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Analgesic efficacy of ultrasound-guided PECS II and transeversus thoracic plane blocks compared to serratus anterior plane block for modified radical mastectomy: A randomized prospective study

Alshaimaa Soliman Alasrag[1], Amira Mahfouz Elkeblawy[1,2], Mohammed Mohye Eldin Abo Elyazid[1,3] and Hoda Alsaid Ahmed Ezz[1,3]

[1]Demonstrator of Anesthesiology, Surgical ICU and Pain Medicine Department, Faculty of Medicine, Tanta University, Tanta, Egypt; [2]Lecturer of Anesthesiology, Surgical ICU and Pain Medicine Department, Faculty of Medicine, Tanta University, Tanta, Egypt; [3]Professor of Anesthesiology, Surgical ICU and Pain Medicine Department, Faculty of Medicine, Tanta University, Tanta, Egypt

ABSTRACT

Background: Chronic pain and discomfort after breast cancer surgery could be reduced by improving acute postoperative pain management.

Aim: The aim is to compare the analgesic effectiveness of ultrasonography (US) guided serratus anterior plane (SAP) block vs combined modified pectoral nerve (PECS II) and transeversus thoracic plane (TTP) blocks by for modified radical mastectomy patients. The study was registered on Clinicaltrials.gov with registration code: NCT04908878

Patients and methods: 70 patients were divided into two equal groups (35 each). After induction of general anesthesia, Group I got unilateral us-guided PECS II-TTP blocks on the procedure side. Group II: received unilateral us-guided SAP block on the operation side. The 24 hours' postoperative morphine consumption (mg) was the primary outcome. Secondary outcomes were VAS score, time to first need for rescue analgesia, patient satisfaction and complications.

Results: In combined PECS II-TTP blocks there was a significant decrease in the 24 hours' postoperative morphine consumption [median (IQR); 3 (3, 6) and 9 (9, 12) mg], VAS scores [median (IQR); 3 (2, 3), 3 (3, 4) at 4 hrs. and 3 (3, 3), 3 (3, 5) at 6 hrs. in group I and II respectively] and prolonged time for 1st rescue analgesia [median (IQR); 8 (6, 12) and 6 (4, 8) hrs in group I and II respectively]. While, there were no significant differences between the two groups in intra-operative fentanyl consumption, hemodynamics or complication.

Conclusion: The PECS II-TTP blocks provide effective and long-lasting postoperative analgesia than SAP block in modified radical mastectomy.

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Mastectomy; transeversus thoracic plane block; serratus anterior plane block; PECS II block

1. Introduction

Mastectomy is one of the most popularly performed surgical procedures, however 25% to 60% of people who had breast cancer operations experience prolonged discomfort following surgery. Regional anesthesia reduced chronic pain by improving the quality of acute pain management [1,2].

The lateral mammary area is anaesthetized via the pectoral nerve (PECS II) block. It inhibits the long thoracic and thoracodorsal nerves, the medial cutaneous nerve of the arm and forearm, as well as the lateral cutaneous and intercostobrachial branches of intercostal nerves (T2–6). However, PECS II block cannot block the internal mammary region, which is one of its main drawbacks [3]. The T2- to 6-intercostal nerves, which innervate the internal mammary region, may have several anterior branches that could be blocked by an ultrasound (US)-guided transeversus thoracic plane (TTP) block. Consequently, PECS II and TTP blocks combination could be efficient for post-operative pain control after surgery for breast cancer [4].

The serratus anterior plane (SAP) blocks the anterolateral chest wall's sensory pathways. By injecting local anaesthetics in a plane that is either deep beneath or superficial to the serratus anterior muscle between the fourth and fifth ribs at the mid-axillary line [5]. We postulated that combination of PECS II and TTP blocks would provide more potent analgesic effect than SAP block in female patients following modified radical mastectomy.

So, the aim of this study was to compare the analgesic efficacy of combined US-guided PECS II-TTP blocks to US-guided SAP block.

2. Patients and methods

This prospective, randomized, double-blind clinical trial was conducted at Tanta University Hospitals. The

CONTACT Hoda Alsaid Ahmed Ezz hodaezz714@yahoo.com Department of Anesthesia and Surgical Intensive Care faculty of Medicine, Tanta University, El Geish Street , El Gharbia Governorate, Tanta, Egypt

practical part of the study started in June 2021 to June 2022 after approval of the institutional ethical committee of the Faculty of Medicine, Tanta University with approval code: 33972/7/20 and registered on Clinicaltrials.gov with registration code: NCT04908878 and a written informed consent was obtained from each patient, who had a private file and secret code. An explanation of the purpose and the protocol of the study were given to all patients and they were taught how to use the VAS score during the pre-operative visit.

Female patients between the ages of 21 and 60 years who were scheduled for unilateral modified radical mastectomy and had an ASA physical status II participated in this study. Patients who refused to participate, had hypersensitivity to local anesthetics, coagulation disorder, infection at the injection site, with BMI>35 kg/m^2, ASA > II, uncooperative or psychiatric were excluded.

70 patients were randomly allocated into two equal groups (35 patients each) using computer-generated random numbers put into opaque sealed envelopes which were pulled by a nurse blind to group allocation. Also, the patients, the anesthetist collecting the intraoperative and postoperative data and the person who analyzed the data were blind to the study group assignment.

After induction of general anesthesia, group I (PECS II-TTP group) got a unilateral, US-guided PECS II and TTP blocks on the side of the procedure. While, group II (the SAP group) got US-guided SAP block on the side of the operation.

On arrival at the preoperative area, a peripheral intravenous (IV) line was inserted, and all patients received midazolam (0.03 mg/kg) IV. On entering operating room (OR), the routine monitoring was applied including noninvasive blood pressure (NIBP), pulse oximetry, ECG, while, temperature probe and end tidal capnography were applied after endotracheal intubation. Intravenous induction of anesthesia was achieved with propofol 2 mg/kg , fentanyl 1 µg/kg, atracuruim 0.5 mg/kg and then endotracheal tube was inserted. Isoflurane 1.5% in 50% oxygen and air was used to maintain anesthesia and atracurium 0.1 mg/kg was administered as a bolus dose when needed. After endotracheal intubation the regional technique was performed according to group allocation by the same anesthesiologist who played no further role in the study. Fentanyl 0.5 µg/kg as a IV bolus was given If there was an increase in heart rate (HR) and/or mean arterial blood pressure (MAP) of more than 20% above baseline, and the number of patients who needed intraoperative fentanyl was recorded. At the end of surgery, isoflurane was turned off and muscle relaxant was reversed with neostigmine 0.05 mg/kg IV and atropine 0.01 mg/kg IV. Paracetamol (15 mg/kg IV infusion) was administered after extubation and then every 6 hours.

On admission to the post-anesthesia care unit (PACU), 30 minutes later and then at 1, 2, 4, 6, 12, 18 and 24 hours after the procedure, postoperative pain was evaluated using the VAS (0–10 scale, where 0 indicates no pain and 10 represents the worst pain). If the VAS score was ≥4, rescue analgesia in the form of morphine (3 mg IV) was administered with 5-minute lockout interval, guided by the occurrence of complications, until the VAS score was reduced to < four. The total dose of morphine (mg) used during the first 24 postoperative hours was reported which was the primary outcome. While, the secondary outcomes were; the demographic data [age (in years), BMI (Kg/m^2)] and, duration of surgery (in minutes), number of patients who needed intraoperative fentanyl (µg), the time to the first need for rescue analgesia (hours). Patient satisfaction was assessed 24 hrs. postoperatively using a 3- point scale (1= unsatisfied, 2= fair, 3= satisfied). Moreover, any unfavorable side effects were recorded.

2.1. Ultrasound-guided PECS II block technique [3]

The block was performed under aseptic technique. Patients were positioned supine with abducted arms on the operating table. A high-frequency linear US probe was placed just below lateral third of the clavicle. After confirming the location of the axillary vein and artery, the US probe was positioned infero-laterally until the pectoralis major, minor and serratus anterior muscles could be seen through one plane at the level of the 3rd and 4th ribs. 100 mm, 22-gauge needle was advanced in plain view until it reaches the inter-fascial line between the pectoralis minor and major muscles. Then 10 ml of 0.25% bupivacaine was injected after confirmation of the needle tip position. The needle was then advanced till its tip reaches the interfascial plane between the serratus anterior and pectoralis minor muscles (above the serratus anterior muscle), and the patient received another 20 cc of 0.25% bupivacaine fig1 (1).

2.2. Ultrasound-guided transversus thoracic block technique [6]

Patients were positioned supine. To identify the anterior T4-T5 interspace, a high-frequency linear US probe was positioned, at the midclavicular line lateral to the sternal border in the longitudinal plane till the TTM between the fourth and fifth ribs and the internal intercostal muscle were seen in a parasternal sagittal view above the pleura which was seen as a hypoechoic band. The tip of a 100 mm 22-gauge needle was

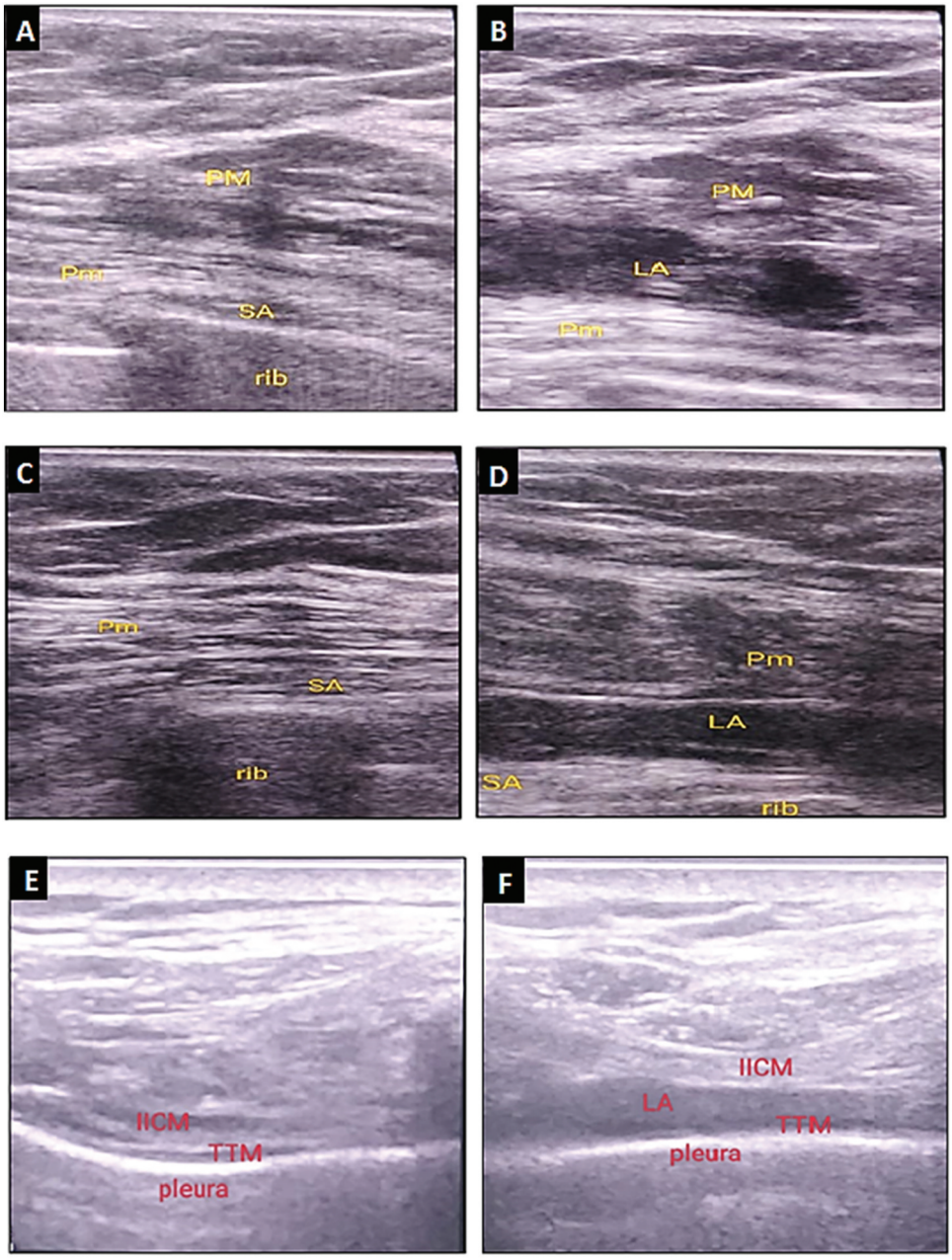

Figure 1. PECS II block -TTP block. A) anatomy of First injection. B) local anesthetic injection between PM and Pm. C) Anatomy of second injection D) Local anesthetic injection between Pm and SA E) TTP anatomy. F) local anesthetic injection between TTM and internal intercostal muscles, SA (serratus anterior muscle), PM (pectoralis major muscle), Pm (pectoralis minor muscle), TTM (transeversus thoracic muscle), LA **(local anesthetic).**

advanced in caudal to cranial direction in plane with the transducer till it reaches into the TTP, between the TTM and the internal intercostal muscle. After negative aspiration and hydro-dissection with 1–3 mL normal saline to exclude intravascular and intrapleural insertion, 10 ml of 0.25% bupivacaine was injected, Fig1 (1).

2.3. Ultrasound-guided serratus anterior plane block technique [5]

While the patient was positioned supine with abducted arm, the high-frequency US probe was placed over the mid-clavicular area at the sagittal plane. The ribs were counted Up to the 5th rib. The probe was moved infero-posteriorly with coronal orientation to the mid axillary line. Overlying the 5th rib; the serratus (deep and inferior), latissimus dorsi (superficial and posterior), and teres major (superior) muscles could be identified. Color Doppler was used to identify the thoracodorsal artery in the plane between the serratus anterior and latissimus muscles to ensure correct needle (a 100 mm 22-gauge) position and avoid intra-arterial injection, then 30 ml of 0.25% bupivacaine was injected in this plane, Fig2 (2).

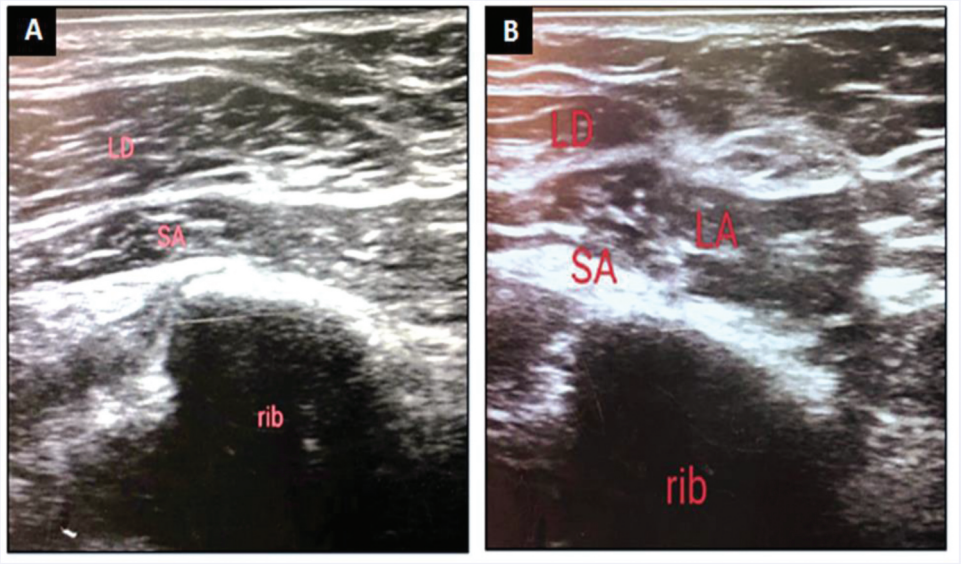

Figure 2. SAP block. A) Anatomy of SAP; LD, SAM. B) Local anesthetic between latissimus dorsi and serratus anterior muscles, LD (latissimus dorsi muscle), SAM (serratus anterior muscle), LA (local anesthetic).

3. Sample size calculation

The sample size was determined with the help of the Epi-Info, version 2002. The dose of the first 24 hours' postoperative morphine consumption (mg) was the primary outcome. Based on a data from a pilot study in our institute, the following criteria were used to determine the sample size: a mean ± SD of 9.2 ± 4.28 in SAP block group and 6.44 in PECS-TTP group with an alpha error of 0.05, 80% study power, group: group ratio of 1:1 and detection of≥30% difference between the two groups in the first 24 hours postoperative morphine consumption. $N > 29$ patients were required for each group to detect a significant difference between the two groups. The sample size was expanded to 35 patients in each group to compensate for the non-parametric nature of data (15%) and the potential dropouts (5%).

4. Statistical analysis

SPSS statistics for Windows, version 26 was used for statistical analysis on the data. Shapiro-Wilk test was carried out to determine if the data followed the normal distribution or not. Data which followed the normal distribution are presented with mean ± standard deviation, whereas median and interquartile range (IQR) were used for presentation of variables which did not normal distribution. Frequency and number % were used to denote categorical variables. For comparing continuous parametric and non-parametric data within groups (between participants), independent sample T and Mann Whitney tests respectively were used. The follow-up findings were compared to their baseline values using repeated measured ANOVA, with Bonferroni adjustment of the p value for multiple comparisons, for pair-wise data comparison (within subjects). Every test was run with a 95% confidence level. P value≤0.05 were regarded as statistically significant.

5. Results

80 female patients were assessed for eligibility, with seven patients didn't fulfil the inclusion criteria (2 uncontrolled diabetes mellitus, 1 patient with history of recent myocardial infarction, 3 patients: BMI>35, 1 patient had coagulation disorder) and 3 patients refused to participate in the study. The remaining 70 patients were randomly assigned into two groups (35 patients in each group). All of them were followed up and their data were statistically analyzed, Fig3.

Regarding patient's characteristics (age, BMI and duration of surgery), there was no significant difference between the two groups, p values>0.05, Table (1).

The median dose (IQR) of post-operative morphine consumption in the first 24 hrs was significantly increased in group II {9 (9,12) mg} compared to group I {3 (3,6) mg} (P < 0.001), Table (2). Postoperative VAS scores were significantly decreased in group I compared to group II with median (IQR) values of 3 (2, 3), 3 (3, 4), and 3 (3, 3),3 (3, 5) with p values of 0.011, 0.046 at 4 and 6 hrs in group I and group II respectively, while, there were no significant differences between the two groups at PACU, 30 min, 1,2,12,18 and 24 hrs postoperative, with p values>0.05 Fig4 (4).

Median (IQR) time of first postoperative rescue analgesia was prolonged in group I {8 (6,12) hrs.} than in group II {6 (4,8) hrs.}, but there were no significant differences between the two group as regard number of patients who needed intraoperative fentanyl, patients' satisfaction, nausea and vomiting $p > 0.05$, Table (2). While, block related complications as pneumothorax,

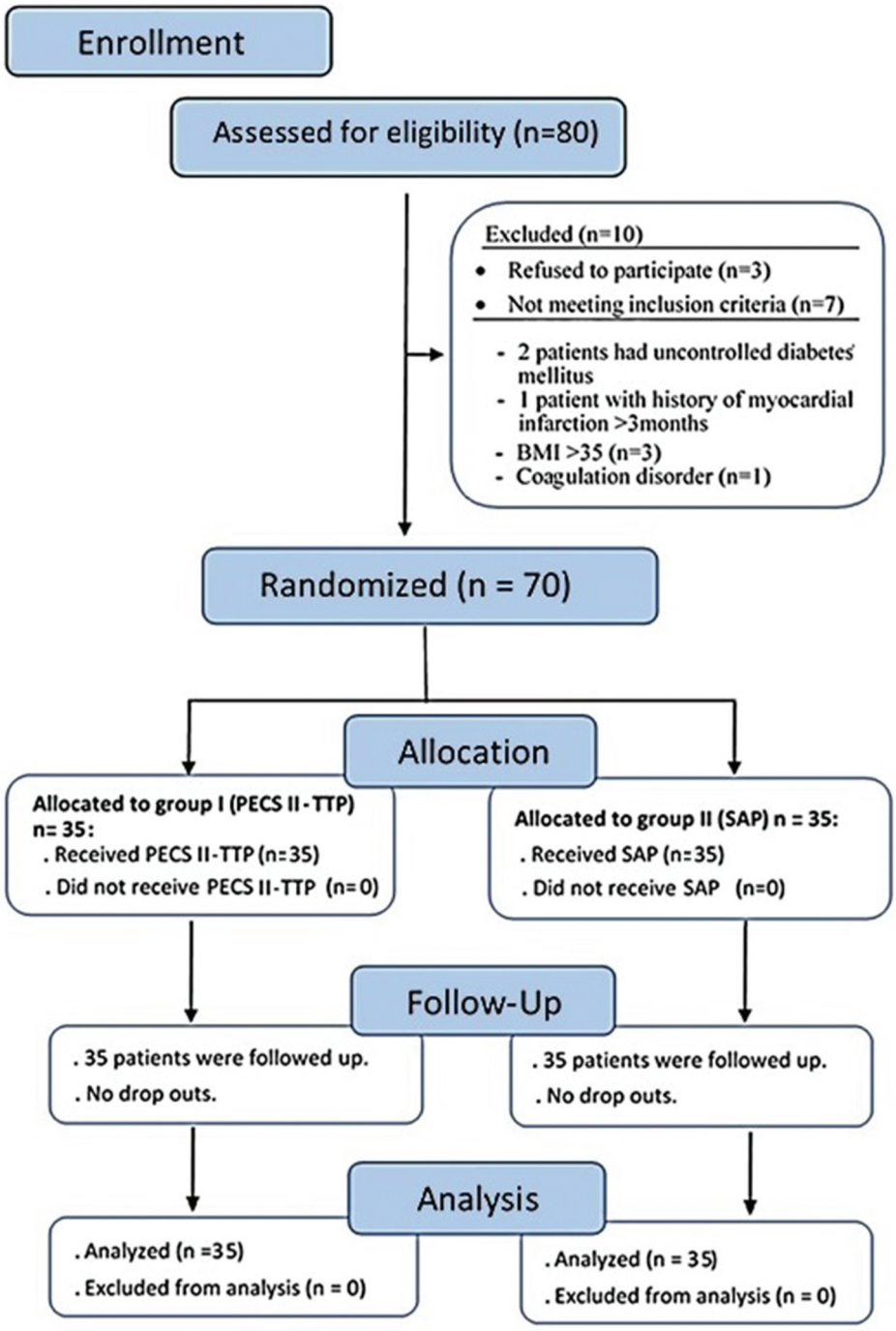

Figure 3. Participant flow diagram.

Table 1. Patient's characteristic in the two groups.

	Group I ($n = 35$)	Group II ($n = 35$)	95% CI	P
Age (years)	48 ± 6	50 ± 6.2	−4.84, 0.78	0.154
BMI (kg/m^2)	27.80 ± 2.80	29.05 ± 3.59	−2.79, 0.28	0.109
Duration of surgery (minutes)	111 ± 16.14	105 ± 15	−1.41, 13.41	0.111

Abbreviations: ASA American Society of Anesthesiologists, BNI: body mass index Data presented as mean ± SD or number (n)%. Significant at $p < 0.05$

Table 2. Dose of postoperative morphine (mg), intraoperative fentanyl (μg), patient satisfaction and complications in the two groups.

		Group I ($n = 35$)	Group II ($n = 35$)	95% CI	P
Total dose of morphine in the first 24 hours (mg)		3 (3, 6) *	9 (9, 12)	−6.0, − 3.4	**<0.001***
Time of first request of analgesia (hours)		8 (6, 12) *	6 (4, 8)	0.27, 3.96	**0.026***
Patients needed intraoperative fentanyl (n)%		3 (8.6%)	5 (14.3%)		0.452
Patient satisfaction	• Satisfied (n)%	33 (94.3%)	31 (88.6%)		0.673
	• Fair (n)%	2 (5.7%)	4 (11.4%)		
	• Unsatisfied (n)%	0	0		
Nausea and vomiting (n)%		9 (25.7%)	5 (14.3%)		0.232

- Data presented as median (IQR) or number (%).
*Significant at $p < 0.05$.

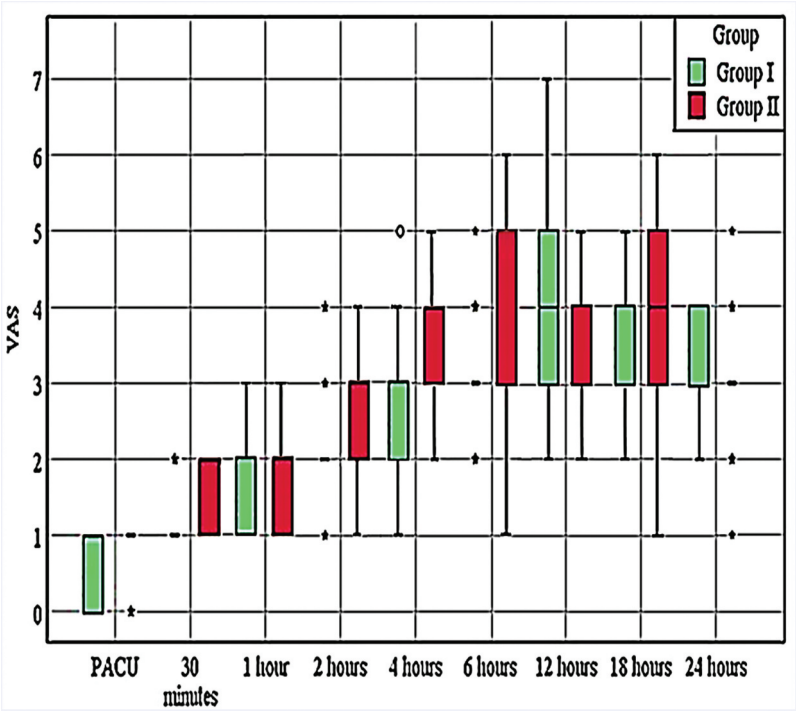

Figure 4. VAS score changes in the two groups.

hematoma, or local anesthetic toxicity were not reported in the two groups

6. Discussion

Our results revealed that the combined PECS II-TTP blocks provided effective and long-lasting postoperative analgesia than SAP block. Also, they provided lesser morphine consumption postoperatively and prolonged time to the first postoperative analgesic administration (median 8 hours) than SAP block (median 6 hours), but no significant differences between groups regarding the intraoperative fentanyl consumption, patient satisfaction, and complication were noted.

These findings could be explained with the ability of TTP block to block various intercostal nerves, mostly anterior branches of the (Th2–6), which supply the internal mammary region [4], and PECS II block ability to block the lateral cutaneous and intercosto-brachial branches of the (Th2–6) intercostal nerves, long thoracic and thoraco-dorsal nerves as well as, the medial cutaneous nerve of the arm and forearm [6,7]. SAP block targets the lateral cutaneous branches of the T2–T9 intercostal nerves while, anterior branches of intercostal nerves are not blocked with preserved sensation over the parasternal part of the thorax [8].

To the best of our knowledge, there is no available randomized trial comparing the analgesic efficacy of combined PECS II-TTP blocks versus SAP block in patients undergoing modified radical mastectomy. However, the analgesic efficacy of combination of PECS II-TTP blocks was supported in many studies; Zhao, et al. [9], retrospectively compared the postoperative analgesic effects of US-guided PECSII-TTP blocks with thoracic paravertebral block (TPVB) after modified radical mastectomy. They found that the TTP-PECS group consumed less fentanyl and flurbiprofen axetil postoperatively in the first 24 hours than the TPVB group, with longer duration of analgesia. However, the duration of analgesia in their study was longer (12.5 hours) than that in the present study (8 hours) and this may be related to the different

analgesic regimen and the concentration of local anesthetic drug injected (30 ml 0.5% ropivacaine) compared to that of the present study (30 ml for PECS II and 10 ml 0.25% bupivacaine for TTM blocks).

Additionally, Nakanishi et al. [10] described TTP, Pecs II blocks, and dexmedetomidine as sedation in a case of achondroplasia who had undergone a partial mastectomy in the upper part of the right breast and a biopsy from sentinel lymph node and without general anesthesia. No severe pain or need for additional analgesic was reported during the first 24 hours postoperative. Moreover, Ueshima and Kitamura [4], reported TTP with PECS II blocks in 86-year-old woman who had significant cardiac dysfunction scheduled for segmental excision in the upper outer part of the left breast without general anesthesia. The two blocks enabled successful breast resection with uneventful postoperative course.

Also Aydin et al [11] and Hamed, et al [12] supported the analgesic efficacy of TTP after cardiac surgery.

On the contrary, Abo Elamaym, et al [13], studied the analgesic efficacy of PECS II and TTP blocks in comparison with general anesthesia alone in 90 patients undergoing modified radical mastectomy. They observed that PECS II – TTP blocks had considerably reduced intraoperative fentanyl doses. While, there was no significant difference between the two groups in terms of the severity of postoperative pain, the time to request rescue analgesia, or the frequency of rescue analgesia in the first 12 postoperative hours. Their findings did not agree with our findings, most likely because their research was retrospective and although pain ratings were frequently recorded three to four times per day, those periods may not have coincided with the block's claimed 8-hour duration.

The analgesic efficacy of SAP block was confirmed by Arora, et al (14), who compared the efficacy of US-guided SAP block with thoracic paravertebral block for postoperative analgesia thoracic paravertebral block. They reported that the time to first rescue analgesia was significantly longer in the SAP group, less total postoperative analgesic consumption in the first 24 hours, and lower postoperative pain scores. However, the duration of analgesia with SAP in the present study (6 hours) was longer than that found in the study of Arora, et al (4 hours), this may be attributed to the lower volume of local anesthetic used in their study (they used about 23 mL local anesthetic while up to 30 mL of local anesthetic has been used in the present study, also they injected the local anesthetic deep to the serratus anterior muscle while, in the present study the local anesthetic was injected between the serratus anterior and the latissimus dorsi muscles).

While, Jain et al [8] found that SAP block result in a greater spread of the local anesthetic and provide equivalent analgesia to TPVB for breast surgeries and was superior to the PECS II block. Moreover, Yao et al [14] observed that pre-operative SAP, reduced postoperative pain scores at rest and 24 hours' postoperative cumulative opioid consumption compared with the control group.

And, Bakeer, et al [15], concluded that both SAP and PECSII and blocks provide adequate analgesia after modified radical mastectomy. Both blocks were associated with prolonged time to first rescue analgesia, reduced postoperative morphine consumption, intraoperative fentanyl requirements and VAS scores compared to the control group. These findings could be explained on the basis that all their patients received adaquate basal intraoperative analgesia in the form of fentanyl (1 µg/kg) IV with induction of anesthesia and, paracetamol 1 gm/100 mL IV infusion and ketorolac 30 mg IV slowly before surgical incision. Also, they received basal analgesia in the form of paracetamol 1 gm/100 mL IV infusion every 8 hours and ketorolac 30 mg every 12 hours postoperatively which may mask the difference between the two groups. Moreover, they didn't identify the site of the of the mass resected in their patients and didn't clarify the dermatomes blocked by each block.

With respect to the incidence of complications in our study, there were no significant differences between the two groups as regards pneumothorax, hematoma, nausea and vomiting, local anesthetic toxicity. The safety of PECS II-TTP blocks in modified radical mastectomy was demonstrated by Abo Elamaym, et al [13] who reported no block related complications, such as bleeding, pneumothorax or local anesthetic toxicity. Also, the safety of SAP block was supported by the study of Arora et al [16] and Chong et al [17] who reported no block related complications and reduced incidence of PONV and pruritus as compared with non-block care.

However, the current study has several limitations, including a limited sample size. Also, the dermatomal level blocked was not assessed in the studied groups. In addition, further studies are needed to investigate the role of the two blocks in preventing chronic pain and modifying immune response in patients with modified radical mastectomy.

7. Conclusion

The PECS II-TTP blocks provide effective and long-lasting postoperative analgesia than SAP block in modified radical mastectomy.

Disclosure statement

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self funded

ORCID

Hoda Alsaid Ahmed Ezz http://orcid.org/0000-0002-9493-3797

Author contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Alshaimaa Soliman Alasrag and Amira Mahfouz Elkeblawy. The first draft of the manuscript was written by Hoda Alsaid Ahmed Ezz and Mohammed Mohye Eldin Abo Elyazid, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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