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# Combined pectoralis II block and transversus thoracic plane block compared to erector spinae plane block for post-operative analgesia in patients undergoing modified radical mastectomy: A randomized clinical trial

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#### ABSTRACT

**Background:** About 30% of Egyptian females had breast cancer. Surgery is a cornerstone of the treatment plan. New fascial plane block techniques enhance recovery and improve intra-operative and post-operative pain control.

**Aim of the study:** Effect of combined pectoralis II plus transversus thoracic plane blocks (PECS II-TTP) versus erector spinae plane block (ESPB) on post-operative morphine consumption, and interleukin-6 (IL-6) levels 24 hours after surgery.

**Methods:** Sixty-four female patients 18–60 years of age, ASA I or II were divided into two equal groups (32 patients each). Group (P) received a combination of PECS II and TTP blocks (injection of 10 ml 0.25% bupivacaine between pectoralis major (PM) and minor (Pm) muscles and 10 ml between the Pm and serratus anterior (Sa) muscles) at the third or the fourth rib, then 10 ml and the internal inter-costal muscles and the transversus thoracic muscle. Group (E) received ESPB (30 ml of 0.25% bupivacaine injected deep to the erector spinae muscle at the transverse process of the fifth thoracic vertebrae).

**Results:** Morphine consumption was significantly lower in group (E) throughout the 24 hours period of post-operative follow-up ( $0.93 \pm 0.63$  vs.  $2.13 \pm 0.42$  (mg); p = 0.03). Both groups had comparable time till the first analgesic request (p = 0.23). There was statistically non-significant difference between the two groups regarding the numeric rating scale (NRS) (P > 0.05), and post-operative IL6 either at baseline ( $10.03 \pm 4.09$  vs.  $10.73 \pm 3.54$ ; p = 0.48) or at 24 hours after surgery ( $239.01 \pm 122.11$  vs.  $278.08 \pm 151.29$ ; p = 0.30). Both groups had non-significant difference regarding post-operative nausea and vomiting.

**Conclusion:** ESPB is as effective as PECS II-TTP with lower morphine consumption in the first 24 hours and comparable NRS, time to first analgesic request, and interleukin-6 levels. Both blocks were safe without any major complications.

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ESPB; PECSII-TTP; morphine consumption; mult-imodal analgesia

# 1. Introduction

Breast cancer incidence has risen 0.5% annually in the last decade (2010–2019). In contrast, its mortality rates dropped 43% during 1989–2020 [1]. About 30% of Egyptian females had breast cancer [2].

Current analgesic modalities for the management of acute post-operative pain include acetaminophen, opioids, (NSAIDs), epidural anesthesia, Para-vertebral block, local anesthetic infiltration, peripheral nerve blocks, as well as analgesic adjuncts such as steroids, and  $\alpha$ -2 agonists [3].

Surgery is a cornerstone in the treatment plan, and multi-modal analgesic regimen is a fundamental component of the Enhanced Recovery After Surgery (ERAS) pathways. The goal of a multi-modal analgesic regimen is to maximize physiologic and pharmacologic benefits and minimize the adverse effects to facilitate the patient's recovery [4].

Ultrasound-guided peripheral nerve and fascial plane blocks reduced the incidence of major complications such as vascular injury, local anesthetic systemic toxicity, and pneumothorax [5].

Blanco et al. [6] described the PECS II block or the modified pectoralis block, which aims to block the axilla that is vital for axillary clearances and to reach the long thoracic nerve. Also, it blocks the lateral branches of the inter-costal nerves from T2 to T6, which gives sensory innervation to the mammary gland and skin.

Ueshima and Kitamura [7] explained the transversus thoracic plane (TTP) block that is performed in the para-sternal location in order to block the anterior cutaneous branches of inter-costal nerves (Th2–6).

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The first illustration of Erector spinae plane block (ESPB) was in 2016 by Forero et al. [8], to treat chronic thoracic neuropathic pain. ESPB, in comparison with GA, effectively reduced morphine consumption within the first 24 hours after breast cancer surgery [9].

# 2. Aim of the work

We aimed to compare the analgesic effect of combined pectoralis II plus transversus thoracic plane blocks (PECS II- TTP) versus erector spinae plane block (ESPB) in modified radical mastectomy. The primary outcome was the morphine consumption in the first 24 hours post-operative while secondary outcomes were, interleukin-6 (IL-6) levels at baseline and 24 hours after surgery as an indicator of stress response, time to first analgesic request, recovery time, and numeric rating scale (NRS) in addition to procedure-related complications such as vascular injury, local anesthetic systemic toxicity, and pneumothorax, hypotension, nausea, and vomiting. postoperative adverse effects, and peri-operative hemodynamics were analyzed.

## 3. Methods

This prospective interventional single-blinded randomized controlled study was done in Assiut University Hospitals, Faculty of Medicine, Assiut University, Assiut, Egypt, the medical ethics committee approval was taken (Protocol ID: IRB17200328), and Registration at ClinicalTrials.gov (Identifier: NCT03903224) was obtained prospectively before starting to enroll the first patient. All patients signed the consent forms after a comprehensive discussion of the study's purpose, interventions, outcomes, and adverse events. The study did follow the ethical principles and guidelines of the Declaration of Helsinki.

#### 4. Patients

Sixty-four female patients, 18–60 years of age with ASA status I or II undergoing MRM were included. Patients who refused the intervention, had a BMI  $\geq$  35, had a previous allergy to local anesthetics, uncooperative patients, alcohol abusers, had an infection near the injection site, or had skeletal deformities were excluded from the study.

For randomization, a random number sequence generated using an online website (http://www.ran dom.org/) for patients' allocation. The random number sequence was kept in sealed dark envelopes and opened at the time of intervention by an independent physician who had no role in the study. Patients were assigned randomly to two groups (32 patients in each group). Group (E) received (ESPB) plus general anesthesia (GA), and group (P) received combined (PECS II- TTP) plus (GA) (Figure 1).

# 5. Application of block techniques

After monitoring with the standard ASA monitors, all blocks were given to awake patients before induction of general anesthesia. Baseline serum IL6 was sampled from each patient pre-operatively. Venous blood (5 ml) was sampled and placed into a serum separator tube. After clotting for 2 hours at room temperature, they were centrifuged, and the resulting serum was stored in smaller aliquots at -20°C for later analysis. Serum IL6 was measured using (ELISA) done by ELK Biotechnology kits (ELK Biotechnology CO., Ltd., Denver, USA).

Group (E) (n = 32) with a completely sterile environment, 2 ml of lidocaine 2% was injected to make a wheel at the site of injection. A 8-cm 22-gauge block needle (Pajunk, sonoplex stim cannula, Getsingen, Germany; 80 mm), was inserted in cranio-caudally direction till the tip was inferior to the erector spinae muscles where 30 mL of 0.25% bupivacaine was injected between the muscles and the fifth dorsal transverse process. The block was done while standing behind the sitting patient, facing the ultrasound (US) machine (Sonosite, Turbo M3), and a linear US probe (38 mm, 7–12 MHz frequency) was placed longitudinally 3 cm lateral to the T5 spinous process. The location of this spinous process was defined by counting down from the seventh cervical spinous process (Figure 2).

Group (P) (n = 32) was given combined US-guided PECS II- TTP blocks with preservation of the absolute sterile conditions. For PECS II block, Patients were supine with their arms abducted ninety degrees. The probe was placed below the clavicle to locate the coracoid process in the para-median sagittal plane. An in-plane needle trajectory was enabled by a slight rotation of the probe. Ten ml of bupivacaine 0.25% was injected between the pectoralis major and minor muscles before we advance the needle to inject another 10 ml of bupivacaine 0.25% between the muscles, pectoralis minor and serratus anterior; at the third or fourth rib. Finally, we performed the TTP block, 10 ml bupivacaine 0.25% was injected between the deep transversus thoracic and the superficial internal inter-costal muscles para-sternal between the third and fourth left ribs under US guidance (Figure 2).

# 6. Anesthesia and monitoring

Pre-oxygenating the patient with 100% FiO<sub>2</sub> for 3 minutes via a face mask before induction of anesthesia, Standard ASA monitoring included 5-lead ECG, SpO<sub>2</sub>, non-invasive blood pressure, and end-tidal CO<sub>2</sub>. General anesthesia was induced with propofol 1.5–2 mg/kg body weight, fentanyl 1 ug/kg, and atracurium

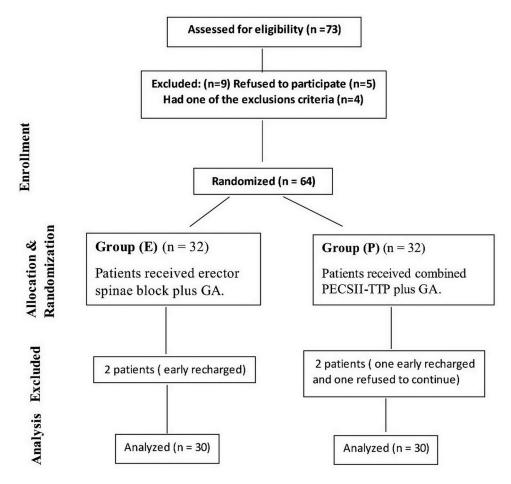


Figure 1. Consort flow chart of the two studied groups. Group E: Erector Spinae Block (ESPB); Group P: Modified pectoralis nerve block plus transversus thoracic plane block (PECS-II-TTP);.

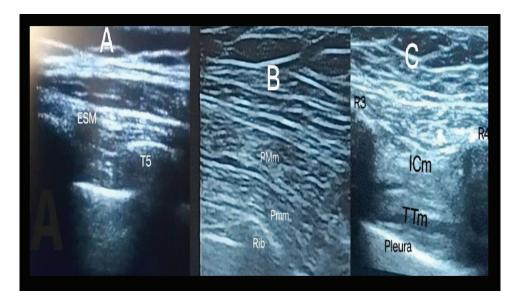


Figure 2. Ultrasonographic visualization of different study blocks. A: Erector spinae plane block (ESPB). B: Modified pectoralis nerve block (PECS II block). C: Transverses thoracic plane block (TTP).

0.5 mg/kg. Isoflurane 1–2 MAC in 50% air: oxygen mixture was used to maintain anesthesia. Mechanical ventilation was adjusted to keep end-tidal  $CO_2$  35–40 mmHg. Intravenous (IV) ketorolac 30 mg and dexamethasone 8 mg were given to all patients after intubation. Bolus doses of atracurium 0.1 mg/kg every 20 minutes. At the end of the surgery, 1 gram of paracetamol was given intravenously, all anesthetic agents were turned off, FiO2 was increased to 100%, and the muscle relaxant was reversed when clinically appropriate. Patients were extubated when they were fully awake and breathing well fullfiling extubation criteria. Heart rate (HR), Mean arterial blood pressure (MAP), end-tidal CO<sub>2</sub>, and SpO<sub>2</sub> were recorded at baseline, induction time, skin incision, and every 20 minutes till the end of the surgery. Intra-operative bradycardia (HR < 50 bpm) was treated with IV (0.5–1 mg) atropine sulfate, Intra-operative hypotension (MAP < 20% of baseline) was treated by decreasing the level of anesthesia, or by 6 mg ephedrine boluses. The patients were followed for 24 hours regarding SpO2, MAP, HR, NRS, time to first analgesic request, total morphine consumption, and development of any side effects. Patients were given 4 mg morphine as rescue analgesia whenever the NRS reached  $\geq$ 4. Another 5 ml venous blood was sampled after 24 hours from each patient to measure the post-operative serum level of IL6.

#### 7. Sample size calculation

The primary endpoint was morphine consumption at the post-operative 24 hours. Based on a previous study [10] which documented a mean morphine consumption at post-operative 24 hours was  $5.76 \pm 3.8$  mg in the ESPB group and to detect a difference (effect size) of 50% with combined pectoralis and transversus plane block group, with  $\alpha$  error 0.05,  $\beta$  error 0.05 and power 80%, 54 patients in both groups was required (https://www.medcalc.org). After consideration of a dropout ratio of 15% (8.1 patients) to compensate for the dropouts and protocol violation, another ten patients were additionally included. So, 64 patients were enrolled and randomized into two equal groups (32 in each group).

#### 8. Statistical analysis

Statistical analysis was accomplished using the SPSS statistical software computer program version 22 (Statistical Package for Social Science version 22, IBM, and Armonk, New York). Data were expressed as mean (SD), median and range (minimum-maximum), numbers, and percentages. The normality of continuous data was checked by visual inspection of histograms and by the Shapiro - Wilk test. For parametric data, independent samples t-test was used to compare quantitative variables between the two groups. This data type was compared with the Student t-test (between two different means of the studied groups) and the Paired t-test (between two different means at different time points in the same group). For nonparametric data, the Mann-Whitney U test was used to compare quantitative variables between the two groups. The Mann-Whitney test is used between two different medians of the studied groups and Wilcoxon test between two different medians at different time points in the same group. Chi-square and Fisher Exact tests were used to analyze qualitative variables as

appropriate. The level of confidence was kept at 95%, and hence, A two-tailed P-value <0.05 was considered statistically significant.

## 9. Results

The two studied groups showed non-significant differences regarding age (years), body mass index (BMI), and ASA physical status. Also, both groups had nonsignificant differences regarding operative time and intra-operative fluid intake. On the other hand, the majority of both groups did not develop procedure-related complications, whereas 12 patients of ESPB group (40%) and nine patients of PECS-II group (30%) developed hypotension with no significant difference regarding intra-operative total ephedrine dose. Both groups had non-significant difference regarding post-operative adverse events such as nausea and vomiting (Table 1).

Total morphine consumption within 24 hours after surgery was significantly lower in group (E). Meanwhile, recovery time was significantly longer among group (E). At the same time, both groups had comparable time till the first analgesic request. It was also found that both groups had comparable levels of interleukin-6 pre operatively and 24 hours after the surgery (Table 2).

Both groups had non-significant differences regarding NRS at different times of assessment. In each group, NRS was significantly increased at the 2<sup>nd</sup> postoperative hour and thereafter compared to immediately after surgery (Figure 3).

Heart rate (HR) showed non-significant difference in the peri-operative period, with the exception group (E) had significantly higher HR at the 100<sup>th</sup> minute intraoperatively, at the end of the surgery, and 4 hrs, 8 hrs, 12 hrs, and 24 hrs post-operatively. In group E, HR showed significant changes at different assessment times intra-operatively and post-operatively compared to baseline except at the time of skin incision, 100<sup>th</sup> intra-operative minute, and immediately after surgery. However, group (P) showed significant changes at different times intra-operatively and post-operatively compared to baseline except at intubation, skin incision, and end of surgery.

Mean arterial blood pressure (MAP) had a nonsignificant difference at peri-operative times except in group (E), which had significantly lower MAP immediately after surgery and two hours after surgery (Figure 4). In each separate group, there was a significant reduction in MAP at different assessment times compared to baseline, except in group (E), there was a non-significant difference at baseline *vs.* end of surgery.

# 10. Discussion

This present study investigated the efficacy of combined pectoralis II block plus transversus thoracic plane

| Table 1. Demographic and baseline da    | ata, operative time, fluid intake, procedure- |
|---|---|
| related complications (hypotension), ep | hedrine dose, and post-operative complica-    |
| tions in the two studied groups.        |   |

|  | Group E            | Group P          | <b>.</b> . |
|--|--------------------|------------------|------------|
|  | ( <i>n</i> = 30)   | ( <i>n</i> = 30) | P value    |
| Age (years)                                    | 54.67 ± 7.24       | 51.44 ± 9.97     | 0.21       |
| Body mass index (kg/m <sup>2</sup> )           | $30.83 \pm 2.65$   | $31.43 \pm 2.82$ | 0.55       |
| ASA class                                      |                    |                  | 0.60       |
| Class-I  | 16 (53.3%)         | 15 (50%)         |            |
| Class-II                                       | 14 (46.7%)         | 15 (50%)         |            |
| Operative time (minute)                        | $121.60 \pm 13.45$ | 125.23 ± 12.98   | 0.50       |
| Fluid intake (l)                               | $1.68 \pm 0.25$    | $1.67 \pm 0.27$  | 0.80       |
| Procedural-related complications (hypotension) |                    |                  | 0.29       |
| No   | 18 (60%)           | 21 (70%)         |            |
| Yes  | 12 (40%)           | 9 (30%)          |            |
| Ephedrine dose (mg)                            | $3.80 \pm 0.97$    | 3 ± 1.61         | 0.40       |
| Postoperative complications                    |                    |                  |            |
| Nausea   | 4 (13.3%)          | 5 (16.7%)        | 0.67       |
| Vomiting                                       | 4 (13.3%)          | 2 (6.7%)         | 0.57       |

Data is expressed as mean  $\pm$  (SD), frequency (percentage), test used (Chi2test), and student t-test. P-value was significant if < 0.05.

Group E: Erector Spinae Block (ESPB); Group P: Modified pectoralis nerve block plus transversus thoracic plane block (PECS-II-TTP).

ASA: American Society of Anesthesiologists.

Table 2. Recovery time, morphine consumption, time to first analgesia, and IL6 levels among the studied groups.

| ( <i>n</i> = 30) | Group P<br>( <i>n</i> = 30)  | P value  |
|------------------|--|--|
| 11.17 ± 2.27     | 9.83 ± 1.82  | 0.01*  |
| $0.93 \pm 0.63$  | $2.13 \pm 0.42$  | 0.03*  |
| $6.13 \pm 3.43$  | 8.13 ± 1.53  | 0.23   |
|                  |  |  |
| $10.03 \pm 4.09$ | $10.73 \pm 3.54$   | 0.48   |
| 239.01 ± 122.11  | 278.08 ± 151.29  | 0.30   |
|                  | $11.17 \pm 2.27 \\ 0.93 \pm 0.63 \\ 6.13 \pm 3.43 \\ 10.03 \pm 4.09$ | $11.17 \pm 2.27$ $9.83 \pm 1.82$ $0.93 \pm 0.63$ $2.13 \pm 0.42$ $6.13 \pm 3.43$ $8.13 \pm 1.53$ $10.03 \pm 4.09$ $10.73 \pm 3.54$ |

Data is expressed as mean  $\pm$  (SD). The test used (student t-test).

*P* value was significant if < 0.05.

\*Significant difference.

Group E: Erector Spinae Block (ESPB); Group P: Modified pectoralis nerve block plus transversus thoracic plane block (PECS II-TTP).

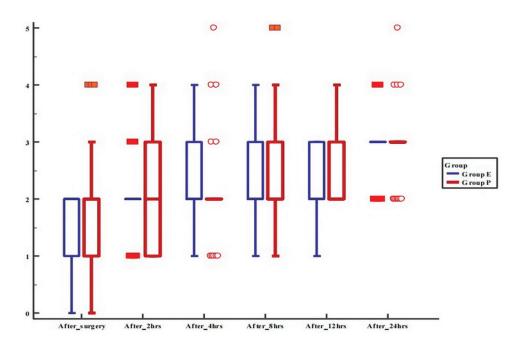
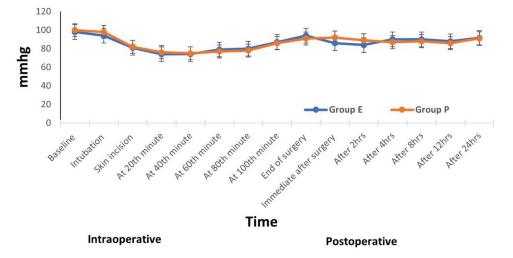


Figure 3. Numeric rating scale (NRS) in the two studied groups. Group E: Erector Spinae Block (ESPB); Group P: Modified pectoralis nerve block plus transversus thoracic plane block (PECS-II-TTP);.



Perioperative assessment of MAP among the studied groups

Figure 4. Perioperative assessment of Mean arterial blood pressure (MAP) changes in the two studied groups. Group E: Erector Spinae Block (ESPB); Group P: Modified pectoralis nerve block plus transversus thoracic plane block (PECS-II-TTP);.

block (PECS II- TTP) versus erector spinae plane block (ESPB) regarding their effect on post-operative morphine consumption and interleukin-6 (IL-6) levels 24 hours after surgery.

The present study showed that ESPB had lower morphine consumption than the combined Pecs II-TTP block. The network meta-analysis done by Hong et al. [11], stated that ESPB and PECS II are more effective than systemic analgesia alone. There was no significant difference between ESPB and PECS II regarding opioid consumption. On the contrary, Altiparmak et al. [12] showed higher opioid consumption in ESPB than PECS II group. However, it is essential to note that the volume of local anesthetics in the two trials was higher in PECS II group.

In our study, NRS and time till the first analgesic request showed non-significant difference between both groups at different times of assessment. However, NRS was significantly increased at the 2nd post-operative hour and thereafter in comparison to immediately after surgery. Mohsin et al. [13], compared PECS II versus ESPB versus control, showed higher opioid consumption in ESPB than PECS II group. All groups showed a similar rise in the visual analogue scale (VAS) after surgery. However, the PECS II group had the lowest VAS score and the longest time to first rescue analgesia. In another aspect, they documented that both blocks led to improvement in the quality of recovery measured by QOR40 [14] scores.

We found that both groups had comparable levels of interleukin-6 either at baseline or at 24 hours after surgery. Both groups showed increased levels of postoperative levels of IL6 compared with baseline levels. This was in line with a study done by Matsumoto et al. [15], upon patients undergoing radical mastectomy who received GA only or GA plus combined SAM block-PECS I had post-operative IL6 levels higher than baseline. Explanation could be that mastectomy raised IL6 in cancer-associated adipocytes [16]. Disagreeing with our findings, Zhao et al. [17], compared PECS II-TTP vs. TPVB, showed that the level of IL-6 was significantly decreased in PECS II group 12 hours postoperatively.

Our results proved that both blocks had a low incidence of hypotension, post-operative nausea, and vomiting, with no significant difference between the two groups. Mona Abo Elamaym et al. [18] showed that only 9 patients (20%) in each PECS II- TTP and control group complained of nausea or vomiting. Moreover, Hussain et al. [19], in their meta-analysis, found that ESPB markedly decreased PONV.

Three trials compared combined PECS II- TTP versus TPVB, control, or serratus anterior plane block. They agreed on the superiority of the combined PECS II- TTP block compared to the other groups [17,18,20]. However, Alasrag et al. [20] used larger volumes of local anesthetics in combined PECS II- TTP block. TTP blocks the anterior cutaneous branches of inter-costal nerves of the (T 2–6), which supply the para-sternal area, while PECS II blocks the lateral and medial pectoral nerves, nerve to serratus, nerve to latissimus dorsi, anterior divisions of the lateral cutaneous branches of the inter-costal nerves and inter-costo-brachial nerve [21].

ESPB is a fascial plane block that reduced opioid consumption, pain scores, intra-operative opioid use, nausea and vomiting, and rescue analgesia needed in the first 24 hours after surgery in comparison with the no-block group [9]. However, its mechanism of action still needs to be fully understood. Direct spread of LAs to the para-vertebral or epidural space, analgesia mediated by raised plasma levels of LAs due to systemic absorption and LAs action on neural targets [22]. On the contrary, Ivanusic et al. [23] stated that the dye only spread posterior to the costo-transverse foramen to stain the dorsal rami without any anterior spread to the para-vertebral space.

Both blocks are supposed to cover the surgical area of modified radical mastectomy. We have used similar volumes of LAs in both groups. The volume of LAs in ESPB might increase their spread laterally and cranio-caudally. Also, in combined PECS II- TTP, we injected 10 ml of LA between the pectoralis minor and serratus anterior muscles, which might be the cause of discrepancies in our results versus the other studies.

## 11. Limitations

The limitations of the current study may include that we did not assess NRS at movement, other stress markers were not measured, and the incidence of chronic pain following surgery was not included. In addition, further studies with larger sample sizes or higher volumes of local anesthetics are advised to reveal the best block for breast cancer surgery.

## 12. Conclusion

Based on the results of the current study, we could conclude that both ESPB and PECS II- TTP blocks were safe and easily administered without major complications for post-operative analgesia in patients undergoing MRM. However, ESPB was more successful than PECS II-TTP block regarding the reduction of morphine consumption.

#### **Disclosure statement**

The authors affirmed that they have no conflicts of interest.

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