thoracic analgesia. Previous clinical studies reported that ESPB provides a good analgesic effect after VATS (comparable with PVB)(8) and decreases morphine consumption after Lateral thoracotomy surgery (9,10). Thus, anesthesiologists now have a greater choice for regional anesthesia for thoracic analgesia. Although ESPB and RLB have similar puncture sites, Only one clinical

study comparing ESPB and RLB in breast surgery has been reported (11), The mentioned study was also limited only to female patients. both blocks were compared with PVB(7,8) but There is no clinical study that compares ESPB and RLB directly in VATS. Although the mechanisms of action of both ESPB and RLB have not yet been completely clarified, one cadaveric study indicated that ESPB leads to a broader spread of the local analgesic into a more extensive range of intercostal spaces from a single point of injection than RLB (12). Another cadaveric study reported that the lateral pathway, which is involved in the blockade of the intercostal nerve or the lateral cutaneous branches of the intercostal nerves, is the primary mechanism of ESPB, in contrast to RLB (13,14).

Based on these anatomical studies, we hypothesize that ESPB can be superior to RLB for postoperative analgesia after VATS.

Aim of the work

This prospective, randomized, controlled clinical trial aims to compare the analgesic efficacy of ESPB and RLB after VIDEO ASSISTED THORACOSCOPIC SURGERY.

Objectives:

To compare the efficacy of ESPB and RLB after VATS.

As regards:

- Hemodynamics
- Postoperative pain
- Postoperative analgesic requirements

Hypothesis:

We hypothesize that ESPB can be superior to RLB for postoperative analgesia after VATS.

Ethical Considerations

The study will be conducted after obtaining approval from the institutional research and ethics committee. Written informed consent will be obtained from all participants.

Methodology

I. Study design

A prospective randomized, double-blind controlled study

II. Study setting and location

Cairo University Hospitals, Cardiothoracic, and Vascular Anesthesia Unit

III. Study population

The study will be conducted on patients undergoing VATS.

IV. Eligibility Criteria

Inclusion criteria

1. The age range of 18-75 years.
2. American Society of Anesthesiologists physical status class (ASA) I, II and III
3. Patients undergoing VATS.
4. Patients Gender eligible for the study: both

Exclusion criteria

1- Patient refusal
2- Coagulopathy, bleeding disorders,
3- In-ability to postpone anti-coagulation medications.
4- infection at the injection site
5- pregnancy, breastfeeding,

6- severe obesity (body mass index > 35 kg/m2)

7- allergy to any drug used in the study

8- preoperative daily use of a non-steroidal anti-inflammatory drug (NSAID) or opioids,

9- Previous surgery in the thoracic vertebral region

10- Liver dysfunction.

11- Injury or a lesion at the block site.

V. Study Procedures

Patients will be randomly allocated into two equal groups:

Group I (E): Will receive a US-guided ESPB

Group II (R): Will receive a US-guided RLB

VI. Randomization and Blinding

Patients will be randomized using a computer-generated list of random numbers, which will be sealed in closed envelopes. Patients will be randomly allocated to one of two groups; Group I (E) will receive a US-guided ESPB, while Group II (R) will receive a US-guided RLB. An anesthesiologist who is not involved in the data collection team will perform all nerve blocks. Intra- and postoperative data will be collected by an anesthesiologist or intensivist who is blinded to the study protocol.

Study Protocol

1- Preoperative assessment

Following approval from Research Committee of Anesthesia Department and the Ethics Committee of the Faculty of Medicine, Cairo University, 44 patients will be included in the study (22 patients per group). After obtaining written informed consents, all patients will be subjected to systematic preoperative assessment including history taking, physical examination, and review of the results of routine investigations. Upon arrival to the preparation room, a 20G IV cannula will be inserted into a peripheral vein and midazolam 2-3 mg will be administered unless contraindicated. A 20G arterial catheter will be inserted into the radial artery of the dependent (non-operative) side, after local infiltration with lidocaine 2%.

2- Intraoperative management:

Patients will be transferred to the operating room where routine monitoring is applied, including electrocardiography (ECG), invasive Blood Pressure (IBP) and pulse oximetry are attached. Baseline heart rate, blood pressure, oxygen saturation and respiratory rate will be recorded.

Subsequently, either ultrasound-guided ESPB or RLB will be performed according to group allocation. Both blocks will be executed using a 3 to 12.0-MHz linear array transducer (Linear Ultrasound Transducer Probe L12-3 For Philips) connected to an ultrasound imaging system (Philips HD11XE) by an experienced anesthesiologist skilled in performing both ESPB and RLB. Patients will be positioned in the sitting position.

- Patients allocated to Group I: Will receive a US-guided ESPB before the start of the surgery.
- Patients allocated to Group II: Will receive a US-guided RLB before the start of the surgery.

Under aseptic precautions, the ultrasound transducer will be placed on the patient's back in a longitudinal paramedian orientation approximately 3 cm (ESPB) or 1 cm (RLB) from the midline. A short-bevel, 80 mm 22-gauge insulated nerve block needle will be inserted using an in-plane approach to contact the tip of either the T4 transverse process for ESPB Or the T4 lamina of the vertebra for RLB, After negative aspiration of blood, a total of 20 mL of 0.25% bupivacaine(15) will be injected through the needle. Adequacy of the block will be confirmed by ultrasonographic visualization of fluid spread (seen as a lifting of the erector spina muscles in both block) and after 15 min, documenting the sensory blockade will be done by using a piece of ice or cold object. If the desired sensory level fails to be achieved (T4 – T8), patients will be excluded from the study.

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Anesthesia will be then induced with Propofol 2–3 mg/kg, together with fentanyl 2 mg/kg until loss of verbal response. Muscle relaxation will be achieved with atracurium 0.5 mg/kg and the patient's trachea will be intubated using a double-lumen tube, as indicated by the surgical procedure. Anesthesia will be maintained by isoflurane, and muscle relaxation will be maintained with atracurium 0.3 – 0.5 mg/kg/hr.

The lungs will be ventilated with positive pressure ventilation to maintain end-tidal carbon dioxide (EtCO2) between 32 and 36 mmHg.

Acetaminophen (1gm) will be intravenously administered 90 min after the block procedure in both groups. As for their routine procedure, the surgeons will not perform local anesthetic wound infiltration at all.

Patients' heart rate and blood pressure (systolic, diastolic, and mean arterial blood pressure) will be monitored continuously and recorded at ten-minute intervals until the end of surgery. Any attack of hypotension, defined as a drop of > 20% of baseline blood pressure, will be managed by ephedrine 0.2 mg/kg IV, and

administering I.V. fluids. On the other hand, hypertension, defined as an increase of > 20 % of baseline blood pressure, will be managed by increasing the depth of anesthesia and administering bolus doses of fentanyl 1 mic/kg (up to 3 mic/kg maximum dose). Bradycardia (heart rate < 50 beats/min) will be managed by atropine 0.02 mg/ kg IV

At the end of surgery residual neuromuscular blockade will be reversed and the endotracheal tube will be removed.

Postoperative management:

Patients will be transferred to the ICU and will be monitored for 24 hours where all patients will receive a standard 1 gm. of IV Acetaminophen every 6 hours. Patients' heart rate, blood pressure, oxygen saturation, respiratory rate and the pain score using visual analogue scale will be monitored at regular intervals of 4 hours over the duration of 24 hours. A VAS equal to or more than four will necessitate administering rescue doses of Morphine (0.05 mg/kg). The number of patients requiring rescue analgesia, the total dose of Morphine, and the elapsed time from the block procedure until the administration of the first postoperative rescue analgesic will be recorded.

VII. Measurement tools

- Hemodynamic parameters: Arterial blood pressure (systolic, diastolic, and mean)

  HR

- VAS
- Time for the first rescue analgesia
- Total analgesic consumption

VIII. Study outcomes

1. Primary outcome

Total amount of morphine consumption in the first 24-hour postoperative in the two groups

2. Secondary outcome(s)

- Time is required to perform the technique (between the start of US scanning and the local anesthetic injection).
- Hemodynamic parameters:

  HR

  Arterial blood pressure (systolic, diastolic, and mean)

  Hemodynamic parameters will be measured 15 minutes after blocks are done before the induction (baseline), immediately after intubation, every 10 minutes intraoperative, immediately after extubation, and every 4 hour in the ICU for the first 24 hours.
- Intraoperative cardioactive drug use:

  The number of patients requiring ephedrine and atropine.
- Intraoperative analgesics:

  The number of patients requiring additional doses of fentanyl.

  Total intraoperative IV fentanyl dose (above the standard two μg/kg).
- Pain score:

VAS value obtained from the patient immediately after recovery from anesthesia then every 4 hours during the first 24 hours postoperatively.

- Postoperative analgesics:

The elapsed time from the block procedure until the administration of the first postoperative rescue analgesia

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- Incidence of side effects related to opioid use (postoperative nausea and vomiting (PONV), constipation, pruritus, urinary retention) in postoperative time.
- Incidence of complications or side-effects related to the block (bradycardia, hypotension, hematoma formation or intravascular injection).

Statistical Analysis

I. Sample size

Our analysis will be performed using G power software on the level of total amount of morphine consumption in the first 24-hour postoperative as it is the primary outcome in the current study using a student t-test.

A previous study showed that total amount of morphine consumption in the first 24-hour postoperative after VATS , mean(SD) after ESPB was 20.6046(7.9398) mg .(9) this was calculated from median and range based on Lou et al (16) and Wan et al (17).

Based on assumption that a 30% difference between groups is a clinically significant difference and for a power of 0.95 and alpha error of 0.05.

A minimum of 20 patients was calculated for each group. The sample size will be increased to 22 for each group to compensate for possible dropouts.

Statistical analysis

Data analysis will be performed using Statistical package for social science (SPSS) software, version 15 for Microsoft Windows (SPSS Inc., Chicago, iL, USA). Categorical data will be reported as numbers and percentages and analyzed using the chi-squared test. Continuous data will be checked for normality using the Kolmogorov-Smirnov test. Normally distributed data will be presented as means (standard deviations) and analyzed using an unpaired student t-test. Skewed data will be expressed as medians (quartiles) and analyzed using the Mann-Whitney U test. For repeated measures, a two-way repeated-measures ANOVA will be used to evaluate the block (between-groups factor) and the time (repeated measures)". Post-hoc pairwise comparison will be performed using the Bonferroni test. A P-value of 0.05 or less will be considered significant.

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