EGYPTIAN JOURNAL OF ANAESTHESIA
2023, VOL. 39, NO. 1, 869–875
https://doi.org/10.1080/11101849.2023.2281104



# Ultrasound continuous erector spinae catheter versus paravertebral catheter for pain management in modified radical mastectomy for cancer patients: A randomized double-blind

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**ABSTRACT**

**Background:** Regional analgesia provides adequate management of pain during mastectomies and early postoperative period. The erector spinae plane block (ESPB) is a promising regional technique. This study compared the efficacy of ESPB versus paravertebral block (PVB) catheters for pain management in modified radical mastectomy (MRM).

**Methods:** This randomized, double-blind, non-inferiority study recruited 70 adult female cases planned for MRM. The patients were equally randomized into two groups: group ESPB and group PVB. The blocks were performed before general anesthesia induction with 20 ml bupivacaine 0.25%, then 0.1 ml/kg/hr continuous infusion through a catheter.

**Results:** The duration of block performance was significantly lower in the group ESPB than in the group PVB ($P < 0.001$). The total morphine consumption in 48 h postoperative was 1.54 ± 3.74 mg in group ESPB and 1.68 ± 3.48 mg in group PVB ($P = 0.878$). Patients required fentanyl and postoperative morphine in the 1st 48 h, time to 1st request analgesia insignificantly differed between groups. Intraoperative and postoperative heart rate, mean arterial pressure and oxygen saturation, and visual analog scale at rest and movement insignificantly differed between groups. Postoperative pneumothorax occurred in one case in group PVB and did not occur in group ESPB.

**Conclusions:** In MRM, analgesic efficacy of preoperative ultrasound-guided ESPB and PVB is comparable, and ESPB is an easier technique and more safer to perform when compared to PVB.

**ARTICLE HISTORY**
Received 7 September 2023
Revised 6 October 2023
Accepted 26 October 2023

**KEYWORDS**
Analgesia; breast cancer; catheter; erector spinae plane block; paravertebral block

## 1. Introduction

Modified radical mastectomy (MRM) is the standard technique for breast cancer. Analgesia for MRM is challenging due to the complexity of the procedure and the precise nerve supply of the breast [1]. Inadequate management of acute pain following MRM can result in undesirable short-term results, including prolonged hospitalization, delayed ambulation, and patient anxiety [2].

Regional nerve blocks adequately provide pain management, lower the need for perioperative analgesic and anesthetic drugs and postoperative nausea and vomiting (PONV) and accelerate rehabilitation [3,4].

Paravertebral block (PVB) is a common efficient regional anesthetic method for multimodal analgesia [5]. PVB acts by blocking multiple dermatomes, achieving a wide range of beneficial effects, including improved postoperative pulmonary functions, decreased need for opioid analgesics, prevention of PONV, and reduced risk of malignancy recurrence and thrombotic diseases [5,6].

However, PVB is challenging due to its proximity to the pleura and central neuraxial system. Pneumothorax, sympathetic block, spinal cord damage, and hypotension are all possible complications of PVB [7–9].

Ultrasound (US)-guided erector spinae plane block (ESPB) is an interfacial plane block used as an alternative analgesic therapy after surgery, trauma, persistent neuropathic pain with a high effectiveness rate in reducing somatic and visceral pain [10,11].

Forero et al. [12], Fang [13], and Ibrahim [14] utilized the ESPB in several trials to provide postoperative analgesia in breast, thoracic, and percutaneous nephrolithotomy procedures, with good outcomes. ESPB was efficient in managing postoperative pain. The adequate analgesia produced by ESPB minimizes opiate use and pain scores after surgery.

However, there is conflicting literature on the most effective analgesic technique in MRM. A recent randomized study reported the superiority of PVB over ESPB to reduce pain intensity and postoperative opioid consumption other study showed similarity of both blocks after mastectomies; one study was in favor of ESPB, that after mastectomy, patients who received PVB had significantly reduced opioid needs, pain scores, and

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sensory blockage compared to those who received ESPB [2]. In contrast, other studies concluded that PVB and ESPB could effectively manage pain after a mastectomy with reduced intra and postoperative opioids consumption [1,15]. In contrast, another study highlighted that the ESPB provided lower pain scores and better analgesic effects than PVB [16].

ESPB catheters could provide effective post-mastectomy pain control similar to PVB without the occurrence of complications. Therefore, we conducted this trial to compare the analgesic effect of continuous ESPB versus PVB to control pain in MRM.

## 2. Materials and methods

This randomized, non-inferiority, double-blind study recruited 70 female cases aged 20–70 years, physical status II or III according to the American Society of Anesthesiologists (ASA) planned for MRM.

The study was performed at the National Cancer Institute, Cairo University, Egypt, from July 2022 to August 2023, after being approved by the Institutional Ethical Committee and registered at clinicaltrials.gov (ID: NCT05771116). Signed consent was acquired from each patient.

Exclusion criteria were coagulopathy, ipsilateral breast surgery local anesthetic (LA) hypersensitivity, injection-site infections, or a history of psychological impairments.

## 3. Randomization and blindness

The cases were randomized parallelly using sealed opaque envelopes and a random list created by a computer. Cases were categorized into two groups equally: ESPB and PVB groups. Participants to the performed regional anesthesia technique were blinded. The intra and postoperative parameters were measured by an anesthesiologist who was not involved in the study design.

The patient's medical history taking physical examination, and standard laboratory testing were performed for all participants. Patients were given instructions on how to estimate the severity of their pain regarding the visual analog scale (VAS) that varies from 0 (no pain) to 10 (imaginable pain).

All patient standard monitoring was attached to each patient including (ECG m Blood pressure, pulse oximeter) had an intravenous (IV)18-G cannula in the operating room in contralateral arm. All patients were monitored by pulse oximetry, electrocardiography, non-invasive blood pressure, capnogram, and temperature probe.

The blocks were done while the patient was seated by the same anesthesiologist before induction of GA under complete sterilization. Using 3 ml of 1% lidocaine, the skin was anesthetized. A 20-gauge block needle was used and ultrasound guided by a high-frequency linear (7–13 MHz) ultrasound transducer (Manuf Sonosite Model edge 2).

## 4. The US-guided ESPB technique

While the patient was seated by the same anesthesiologist before induction of GA, the transducer was placed 3 cm to the side of the T7 spinous process then lamina, then facet joint and transverse block. Three superficial muscles were revealed: trapezius, rhomboid major, and ES and our target between transverse process and erector spine. In the deep (anterior) aspect of the ES muscle, the needle was inserted in-plane, cephalo-to-caudal, into the fascial plane. Visible LA diffusion that lifted the ES muscle off the transverse process confirmed its location.

## 5. Paravertebral block technique

While the patient was seated by the same anesthesiologist before induction of GA, the transducer was positioned in the para-median sagittal plane almost 2.5 cm laterally of the midline the needle is inserted in-plane and directed medially between the transverse process and the pleura. The tip of the needle then traverses the superior costo-transverse ligament and enters the paravertebral space where local anesthetic is deposited until the internal intercostal membrane, transverse process, and pleura at the T3 and T6 levels were identified. Paravertebral space (PVS) was accessed by out-of-plane cephalad-to-caudal needle insertion.

After negative aspiration, 20 ml bupivacaine 0.25% was administered in both groups. A catheter was then inserted and the needle was withdrawn. The catheter was held in place with adhesive for up to 3 days.

After 30 min of injection, a lack of pinprick sensation at the dermatomal location of the block indicated the blocks had been successful, and patients whose blocks had failed were replaced to maintain a constant sample size.

To induce GA, 2–2.5 mg/kg of propofol and 2 µg/kg of fentanyl were injected IV. 0.5 mg/kg was given for rocuronium neuromuscular blockade. A properly sized endotracheal tube was used to maintain airway security. Oxygen: air (total fresh gas flow: 1:1) and titrated isoflurane to a minimum alveolar concentration of 1.0 were used to maintain balanced anesthesia in the patient. Bolus IV doses of 0.1 mg/kg rocuronium were administered according to the train of four. The patients were then mechanically ventilated to maintain an end-tidal $CO_2$ of 30–35 mmHg. When the mean arterial blood pressure (MAP) or heart rate (HR) was increased by more than 20% from baseline readings. Top up dose given in catheter.

At the end of the surgery, 0.02 mg/kg atropine and 0.05 mg/kg neostigmine were administered to reverse

the neuromuscular blockade. Patients were transferred to a post-anesthesia care unit (PACU) after extubation.

HR and MAP, oxygen saturation, and VAS (both at rest and with movement) were assessed at PACU, 2, 4, 6, 8, 12, 18, 24, 36, and 48 h after surgery.

Paracetamol 1 gm/8-h IV was administered to all patients as part of routine analgesia. In the case of VAS > 3, patients received 3 mg IV morphine as rescue analgesia after consulting doctor. Patient stay in PACU 2 hr to assess VAS score. The total opioid administration and the time to first rescue analgesia were also recorded.

The following complications were recorded: postoperative pneumothorax, hematoma, and motor and neurologic deficit.

The $1^{ry}$ outcome was the total 48-h postoperative opioid consumption as time of catheter present until removing it. The $2^{ry}$ outcomes were time to $1^{st}$ request for analgesia, any hemodynamic instability, and complications.

## 6. Sample size calculation

The required 32 patients were determined using PASS software (release 11.0; NCSS PASS, UT, USA). The total morphine consumption in the first 48 h postoperatively was tested as the 1ry outcome to determine non-inferiority. The following criteria were used: the non-inferiority margin was established at 3 mg, the confidence limit was 95%, the power of the trial was 95%, the group ratio was 1:1, the common standard deviation of the total postoperative morphine intake in the first 48 h was 3.63 mg according to a pilot study, and three cases were added to each group to account for dropout and method failure rate; Therefore, 35 patients were assigned into each group.

## 7. Statistical analysis

The data were analyzed using IBM's SPSS v26 (Chicago, Illinois, USA). The normal distribution quantitative variables were compared using the unpaired Student's t-test and provided as means and standard deviations (SD). Abnormal distribution quantitative data were compared using the Mann–Whitney test and provided as a median and IQR. Qualitative data were compared using Chi-square or Fisher's exact tests and provided as frequency (%). An evaluation of the 95% confidence interval (CI) was performed. The cutoff for statistical significance was set at a two-tailed $P$ value < 0.05.

## 8. Results

In this study, 103 patients were assessed for eligibility; 21 did not meet the criteria, five refused to participate, and seven failed blocks persistent of pinprick sensation after 30 min. Patients who remained were allocated evenly between two groups (35 patients each). All allocated patients were followed-up and analyzed statistically. Figure 1

Demographic data, side of the operation, and duration of surgery showed insignificant differences between groups. Block performance duration was significantly less in the group ESPB than in the group PVB ($P$ value < 0.001). Table 1

Intraoperative and postoperative HR, MAP, and oxygen saturation at all measurements differed insignificantly between both groups. Figure 2

VAS measurements at rest and movement were comparable between groups. Table 2

The mean total morphine consumption in $1^{st}$ 48 h postoperative was 1.54 ± 3.74 mg in the ESPB group and 1.63 ± 3.44 mg in the PVB group. The mean time to $1^{st}$ request analgesia was 26 ± 11.8 h in the ESPB group and 25.71 ± 10.8 h in the PVB group. Total morphine consumption within the $1^{st}$ 48 hours, and time to $1^{st}$ request analgesia postoperatively were similar between groups. Table 3

Pneumothorax occurred in one case in group PVB patient presented by shortness of breath, follow-up Chest x-ray done, consult surgeon, and decide to insert a chest tube but did not occur in group ESPB. Hematoma and postoperative motor and neurologic deficits did not appear in any patient in both groups. Table 4

## 9. Discussion

The analgesic effect of PVB refers to the LA injection into the PVS, where it reaches the spinal nerve roots and expands into the epidural area [17]. Somatic and sympathetic nerve blocks may be induced unilaterally by the PVB [18].

The ESPB could effectively block the ventral and dorsal rami of the spinal nerves as the LA is efficiently delivered to the ES muscle with an anticipated paravertebral spread in the craniocaudal axis [19,20]. It is thus a regional method of the peri-paravertebral space [21].

Due to the extensive length of the ES fascia, which begins at the nuchal fascia and ends at the sacrum, LA agents can reach deep into the tissue and produce a wide-ranging block [22].

According to the results of this study, intraoperative and postoperative HR, MAP, oxygen saturation, and VAS measurements at rest and movement were similar between groups. Intraoperative fentanyl and postoperative morphine amount was minimal and nearly similar in both groups. This finding could be explained by the proper analgesic effect of both blocks. The number of patients who required fentanyl, those who required morphine in first 48 h postoperative, total morphine consumption in first 48 h postoperative, time to first request analgesia, and

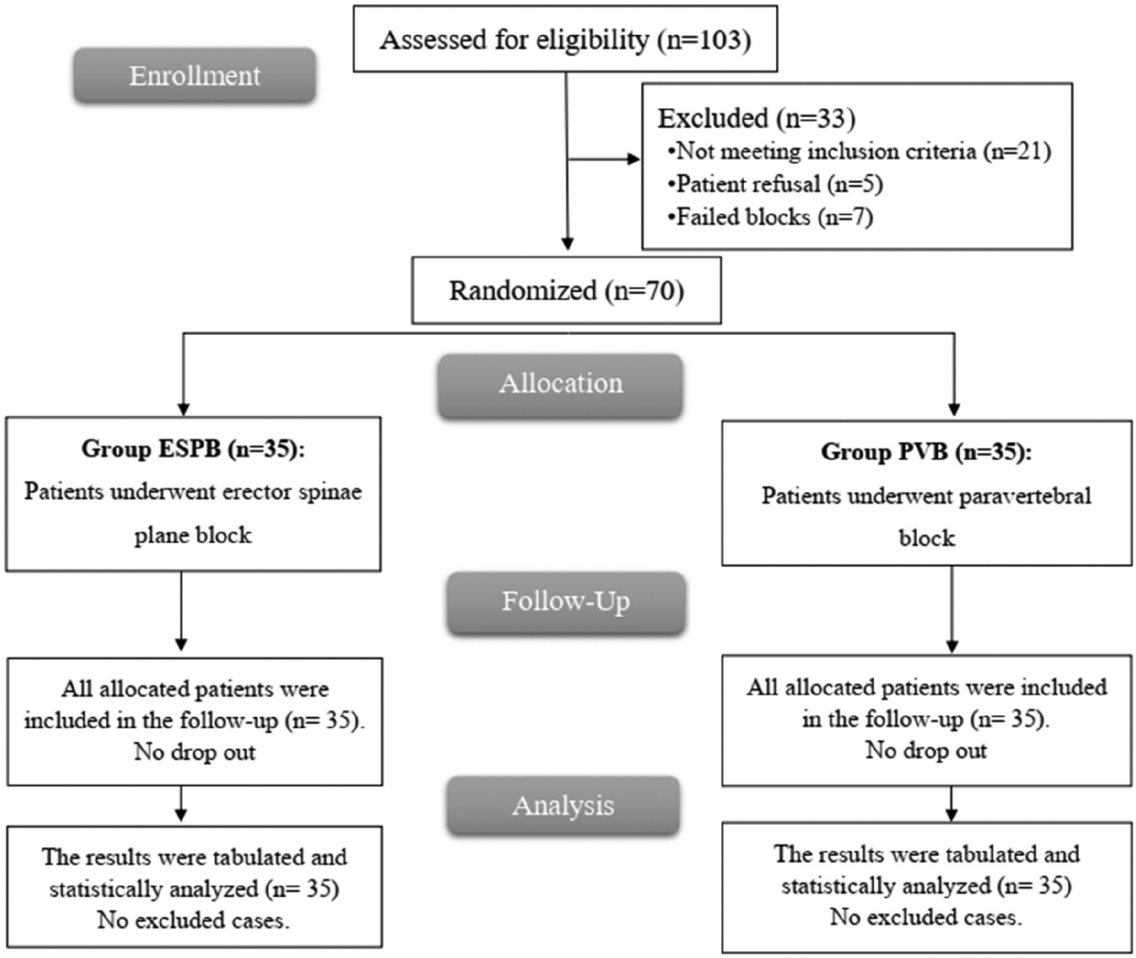


**Figure 1.** CONSORT flowchart of the enrolled patients.

**Table 1.** Demographic data, side of the operation and duration of block performance and surgery between groups.

| | | Group ESPB (*n*=35) | Group PVB (*n*=35) | P value |
|---|---|---|---|---|
| Age (years) | | 46.49 ± 12 | 49.17 ± 9.69 | 0.307 |
| Weight (kg) | | 85.49 ± 12.7 | 83.2 ± 14.36 | 0.483 |
| Height (m) | | 1.69 ± 0.05 | 1.69 ± 0.06 | 0.710 |
| BMI (kg/m$^2$) | | 30.15 ± 5.11 | 29.21 ± 5.75 | 0.471 |
| ASA physical status | II | 16 (45.71%) | 18 (51.43%) | 0.632 |
| | III | 19 (54.29%) | 17 (48.57%) | |
| Side of the operation | Right | 16 (45.71%) | 22 (62.86%) | 0.150 |
| | Left | 19 (54.29%) | 13 (37.14%) | |
| Duration of block performance (min) | | 21.77 ± 4.12 | 33.14 ± 5.14 | **<0.001*** |
| Duration of surgery (min) | | 147 ± 18.16 | 149.86 ± 19.5 | 0.528 |

Data are presented as mean ± SD or frequency (%). BMI: body mass index, ASA: American Society of Anesthesiologists.
*p* value less than 0.05 statistically significant value.

postoperative complications were insignificantly different between both groups.

El Ghamry et al. [17] reported that PVB and ESPB were effective in pain management post-mastectomy with comparable opioid consumption, analgesic effect duration, and hemodynamic stability. Elewa et al. [1] reported that the duration of postoperative analgesia and the 1$^{st}$ morphine consumption did not vary significantly between ESPB and PVB. Similar findings were observed by Moustafa et al. [23], where there were no changes between the opioid-sparing effects of ESPB and PVB in MRM.

A recent systematic review and meta-analysis found no statistically significant differences between the PVB and ESPB in postoperative analgesia following breast surgery [24].

Nevertheless, the present study's findings were in a recent randomized, double-blind study by Swisher et al. [25]. They showed that PVB provides better postoperative analgesia than ESPB in breast surgeries. Compared to the ESPB, the PVB led to less morphine

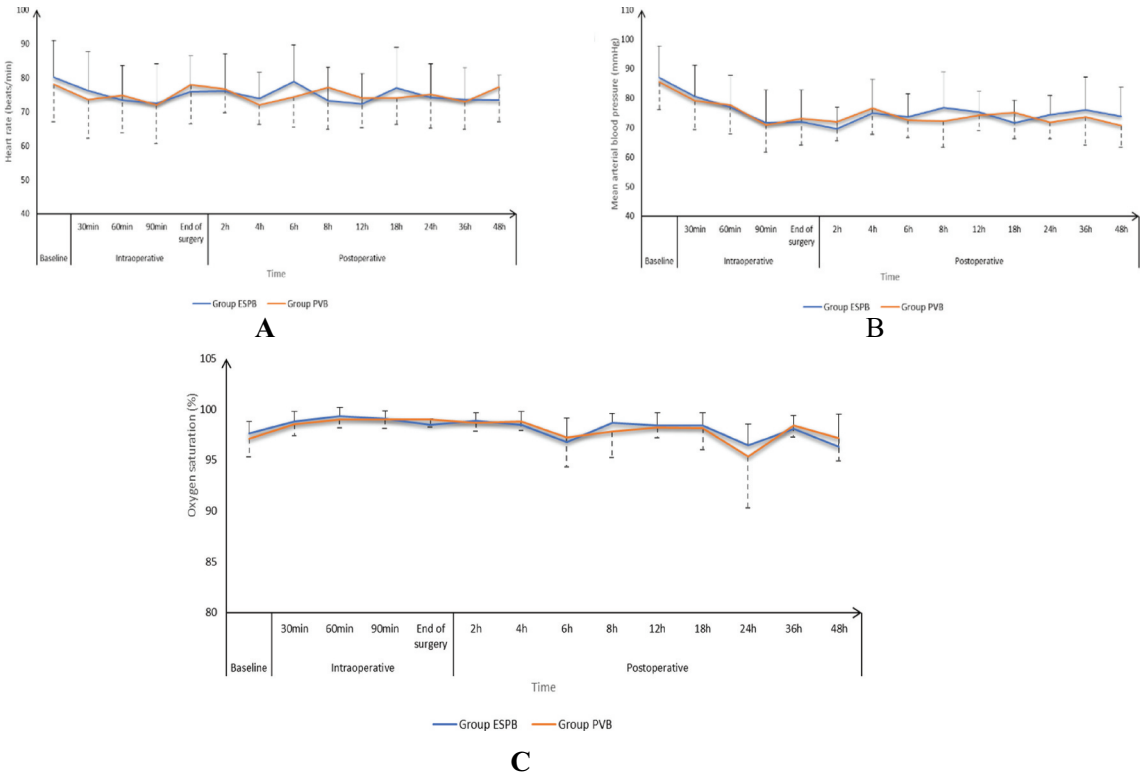


**Figure 2.** Intraoperative and postoperative (a) heart rate, (b) mean arterial blood pressure, and (c) oxygen saturation measurements of the studied groups.

**Table 2.** VAS measurements at rest and movement of the studied groups.

| | Group ESPB (*n*=35) | Group PVB (*n*=35) | P value |
|---|---|---|---|
| **At rest** | | | |
| PACU | 1 (0–2) | 1 (0–2) | 0.540 |
| 2h | 2 (1–2) | 2 (1–2) | 0.823 |
| 4 h | 2 (1–2) | 2 (2–2) | 0.762 |
| 6 h | 2 (2–2) | 2 (2–2) | 0.418 |
| 8 h | 2 (2–2) | 2 (2–2) | 0.831 |
| 12 h | 2 (1–2) | 2 (2–2) | 0.927 |
| 18 h | 3 (2–2) | 2 (2–2) | 0.509 |
| 24 h | 3 (2–2) | 3 (2–2) | 0.653 |
| 36 h | 3 (2–3) | 3 (2–3) | 0.908 |
| 48 h | 3 (2–3) | 3 (2–3) | 0.625 |
| **At movement** | | | |
| PACU | 2 (2–3) | 2 (2–3) | 0.945 |
| 2h | 3 (2–3) | 2 (2–3) | 0.822 |
| 4 h | 2 (2–3) | 3 (2–3) | 0.684 |
| 6 h | 3 (2–3) | 3 (2–3) | 0.920 |
| 8 h | 3 (2–3) | 3 (2–3) | 0.571 |
| 12 h | 3 (2–3) | 3 (2–3) | 0.857 |
| 18 h | 3 (2–3) | 3 (2–3) | 0.842 |
| 24 h | 3 (2–3) | 3 (2–3) | 0.657 |
| 36 h | 3 (3–3) | 3 (3–3) | 0.683 |
| 48 h | 3 (3–3) | 3 (3–3) | 0.704 |

Data are presented as median (IQR). PACU: post-anesthesia care unit.

use and better VAS scores on the first postoperative 24 h.

The authors suggested that the LA's direct distribution to PVS after PVB, as opposed to the inadequate LAs spreading to the PVS after ESPB, is responsible for the greater analgesic impact of PVB [12,26].

Eskandr et al. [27] found that the analgesic duration, morphine consumption, hemodynamics, and complication frequency were comparable between ESPB and PVB.

Our study was distinguishable from the previous studies regarding a more extended follow-up period of 48 h in addition to the administration of the LA

**Table 4.** Postoperative complications between groups.

| | Group ESPB (*n*=35) | Group PVB (*n*=35) | P value |
|---|---|---|---|
| Pneumothorax | 0 (0%) | 1 (2.86%) | 1.00 |
| Hematoma | 0 (0%) | 0 (0%) | – |
| Motor and neurologic deficit | 0 (0%) | 0 (0%) | – |

Data are presented as frequency (%).

**Table 3.** Intraoperative fentanyl and postoperative morphine consumption of the studied groups.

| | Group ESPB (*n*=35) | Group PVB (*n*=35) | P value | 95% CI |
|---|---|---|---|---|
| Number of patients required intraoperative fentanyl | 4 (11.43%) | 3 (8.57%) | 0.690 | 0.28:6.66 |
| Number of patients who required morphine in 1st 48 h postoperative | 6 (17.14%) | 7 (20%) | 0.759 | 0.25:2.77 |
| Total morphine consumption in 1st 48 h postoperative (mg) | 1.54 ± 3.74 **(*n*=6)** | 1.63 ± 3.44 **(*n*=7)** | 0.921 | −1.8: 1.63 |
| Time to 1st request analgesia (h) | 26 ± 11.8 | 25.71 ± 10.8 | 0.964 | −5.11: 5.68 |

Data are presented as mean ± SD or frequency (%).

through a catheter that offers opportunities for increased flexibility and prolonged analgesia.

We found that the duration of block performance was higher in group PVB than in group ESPB.

In line with the current study's findings, Ghamry et al. [17] reported that the overall performance of ESPB was easier than PVB. Moreover, Xiong et al. [28] found that in both the thoracic and breast groups, the PVB group needed more time to complete the block process than the ESPB group.

Our findings demonstrate that pneumothorax occurs in one case in group PVB, while it did not occur in group ESPB. In a recent randomized controlled study comparing ESPB and PVB for pain management in mastectomy cases, pneumothorax was reported in one case in the PVB group [27]. Moreover, El Ghamry et al. [17] reported that pneumothorax occurred in four cases in the PVB group, one of them need to insert a chest tube, and the other three cases were just conservative, while no pneumothorax cases were recorded in the ESPB group in MRM cases.

Naja et al. [29] reported an incidence of pneumothorax (0.5%) after PVB. Meanwhile, Pace et al. examined 1427 individuals who received PVB and found no cases of pneumothorax. A US-guided method is associated with this success [30].

Injecting ESPB in the tissue plane, away from possibly risky structures, reduces the likelihood of significant complications [31].

ESPB is effective without any vitally problematic structures that needles could injure. As a result, the incidence of spontaneous hematoma is diminished. ESPB is a secure technique that uses the TP as an anteromedial barrier to prevent needle contact with the pleura, reducing the occurrence of pleural damage and postoperative opioid consumption and enhancing the analgesic effect [13].

This study had certain limitations; it was a single-center study with a modest sample size. Additional studies with different blocks, additives, concentrations, and volumes are required.

## 10. Conclusions

ESPB may be a simple and safe alternative to PVB to provide postoperative analgesia in MRM with less inscene to ESPB regarding the lower duration of block performance and without the occurrence of pneumothorax.

## Disclosure statement

No potential conflict of interest was reported by the author(s).

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