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Comparison between Retrolaminar block combined with Erector Spinae Plane block, and Erector Spinae Plane block alone for post-thoracotomy pain

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Study Title

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Introduction

Post-thoracotomy pain is a challenging clinical problem that may be associated with increased morbidity and mortality. (1)

The surgical incision produces post-thoracotomy pain (PTP) via damage to the ribs and intercostal nerves, inflammation of the chest wall, pleura or pulmonary parenchyma cutting, and placement of the intercostal chest tube. Acute PTP inhibits the ability to breathe and cough normally. Numerous analgesic techniques are used to relieve PTP, including systemic opioids, regional techniques (such as paravertebral nerve blockade, intercostal nerve blockade, intrapleural analgesia, and epidural opioids with or without local analgesia), cryo-analgesia, and transcutaneous electrical nerve stimulation (TENS). (2)

Emerging research has shown that the novel erector spinae plane block (ESPB) can be employed as a simple and safe alternative analgesic technique for acute post-surgical, post-traumatic, and chronic neuropathic thoracic pain in adults. (3)

ESPB was first reported in 2016 for ipsilateral thoracic analgesia. (4)It was found to be a safe and effective block that can be performed by an emergency physician in the emergency department setting for addressing acute pain due to multiple rib fractures. (5)

Retrolaminar block (RLB) was first reported in 2006 as an alternative approach to PVB. RLB is performed with US imaging or the landmark technique. (4) The efficacy of continuous RLB has been reported for breast cancer surgery . (6)

However, the efficacy of ESPB has been described in a greater number of clinical reports than has RLB: a rib fracture, breast surgery, thoracoscopic surgery, lumbar spinal surgery, and laparoscopic abdominal surgery. In contrast to RLB, most of the literature on ESPB reported the use of the single-shot technique (80.2%). The local anesthetic was postulated to infiltrate the ventral and dorsal rami of the spinal nerve. However, Ueshima et al. reported that ESPB could not provide adequate analgesia of the anterior branch of the intercostal nerve. (4)

The rationale of the study is that to the best of our knowledge each of ESPB and RLB has limitations regarding sensory block and distribution so our hypothesis is combining both will provide more solid block regarding sensory distribution, time interval of the block efficacy, and postoperative morphine consumption in patients undergoing thoracic surgeries.

Few studies evaluated the efficacy of ultrasound (US) guided erector spinae plane block on post-thoracotomy analgesia, however for the best of our knowledge no one compared the effect of ultrasound (US) guided retrolaminar block combined with erector spinae plane block and ultrasound (US) guided erector spinae plane block alone in patients undergoing thoracic surgeries.

Aim of the work

This work aims to investigate whether adding the RLB to the ESPB would intensify the block decreasing the primitive opioid consumption. Using

20ml for ESPB compared to 10ml ESPB adding to 10ml RLB.

Objectives:

To assess the efficacy of ultrasound (US) guided Retrolaminar block combined with Erector Spinae plane block compared to ultrasound (US) guided solo Erector Spinae plane block for thoracotomy pain.

Hypothesis:

We hypothesize that ultrasound (US) guided Retrolaminar block combined with Erector Spinae plane block will provide more post-operative analgesia than ultrasound (US) guided Erector Spinae plane block alone for thoracotomy pain.

Ethical Considerations

The study will be conducted after taking approval from the research ethical committee; Informed consent will be obtained from the patients. Documentation of any complications -if present- will be documented.

Methodology

I. Study design

This is a randomized controlled, double-blind study.

II. Study setting and location

The study will be conducted at Kasr Al-Ainy Hospital, Faculty of Medicine, Cairo University, cardiothoracic unit.

III. Study population:

Patient undergoing open thoracic surgery through a posterolateral thoracotomy.

IV. Eligibility Criteria

1. Inclusion criteria

- Age from 18–65 years.
- body mass index (BMI) ranged between 20 and 40 kg/m2
- ASA I, II patients undergoing open thoracic surgery through a posterolateral thoracotomy

2. Exclusion criteria

- Patient refusal.
- Sensitivity or contraindication to local anesthetic drugs.
- History of psychological disorders and/or chronic pain.
- Localized infection at the site of the block.
- Coagulopathies, patients on anticoagulants and antiplatelets, and significant liver or renal insufficiency.

V Study Procedures

1. Randomization

Patients will be allocated in a parallel manner into two equal groups: Group 1 (ESPB (control group): (n = 15) patients will receive preoperative US-guided ESPB on the operated side by 20 ml bupivacaine 0.25%. Group 2: US-guided ESPB with 10 ml bupivacaine 0.25% + the US-guided retrolaminar block 10 ml bupivacaine 0.25% group: (n = 15) on the operated side.

Randomization will be accomplished through the use of computer-generated random numbers and closed opaque envelopes. Another anesthesiologist who will not be involved in the other parts of the study will open the envelopes to enroll patients. and both patients and outcome assessors will be blinded to the assignment of groups.

1. Study Protocol

Preoperative assessment of all patients comprised of history taking, clinical examination, laboratory testing (complete blood count, kidney function tests, liver function tests, prothrombin time, and partial thromboplastin time), electrocardiogram, and chest X-ray. The study protocol will be explained to the patients, and their consent will be obtained. All patients will be made familiar with the use of the pain score; visual analog scale score (VAS) identifying 0 as no pain and ten as the worst possible pain.

The patients will be continuously monitored in the holding room for heart rate, blood pressure, and oxygen saturation (baseline values). An intravenous (IV) 18-

gauge cannula will be inserted. Midazolam 2mg boluses IV will be administered for each patient. Patients will receive US-guided ESPB and US-guided ESPB + US-guided Retrolaminar plain block before induction of GA.

US-guided ESPB Blocks will be performed with a US machine (Philips HD 11xe) equipped with an HFL38X high-frequency linear transducer (13–16 MHz). With patients in a sitting position, the transducer will be positioned longitudinally 3 cm lateral to the T5 spinous process. The trapezius, rhomboid major, and erector spinal muscles will be revealed superficial to the shadow of the hyperechoic transverse process. Then, 3 ml lidocaine 2% will be used to anesthetize the skin. Using a 20-gauge block needle inserted in-plane in a cephalad-to-caudad orientation to position the tip into the fascial plane on the deep (anterior) side of the erector spinae muscle, 20 ml bupivacaine 0.25% will be injected. The needle tip's placement was confirmed by observable fluid spread lifting the erector spinae muscle away from the transverse process's bony shadow. (2)

For the retrolaminar block, an in-plane technique under ultrasound guidance will be used to advance the needle towards the posterior surface of the T5 lamina in a cephalic to caudal direction until contact with the lamina will be made. After confirming contact, the correct spread will be verified by injecting 1.0–2.0 ml of saline to create a plane of hypoechoic space on the posterior surface of the T5 lamina,(7) and 10 ml bupivacaine 0.25% will be injected.

The block success will be assessed by a blind observer unrelated to data collection. The presence of the cold sensation in T1-T8 dermatomes in the blocked side after 30 minutes indicated a failed block, and the patient will be excluded . (9)

GA will be induced for both groups using IV fentanyl 2 µg/kg and propofol 2 mg/kg. Tracheal intubation will be facilitated by Atracurium 0.5 mg/kg and will be done either by a left-sided double-lumen endobronchial tube (Mallinckrodt's 35 to 41 F according to patient size), or single lumen ETT and a fiberoptic bronchoscope will be used to ensure the correct position of the tube. The tidal volume will be adjusted to be 6–8 ml/kg, and the respiratory rate will be adjusted to keep the end-tidal CO2 between 30 and 40 mmHg.(2)

Anesthesia will be maintained with inhaled Isoflurane with MAC 1-1.5 in oxygen-enriched air (Fio2 will be adjusted to keep peripheral O2 saturation ≥90%) and top-up doses of Atracurium (0.1 mg/kg) IV will be administered as required. Ringer acetate will be infused to replace their fluid deficit, maintenance, and losses. (2)0

Additional bolus doses of fentanyl one µg/kg IV will be given if the mean arterial blood pressure (MAP) or heart rate (HR) rises above 20% of baseline levels after exclusion of all causes leads to an increase of both HR and MAP as awareness and fading of neuromuscular blockade.

One reading of MAP and HR will be taken before induction of GA to be defined as a baseline reading and then will be recorded immediately before surgical incision and at 30 min intervals intraoperatively. Hypotension will be treated with 100 ml 0.9% normal saline bolus and 5 mg ephedrine IV in incremental doses to maintain MAP above 70 mmHg. Bradycardia (HR <60) will be treated with 0.1 mg/Kg atropine IV.(2)

At the end of the surgery, the residual neuromuscular blockade will be reversed using 0.07 mg/kg Prostigmin IV, and extubation will be performed after complete recovery of the airway reflexes.

Then, patients will be transferred to the post-operative care unit (PACU) and will be observed for two hours. Following that, the patients will be transferred to a ward and given 1 g of acetaminophen IV every 8 hours, ketorolac tromethamine 30mg IM/12h as 2 components of multimodal anesthesia regimen for postoperative pain control. (10)

VAS (at rest and cough), MAP, and HR will be noted immediately on arrival to PACU (0 h) and at 2, 4, 6, 12,18, and 24 h postoperatively. Rescue analgesia will be provided in the form of IV morphine 3 mg boluses if VAS >3. The time to first request rescue analgesia and the total morphine administered during the first 24-hour postoperative will be recorded.

Patient satisfaction (satisfied or not satisfied) will be recorded 24 hours postoperative. Adverse events will be reported (PONV, hypotension, bradycardia, excessive sedation, and hematoma).

Measured Parameters:

- Hemodynamics including MAP and HR throughout the surgery
- VAS (at rest and cough), MAP, and HR will be noted immediately on arrival to ICU (0 h) and at 2, 4, 6, 12,18, and 24 h postoperatively figure (1).

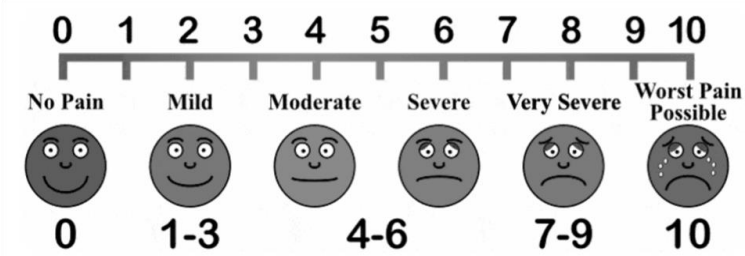

Figure1:Visual analog score (8)

- Post-operative Total amount of morphine consumption in the first 24-hour.
- Incidence of complications, such as nerve injury, hematoma formation, and severe hypotension will be noted.

VI. Study outcomes

1. Primary outcome

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

2. Secondary outcome(s).

- Pain score according to VAS score at 30min, 2h, 4h, 8h, 12h, 24h postoperative.
- Heart rate and MAP at 0 , 15min, 30min, 45min, 60min, 90min, 120min, then every 1h intraoperative.
- First request of analgesia postoperative.
- Opioid requirements intraoperatively.
- Incidence of complications as hypotension, bradycardia, postoperative nausea, vomiting (PONV) and pruritis.

Sample size

Statistical Analysis

1) Sample size

Power analysis was 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 , mean(SD) after ESPB was 8=52(4=29) mg. (9)

Based on assumption that a 50% difference between groups is a clinically significant difference and for a power of 0.95 and alpha error of 0.05.

A minimum of 16 patients was calculated for each group. The sample size will be increased to 18 for each group to compensate for possible dropouts.

2) Statistical analysis

- Microsoft excel 2013 will be used for data entry and the statistical package for social science (SPSS version 24) will be used for data analysis.
- Simple descriptive statistics (arithmetic mean and standard deviation) will be used for the summary of normal quantitative data (median and interquartile range) for a summary of abnormal quantitative data and frequencies will be used for qualitative data.
- Bivariate relationship will be displayed in cross-tabulations and a Comparison of proportions will be performed using the chi-square and Fisher's exact tests where appropriate.
- T-test and post-hook tests will be used to compare normally distributed quantitative data and Kruskal-Wallis for skewed data.
- P value will be calculated to assess statistical significance, a value less than 0.05 will be considered statistically significant.

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