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Effect of Ultrasound Guided Thoracic Erector Spinae Plane Block or Modified Pectoral Fascial Plane Block on the Postoperative Analgesia after Modified Radical Mastectomy: A Randomized Controlled Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: The most common cancer in women worldwide is the breast cancer which needs surgical intervention in large number of cases. The current randomized controlled study aimed to evaluate the postoperative analgesic effect of ultrasound-guided Erector Spinae plane block and ultrasound-guided modified PECs block for female patients subjected to modified radical mastectomy surgeries (MRM).

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Methods: This prospective randomized controlled study was carried out in the Anasthesia Department at the Faculty of Medicine Tanta University Female patients aged between 21 and 64 years with American Society of Anesthesiology (ASA) physical status II-III who were scheduled for unilateral Modified radical mastectomy were included. Patients had randomly classified us into three equal groups: 20 patients in each group. **Group I: Control group (n=20) :**Patients of this group did not receive any nerve block, **Group II: Erector Spinae plane Block (ESB) (n=20) :** Patients of this group received ultrasound guided erector spinae plane block with injection of (20 ml) of plain bupivacaine 0.25% injected beneath the erector spinae muscle sheath at the level of the fourth thoracic segment (T4) after induction of general anathesia, **Group III: US-modified PEC block (n=20) :**Patients of this group received ultrasound guided modified PEC block with injection of (10 ml) of plain bupivacaine 0.25% injected between the serratus anterior and pectoralis minor muscle (PECs2)and (20ml)of the same solution between pectoralis major muscle and pectoralis minor muscle after induction of general anathesia.
Results: NRS showed a statistically significant decrease at T2 in group III compared to group II. (P value < 0.05). Comparison between the three groups in intra-operative and post-operative MAP showed statistically significant difference between groups throughout intraoperative and postoperative durations. MAP showed statistically significant decrease in groups II and III compared to group I (P value = 0.001). there was also a statistically significant difference between group II and group III in T0, T15, T45, T60, T00, T2 and T12 in favor of group III. Comparison between the three groups in intra-operative and post-operative HR showed statistically significant difference between groups throughout intraoperative and postoperative duration. HR showed statistically significant decrease in groups II and III compared to group I (P value = 0.001). There was also a statistically different decrease in HR between group II and group III in favor of group III (modified PECS group).
Conclusions: Both ESB and PECSII blocks provided adequate analgesia as indicated by lowering doses of intraoperative fentanyl consumption, longer duration of postoperative analgesia, lower doses of post-operative morphine consumption compared to general anesthesia alone.

Keywords: Ultrasound Guided thoracic erector spinae plane block; modified pectoral fascial plane block, analgesia; modified radical mastectomy.

1. INTRODUCTION

"The most common cancer in women worldwide is the breast cancer which needs surgical intervention in large number of cases" [1]. "31% of the breast surgeries performed is Modified Radical Mastectomy (MRM)" [2].

"Modified radical mastectomy is commonly performed under general anesthesia, and is very often associated with postoperative pain, nausea and vomiting, causing increased patient suffering" [3].

"The incidence of moderate to severe postoperative pain after mastectomy under general anesthesia was seen to be 70-80.9% on first postoperative day, and 53%, 33% on the second and third postoperative day respectively" [4].

"The presence of acute postoperative pain not only leads to immediate post-operative complication but it may cause in almost 50% of the patients who have severe acute postoperative pain, eventually develop chronic pain syndrome with impaired quality of life" [5].

"Finding the best analgesic technique for breast surgeries has always been a matter of great concern. The beneficial analgesic effect of regional blocks is well known, including decreased need for opioids for analgesia and to decrease the surgical stress response intraoperative, decreased need for postoperative narcotics for pain control, decreased postoperative nausea vomiting, fewer pulmonary complications, and decreased duration of post anesthesia care unit stay (PACU) and early recovery" [6, 7].

"The recently introduced pectoral (PEC) block and modified PEC block, have showed promising results with excellent intraoperative analgesia and comfortable postoperative patients" [8].

"Newest to the list is the Erector Spinae Plane block (ESP block) with numerous case reports showing outstanding results and easier ultrasonographic landmarks and approach" [9].

This clinical randomized controlled study suggested that the use of ESP block or modified PECs block in patients undergoing MRM may decrease the postoperative opoid consumption, decrease intraoperative fentanyl consumption and impove postoperative pain scale.

The current randomized controlled study aimed to evaluate the postoperative analgesic effect of ultrasound-guided Erector Spinae plane block and ultrasound-guided modified PECs block for female patients subjected to modified radical mastectomy surgeries (MRM).

2. PATIENTS AND METHODS

This prospective randomized controlled study was carried out in the Anasthesia Department at the Faculty of Medicine Tanta University over the period from July 2021 to January 2023 after obtaining the Ethical Committe approval (34679/5/21). An informed written consent was obtained from the patients. Every patient received an explanation of the purpose of the study and had a secret code number.

Female patients aged between 21 and 64 years with American Society of Anesthesiology (ASA) physical status II-III who were scheduled for unilateral Modified radical mastectomy were included.

Exclusion Criteria were patient refusal, patient with neurological deficit, patient with bleeding disorders, Uncooperative patient, Infection at the block injection site, Patients with history of allergy to local anesthetics, Advanced hepatic or renal failure, chronic opioid consumption, Body mass index (BMI)≥35 kg m−2, Chronic use of gabapentin or pregabalin, bilateral procedure, and metastasis at site of injection.

Patients were randomly classified using computer generated software of randomization introduced into sealed envelope into three equal groups: 20 patients in each group.

Group I: Control group (n=20) : Patients of this group did not receive any nerve block.

Group II: Erector Spinae plane Block (ESB) (n=20) : Patients of this group received ultrasound guided erctor spinae plane block with injection of (20 ml) of plain bupivacaine 0.25% injected beneath the erector spinae muscle sheath at the level of the fourth thoracic segment (T4) after induction of general anathesia.

Group III: US-modified PEC block (n=20) : Patients of this group received ultrasound guided modified PEC block with injection of (10 ml) of plain bupivacaine 0.25% injected between the serratus anterior and pectoralis minor muscle (PECs2) and (20ml) of the same solution between pectoralis major muscle and pectoralis minor muscle after induction of general anathesia.

Anesthesia technique: All patients were subjected to adequate preoperative assessment: throughout history taking, general and local examination and requesting routine investigations including CBC, coagulation profile, renal funcions and liver functions. Once the patient was admitted to the operating room (OR), a standard monitoring consisting of 5 leads electrocardiography, non-invasive blood pressure, peripheral oxygen saturation was applied. After the placement of an 18-gauge intravenous peripheral line, a 700 mL lactated ringer solution infusion was started. Induction of anathesia was started after 3 minutes of pre-oxygenation using 80% oxygen by a well fitted mask with intravenous propofol 1 mg/kg, fentanyl 2 µg/kg and atracium 0.5 mg/kg, endotracheal intubation was performed by suitable size endotracheal tube, then patient was connected to a mechanical ventilator with its parameters adjusted to maintain end tidal co2 at 32-36 MmHg. The patient had received fentanyl 0.5 µg/kg IV when their heart rate or mean arterial blood pressure exceeded by more than 20% of the baseline values.

All patients received intravenous ondansetron 4 mg, dexamethasone 8 mg for postoperative nausea prophylaxis. Maintenance of anesthesia was provided with isoflurane 1-1.2 MAC introduced into oxygen air by a ratio of 1:1 and incremental doses of fentanyl and atracium as required.

Block interventions: Both ESB and modified PECs were performed after induction of general anathesia.

Technique of Erector spinae plane block: The block was performed under complete aseptic condition after induction of anasthesia and 15 minutes before skin incision, patients in this group were placed in the lateral decubitus position. The anesthesiologist placed the ultrasound probe (Fig. 1) in longitudinal orientation at the level of the T4 spinous process and then moved the probe 2-3 cm laterally from the midline. The ultrasound landmarks, which

includes the T4 transverse process and the overlying erector spinae muscle, were identified. The block needle was inserted in plane at an angle of 30–40° in cranial-to-caudal direction until the tip contacted the T4 transverse process. After hydro-dissection with 2–3 mL of isotonic saline solution confirmed the correct needle tip position. (20 ml) of plain bupivacaine 0.25% was injected deep to the erector spinae muscle.

Technique of pectoral fascial plane block: In the second group, US-guided PECSII block was done on the same side of surgery with the patient lying in the supine position with the ipsilateral arm abducted and externally rotated, and the elbow flexed 90°. The probe (Fig. 1) was put transversely in the ipsilateral clavi- pectoral triangle – between the clavicle medially and above and the shoulder joint laterally. After identification of the PMm, Pmm, and the plane in between, the probe was tilted caudally to identify the pulsating pectoral branch of the thoracoacromial artery, if not identified, the probe was moved 1–2 cm caudally and medially. In a caudal tilt, the artery was easily identified then, the needle was advanced in an in-plane technique targeting the space in which the artery is located. Two mL of normal saline was injected to confirm the location, produce hydro-dissection, and improve needle visualization. Afterward, 10 mL of the same study solution was injected. Then, the probe was moved laterally and caudally towards the anterior axil-lary fold, parallel to the delto-pectoral groove, until the serratus muscle appeared underneath the Pectoralis minor muscle attached to the underlying ribs. The 3rd and fourth ribs and the pleura were then identified. After infiltration of the skin with lidocaine 1%, the needle was advanced in-plane targeting the plane between the serratus and the third rib. Two mL of normal saline was injected; then, 20 mL of bupivacaine 0.25% was injected. The first group did not receive any injection.

Recovery and routine post-operative analgesia: At the end of the surgery, the inhalational anathesia was switched off with reversal of muscle relaxation by combination of neostigmine 0.05 ml/kg and atropine 0.01 ml/kg with fully awake extubation of the patient. The patient was then transported to PACU to complete his monitoring and was discharged from PACU when his modified Aldrete score reached 10 or more.

All patients had received routine post-operative analgesia in the form of paracetamol 1g IV every 6 hours and ketorolac 30mg IV every 12 hours. The Numerical rating scale was used for the assessment of postoperative pain in the three groups. The patients were trained to evaluate their pain intensity according to NRS. The NRS is a 10-point scale consisting of integers from 0 through 10; 0 means ‘no pain’ and 10 means ‘worst pain imaginable’. Patients selected a whole number to describe the intensity of their pain during rest and cough. The NRS scores were recorded at the postoperative immediately, 2hr, 4h, 8-hour, 12th hour and 24th hour by an anesthesiologist who was blinded to the group allocations. After assessment of pain scores, when NRS measured more than (3), patients were given 2 mg morphine, that can be repeated.

Measurements: All data were collected by anasthesiologist who was blinded about the study groups and not participating in the study. Demographic data as (age, gender, Weight, BMI, Duration of surgery), Total morphine consumption in the first 24 h after surgery. (Primary outcome).

Time to first rescue analgesic requirement which is (time from the end of surgery to the first administration of post-operative morphine). Numerical Rating Scale (NRS): at (T 0, 2, 4, 8, 12, 18,24 h) (T1, T2, T3, T4, T5, T6, T7 respectively) where T0= time after surgery before discharging from the post anesthesia care unit (PACU, Intraoperative fentanyl consumption, Hemodynamic Parameters: mean arterial blood pressure, heart rate (MAP & HR) were recorded before block performance at T0, intraoperatively every 15 min at (T 15,T 30,T 45,T 60) after surgery at T (00, 2, 4, 6, 12, 24 hour) where T00 = before discharge from PACU, Adverse events as Pneumothorax, local anesthetic systemic toxicity (LAST), Bradycardia and hypotension. Bradycardia (HR less than 50 b/ min) was treated by atropine intravenous injection (0.01 mg/kg) which may be repeated if needed. Hypotension (MAP decreased by ≥ 20 mmHg from the baseline reading or decrease ≤ 65 mmHg) received intravenous ringer lactate, and bolus of vasopressor (Ephedrine 10 mg), which may be repeated if no response. Pneumothorax treated by a chest tube. Degree of patient satisfaction was assessed on a 3-point scale. (1= unsatisfied 2= neither satisfied nor unsatisfied 3= satisfied).

Our primary outcome was the total morphine consumption in the first 24 hours of the post-

operative period between groups. The secondary outcomes were intraoperative fentanyl need, numerical rating scale scores at different time-points and the incidence of complications in the first 24 hours after surgery.

Statistical analysis: Statistical analysis was done by SPSS v25 (IBM Inc., ARMONK, NY, USA). Quantitative variables were presented as mean and standard deviation (SD) and were compared by paired Student's t- test for the same group. Qualitative variables were presented as frequency and percentage (%). Analyses were performed using SPSS version 21. Quantitative data were presented by Mean ± SD, median, range and interquartile range (IQR) and evaluated by Kruskal Wallis test. Categorical data were presented by number and percent and evaluated by chi square test. P value was considered significant at the level of ≤ 0.05 and highly significant at the level of < 0.01.

3. RESULTS

Seventy-three patients undergoing MRM were enrolled in this randomized controlled study, 13 of them were excluded (9 patients not meeting inclusion criteria and 4 patients refused to participate) the remaining 60 patients were randomly allocated into 3 equal groups with successful follow-up and collection of data from all scheduled patients (Fig. 1).

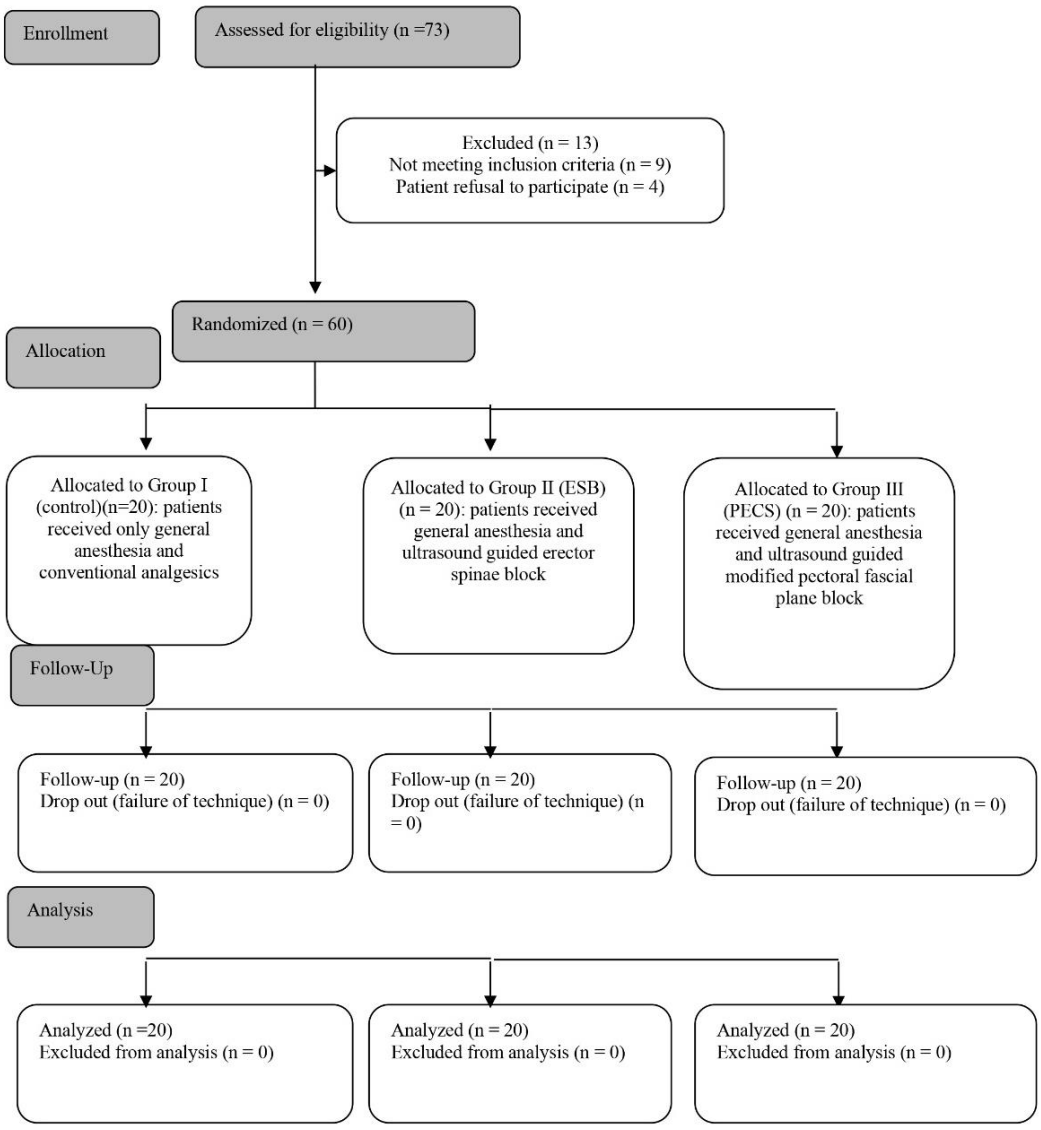

Fig. 1. Consort flow data of the study

Age showed no significant difference (p value=0.366). BMI showed no significant difference (p value=0.752). Duration of surgery showed no significant difference (p value=0.839) between the three groups Table (1).

Total postoperative morphine consumption showed statistically significant decrease in group II and III compared to group I (P1 = <0.001* p2 = <0.001*) with group III showing statistically insignificant decrease compared to group II (p3 = 0.141) Time to first analgesic requirement showed statistically significant increase in group I compared to groups II and III (P1 = <0.001* p2 = <0.001*). There no statistically significant difference in time to first analgesic requirement in group II compared to group III (P value <0.001) (Table 2).

Comparison between the three groups showed statistically significant decrease in NRS at T1 and T2 postoperative periods in groups II and III compared to group I (P value < 0.05). Also, NRS showed a statistically significant decrease at T2 in group III compared to group II. (P value < 0.05) Table 3.

Total intra-operative fentanyl consumption in group I ranged from 150.0 – 250.0 µg with a mean value 172.5 ± 34.32 µg and in groups II and III ranged from 100.0 – 150.0 µg with a mean value 107.5 ± 16.42 µg. Total intra-operative fentanyl consumption showed statistically significant decrease in groups II and III compared to group I (P value <0.001). with no significant difference between groups II and III. (P value > 0.05) Table 4.

Comparison between the three groups in intra-operative and post-operative MAP showed statistically significant difference between groups throughout intraoperative and postoperative durations. MAP showed statistically significant decrease in groups II and III compared to group I (P value = 0.001). there was also a statistically significant difference between group II and group III in T0, T15, T45, T60, T00, T2 and T12 in favor of group III. Comparison between the three groups in intra-operative and post-operative HR showed statistically significant difference between groups throughout intraoperative and postoperative duration. HR showed statistically significant decrease in groups II and III compared to group I (P value = 0.001).

There was also a statistically different decrease in HR between group II and group III in favor of group III (modified PECS group). (P value < 0.05) Table 5.

In group I, only 10% of patients were satisfied with their pain levels and 50% unsatisfied, while in group II and III, 85% of patients were satisfied with their pain levels. With obvious statistical significance. (P value < 0.05) Table 6.

No block complications occurred except in PECS group, hypotension occurred in some patients (Table 7).

4. DISCUSSION

"ESB is a novel ultrasound-guided technique recently described for the management of acute and chronic thoracic pain. ESP block is a regional anesthesia technique in which local anesthetic drug (LA) is injected under US guidance between the erector spinae muscle and transverse process, blocking the dorsal and ventral rami of the intercostal or abdominal nerves. For breast surgeries ESB is injected at the level of T4 transverse process" [10].

Our prospective randomized study aimed to compare the analgesic efficacy of US-guided modified PECS versus US-guided ESB block in patients undergoing modified radical mastectomy under general anesthesia. Sixty patients were included in this study and randomly allocated in three groups (20 patients in each group); PECS II block group and ESB block group, and a control group who didn't receive any block.

Table 1. Demographic data of the participants (n=60)

	Control group (n=20)	ESP group (n=20)	Modified PECS group (n=20)	P value
Age				
Mean ± SD	53.4 ± 4.97	55.5 ± 4.96	54.1 ± 4.75	0.366
Range	43.0 – 59.0	44.0 – 64.0	44.0 – 60.0	
BMI				
Mean ± SD	27.4 ± 3.68	28.4 ± 3.78	27.6 ± 3.90	0.752
Range	22.0 – 35.0	23.0 – 38.0	21.0 – 35.0	
Duration of surgery				0.839
Mean ± SD	108.6 ± 12.70	110.0 ± 11.75	107.8 ± 11.57	
Range	90.0 – 130.0	90.0 – 126.0	90.0 – 125.0	

Group I: control group, group II: ESB group, group III: PECS group

Table 2. Comparison between total postoperative morphine consumption (mg) and Time to first rescue analgesic requirement (hours) in the three groups

	Control group (n=20)	ESP group (n=20)	Modified PECS group (n=20)	P value
Total analgesic consumption (morphine) at the first 24 h after surgery				<0.001*
Mean ± SD	20.4 ± 3.87	13.3 ± 3.74	10.0 ± 3.31	
Range	12.0 – 24.0	8.0 – 18.0	4.0 – 16.0	
	Control group (n=20)	**ESP group (n=20)**	**Modified PECS group (n=20)**	**P value**
Time to first rescue analgesic requirement after surgery				<0.001*
Mean ± SD	0.8 ± 0.26	4.3 ± 1.75	6.2 ± 1.44	
Range	0.5 – 1.0	2.0 – 8.0	4.0 – 8.0	

Group I: control group, group II: ESB group, group III: PECS group
P1 = <0.001* p2 = <0.001* p3 = 0.141 p ≤ 0.05 (Statistically significant)
P1 (Control & ESP) P2 (Control & PECS) P3 (ESP & PECS)

Table 3. NRS of the participants (n=60)

	Control group (n=20)	ESP group (n=20)	PECS group (n=20)	P value
NRS T0				0.002*
Range	0.0 – 2.0	0.0 – 2.0	0.0 – 1.0	
Median (IQR)	1.0 (1.0 – 2.0)	1.0 (0.25 – 1.0)	0.0 (0.0 – 1.0)	
P1 = 0.552 p2 = 0.001* p3 = 0.076				
NRS T2				0.032*
Range	1.0 – 5.0	2.0 – 5.0	2.0 – 3.0	
Median (IQR)	3.5 (1.25 – 5.0)	3.0 (2.25 – 3.75)	2.0 (2.0 – 3.0)	
P1 = 1.000 p2 = 0.090 p3 = 0.050*				
NRS T4				0.042*
Range	1.0 – 6.0	1.0 – 4.0	1.0 – 4.0	
Median (IQR)	2.5 (2.0 – 4.0)	2.0 (1.0 – 3.5)	2.0 (1.0 – 2.0)	
P1 = 0.468 p2 = 0.036* p3 = 0.828				
NRS T8				0.022*
Range	1.0 – 5.0	1.0 – 6.0	1.0 – 6.0	
Median (IQR)	3.0 (2.0 – 5.0)	2.5 (2.0 – 4.0)	1.5 (1.0 – 2.0)	
P1 = 1.000 p2 = 0.022* p3 = 0.169				
NRS T12				0.062
Range	0.0 – 5.0	0.0 – 6.0	0.0 – 6.0	
Median (IQR)	2.5 (1.0 – 4.0)	4.0 (3.0 – 5.0)	2.0 (1.0 – 5.0)	
NRS T18				
Range	1.0 – 6.0	0.0 – 6.0	0.0 – 6.0	0.282
Median (IQR)	2.0 (1.0 – 4.0)	4.0 (1.25 – 6.0)	1.0 (1.0 – 6.0)	

	Control group (n=20)	ESP group (n=20)	PECS group (n=20)	P value
NRS T24				
Range	1.0 – 6.0	1.0 – 6.0	1.0 – 5.0	0.059
Median (IQR)	4.5 (2.0 – 5.0)	3.0 (2.0 – 3.75)	2.0 (1.0 – 3.0)	

Group I: control group, group II: ESB group, group III: PECS group
IQR: Interquartile range p ≤ 0.05 (Statistically significant)
P1 (Control & ESP) P2 (Control & PECS) P3 (ESP & PECS)
T0: immediately post operatively, T2: after 2hr, T4: after 4h, T8: after 8 hour, T12: after 12 hours and T24: after 24 hours.

Table 4. Intraoperative fentanyl consumption of the participants (n=60)

	Control group (n=20)	ESP group (n=20)	Modified PECS group (n=20)	P value
Intraoperative fentanyl				
Mean ± SD	172.5 ± 34.32	120 ± 20.5	107.5 ± 16.42	<0.001*
Range	150.0 – 250.0	100.0 – 150.0	100.0 – 150.0	

Group I: control group, group II: ESB group, group III: PECS group
P1 = <0.001* p2 = <0.001* p3 = 1.000 p ≤ 0.05 (Statistically significant)
P1 (Control & ESP) P2 (Control & PECS) P3 (ESP & PECS)

Table 5. Intra and post-operative MAP and HR of the participants of the participants (n=60)

	Control group (n=20)	ESP group (n=20)	PECS group (n=20)	P value
MAP T0				<0.001*
Mean ± SD	86.3 ± 3.73	78.1 ± 11.10	68.6 ± 6.62	
Range	80.0 – 90.0	60.0 – 91.0	60.0 – 85.0	
P1 = 0.039* p2 = <0.001* p3 = 0.014*				
MAP T15				<0.001*
Mean ± SD	84.3 ± 2.36	81.5 ± 3.32	68.8 ± 7.59	
Range	80.0 – 88.0	77.0 – 87.0	59.0 – 87.0	
P1 = 0.105 p2 = <0.001* p3 = 0.001*				
MAP T30				<0.001*
Mean ± SD	85.5 ± 3.30	76.1 ± 2.61	69.2 ± 6.73	
Range	79.0 – 90.0	73.0 – 79.0	61.0 – 79.0	
P1 = <0.001* p2 = <0.001* p3 = 0.074				
MAP T45				
Mean ± SD	88.3 ± 4.52	76.2 ± 3.27	67.7 ± 5.54	<0.001*

	Control group (n=20)	ESP group (n=20)	PECS group (n=20)	P value
Range	83.0 – 100.0	73.0 – 83.0	60.0 – 78.0	
P1 = <0.001* p2 = <0.001* p3 = 0.011*				
MAP T60				<0.001*
Mean ± SD	90.9 ± 4.33	77.3 ± 3.37	70.8 ± 6.10	
Range	87.0 – 100.0	73.0 – 83.0	60.0 – 78.0	
P1 = <0.001* p2 = <0.001* p3 = 0.042*				
MAP T00				<0.001*
Mean ± SD	92.7 ± 6.12	78.5 ± 2.61	70.7 ± 6.97	
Range	80.0 – 100.0	73.0 – 83.0	60.0 – 79.0	
P1 = <0.001* p2 = <0.001* p3 = 0.015*				
MAP T2				<0.001*
Mean ± SD	94.1 ± 4.36	81.5 ± 3.32	70.8 ± 6.14	
Range	88.0 – 100.0	77.0 – 87.0	62.0 – 82.0	
P1 = <0.001* p2 = <0.001* p3 = 0.005*				
MAP T4				<0.001*
Mean ± SD	90.9 ± 4.33	76.1 ± 2.61	70.7 ± 5.32	
Range	87.0 – 100.0	73.0 – 79.0	63.0 – 78.0	
P1 = <0.001* p2 = <0.001* p3 = 0.069				
MAP T6				<0.001*
Mean ± SD	85.5 ± 3.30	76.2 ± 3.27	71.5 ± 7.05	
Range	79.0 – 90.0	73.0 – 83.0	61.0 – 80.0	
P1 = <0.001* p2 = <0.001* p3 = 0.669				
MAP T12				<0.001*
Mean ± SD	84.3 ± 2.36	87.1 ± 2.49	73.3 ± 7.34	
Range	80.0 – 88.0	80.0 – 90.0	60.0 – 85.0	
P1 = 0.012* p2 = 0.002* p3 = <0.001*				
MAP T24				<0.001*
Mean ± SD	86.3 ± 3.73	80.1 ± 4.16	76.5 ± 5.03	
Range	80.0 – 90.0	75.0 – 90.0	61.0 – 83.0	
P1 = 0.001* p2 = <0.001* p3 = 0.174				
	Control group (n=20)	**ESP group (n=20)**	**PECS group (n=20)**	**P value**
HR T0				0.018*
Mean ± SD	95.5 ± 4.10	94.0 ± 3.71	91.9 ± 3.96	
Range	88.0 – 100.0	89.0 – 100.0	87.0 – 100.0	

	Control group (n=20)	ESP group (n=20)	PECS group (n=20)	P value
P1 = 0.742 p2 = 0.014* p3 = 0.290				
HR T15				0.314
Mean ± SD	78.6 ± 3.90	78.5 ± 3.43	76.7 ± 3.67	
Range	72.0 – 87.0	75.0 – 88.0	71.0 – 82.0	
HR T30				<0.001*
Mean ± SD	88.5 ± 8.54	80.3 ± 3.69	74.5 ± 4.43	
Range	74.0 – 99.0	74.0 – 86.0	68.0 – 83.0	
P1 = 0.063 p2 = <0.001* p3 = 0.007*				
HR T45				0.118
Mean ± SD	78.4 ± 4.47	76.6 ± 3.46	75.5 ± 3.79	
Range	72.0 – 85.0	70.0 – 81.0	67.0 – 80.0	
HR T60				0.040*
Mean ± SD	78.3 ± 4.17	78.6 ± 5.60	74.9 ± 4.84	
Range	71.0 – 86.0	70.0 – 90.0	68.0 – 84.0	
P1 = 1.000 p2 = 0.050* p3 = 0.049*				
HR T00				0.009*
Mean ± SD	78.9 ± 4.42	78.3 ± 4.22	74.7 ± 4.59	
Range	71.0 – 84.0	70.0 – 90.0	68.0 – 83.0	
P1 = 1.000 p2 = 0.010* p3 = 0.078				
HR T2				<0.001*
Mean ± SD	95.5 ± 4.10	82.9 ± 5.23	75.5 ± 3.79	
Range	88.0 – 100.0	70.0 – 90.0	67.0 – 80.0	
P1 = <0.001* p2 = <0.001* p3 = 0.007*				
HR T4				<0.001*
Mean ± SD	95.5 ± 4.10	82.9 ± 5.68	74.5 ± 4.43	
Range	88.0 – 100.0	70.0 – 90.0	68.0 – 83.0	
P1 = 0.001* p2 = <0.001* p3 = 0.010*				
HR T6				0.511
Mean ± SD	79.2 ± 5.80	77.7 ± 4.09	76.7 ± 3.67	
Range	70.0 – 90.0	71.0 – 88.0	71.0 – 82.0	
HR T12				<0.001*
Mean ± SD	81.9 ± 4.06	79.5 ± 3.07	74.7 ± 4.59	
Range	75.0 – 90.0	75.0 – 87.0	68.0 – 83.0	
P1 = 0.259 p2 = <0.001* p3 = 0.008*				

	Control group (n=20)	ESP group (n=20)	PECS group (n=20)	P value
HR T24				
Mean ± SD	78.7 ± 3.95	87.4 ± 9.02	91.9 ± 3.96	<0.001*
Range	70.0 – 88.0	70.0 – 100.0	87.0 – 100.0	
P1 = 0.001* p2 = <0.001* p3 = 0.256				

Group I: control group, group II: ESB group, group III: PECS group
p ≤ 0.05 (Statistically significant) P1 (Control & ESP)
P2 (Control & PECS) P3 (ESP & PECS)
T0: at start of surgery, T15: after 15 minutes intraoperatively, T30: after 30 minutes intraoperatively, T45: after 45 minutes intraoperatively, T60: after 60 minutes intraoperatively. T00 = before discharge from PACU. T2: after 2 hours postoperatively. T4: after 4 hours, T6: after 6 hours, T12: after 12 hours, T24: after 24 hours.

Table 6. Postoperative patient satisfaction between all groups

	Control group (n=20)	ESP group (n=20)	Modified PECS group (n=20)	P value
Patient satisfaction				<0.001*
Unsatisfied	10	1	1	
	50.0%	5.0%	5.0%	
Fair	8	2	2	
	40.0%	10.0%	10.0%	
Satisfied	2	17	17	
	10.0%	85.0%	85.0%	

Group I: control group, group II: ESB group, group III: PECS group

Table 7. Postoperative complications between all groups

	Control group (n=20)	ESP group (n=20)	Modified PECS group (n=20)	Test of sig.	P value
Pneumothorax					
None	20	20	20		
	100.0%	100.0%	100.0%		
LAST					
None	20	20	20		
	100.0%	100.0%	100.0%		
Hematoma					
None	20	20	20		
	100.0%	100.0%	100.0%		
Bradycardia					
None	20	20	20		
	100.0%	100.0%	100.0%		
Hypotension					
	-	-	7		
			35.0%		

p ≤ 0.05 (Statistically significant)

The results of this randomized controlled study revealed that the use of ESB or PECSII block significantly decreased the post operative morphine consumption in the first 24 hours after MRM surgery in comparison to the control group with insignificant difference between ESB and PECSII groups. Also, the time of the first requirement of rescue analgesia was significantly decreased in control group as compared to ESB and PECS II groups with insignificant difference between ESB and PECSII groups. Furthermore, the NRS pain score was significantly decreased in the ESB and PECS II groups in comparison to the control group with insignificant difference between ESB and PECSII groups.

Moreover, the use of ESB or PECSII block significantly decreased the intraoperative fentanyl consumption in comparison to the control group with insignificant difference between ESB and PECSII groups. In addition, the mean arterial pressure and heart rate changes were significantly decreased in the PECS II group as compared to ESB and control groups with significant difference between ESB and control groups.

Furthermore, the patient satisfaction was increased in the PECS and ESB block groups than control group. No reported complications of blocks in the ESB or PECSII groups except hypotension occurred in some cases in PECS group.

In agreement with our study, Omar Shatoury et al., [11] carried out their study “on fourty adult female patients, who were scheduled for elective unilateral MRM, they were randomly assigned to two groups, Pectoral nerves block (Pecs) group, included twenty patients who received preoperative Pecs blocks (combination of Pecs I and Pecs II) followed by general anesthesia, and control group which included twenty patients who received general anesthesia only. They found that there was a significance difference between the PECS group and the control group in both heart rate and mean arterial blood pressure changes post-operatively since arrival to PACU till 16hrs post-operatively. At the 24th hrs post-operative there was no significant difference between the groups as regarding HR or MAP. This significant difference was in favour of PECS II block” [11].

“Furthermore, they found that there was a significant difference between the PECS group and the control group in intraoperative fentanyl consumption. The total number of patients needed intra operative fentanyl dose in the control group was 18 patients and in the PECS group was 9 patients, with p-value 0.001 which is significant. The total amount of fentanyl dose used was higher in control group than PECS group, with pvalue 0.001 which is significant” [11].

There was also a significant difference between the modified PECs and control groups in post-operative nalbuphine consumption. The total number of patients needed post-operative nalbuphine dose in the control group was 16 patients while in the Pecs group was 7 patients, with p-value (0.001) which is significant. Also, the total amount of nalbuphine dose used during 24hrs was higher in control group than Pecs group, with p-value (0.001) which is significant.

Time of first dose of nalbuphine needed postoperative was earlier in control group than that at Pecs group with p-value (0.029).

There was a significant difference between the two group as regarding patient satisfaction, that patients at Pecs group were more satisfied than those in control group.

Also, in a study by Başak Altıparmak et al, [12] “Forty patients (ASA I-II) were allocated to two groups. After exclusion, 38 patients were included in the final analysis (18 patients in the PECS groups and 20 in the ESP group). Postoperative tramadol consumption and pain scores were compared between the groups. Also, intraoperative fentanyl need was measured.

They stated that Postoperative tramadol consumption was lower in PECS group than in ESP group. They found that Intraoperative fentanyl need in PECS group was lower than that in ESP group. The difference was not statistically significant ($p = 0.263$)”.

In the same study, NRS scores at the 15th and 30th min were similar between the groups. However, median NRS scores were significantly lower in PECS group at the postoperative 60th min, 120th min, 12th hour and 24th hour ($p = 0.024$, $p = 0.018$, $p = 0.021$ and $p = 0.011$ respectively).

Moreover, in a meta-analysis by Jia Zhao et al.,[13] “including 9 studies comparing PECSII to control groups in anathesia for MRM, the intraoperative opioid consumption in the PECS II group was significantly lower than that in the

control group. And also, the NRS score in the PECS II group was significantly lower than that in the control group., the postoperative opioid consumption in the PECS II group was significantly lower than that in the control group".

The number of patients requiring postoperative rescue analgesia in the modified PECS II group was significantly lower than that in the control group.

In the same way, Kamiya et al [14], studied the impact of PECS II block on post-operative pain in breast cancer surgery, done on 60 adult female with 30 ml of levobupivacaine 0.25% injected in PECS group and found that, the NRS in PECS group was significantly decreased in the first 2 hours which is similar to our study.

In a study by Bashandy and Abbas [15], a randomized clinical trial to compare PECS II block (30 ml bupivacaine 0.25%) with general anesthesia alone for radical mastectomy on 120 adult female patients, reported that, the mean dose of intraoperative fentanyl consumption was significantly lower in PECS II block.

They also found that, the VAS pain score with PECS II block was significantly decreased in the first 12 hours post-operatively.

The rate of complications after PECS II or ESB is very low with literature containing only some case reports involving espescially bilateral cases like that by David N Flynn et al [16].

In contrary to our results, in a study by Bhavani et al., [17] "a double-blinded randomised controlled study in which Patients scheduled for an elective unilateral modified radical mastectomy surgery of age 18-70 years were enrolled in the study. Sixty patients (ASA I-II) were divided into two groups (30 in the PECS II group and 30 in the ESP group). The patients received respective blocks under ultrasound guidance after general anaesthesia. They concluded that The ESP block had better pain control, reduced postoperative pain scores and rescue analgesia than PECS II".

Moreover, Upasana Majumdar et al., [18] who conducted their randomized, single blinded, prospective study in state cancer institute, Gauhati medical college from April 2020 to April 2021. Sixty patients undergoing unilateral MRM aged 18-65 years were randomly allocated and divided into two groups-Group E (ESB) and group P (modified PECs) by applying simple randomization using the sealed envelope technique.

They stated that The VAS pain score was lower in patients of modified PECS group as compared to patients in ESB group up to at 6th postoperative hour and this difference in pain score was statistically significant. Beyond the 6th post-operative hour, however, the pain scores were comparable between 2 groups and median VAS was 2 for both groups.

Moreover, in the same study, Total tramadol consumption in ESB group was 87.93±39.31 mg and PECS II group was 62.50±22.61 mg and this difference was statistically significant (p=0.040).

The time for request of 1st rescue analgesia for ESB group was 871.30±589.51 min and PECS II group was 460±507.40 min and this difference was also statistically significant (p=0.032).

The main difference between their results and ours can be explained by that they had performed the ESP in sitting position and the PECS in supine position and hence they could not eliminate the discrepancy of position affecting the cephalad spread of the local anaesthetic between the two groups Also, the study population was not blinded as the block was performed before giving general anaesthesia to assess the level of sensory block.

Also, Chandni Sinha, et al., [19] conducted their study "on Sixty four female patients between age 18 to 60 years scheduled for unilateral modified radical mastectomy (MRM) under general anaesthesia, allocating them in this prospective randomised study. Patients in group I received ultrasound guided (USG) ESP block (20 cc 0.2% ropivacaine) while group II received USG guided PECS II block (25 cc 0.2% ropivacaine)".

The NRS scores were significantly lower in PECS group at all time intervals except at 8 and 12 hours. The scores were lower at these time points also but this difference was not statistically significant. They stated that there was no statistical difference in MAP or HR intraoperatively and postoperatively between PECS II group and ESB group.

Our results showed statistically significant difference between PECS and ESB groups in HR and MAP intra and post-operatively, probably due to more frequent measurements throughout the intra and post operative periods in our study.

Moreover, in contrary to our results, Mahajan et al, (2020) (86) conducted “their prospective open label study on 59 patients, planned for Modified Radical Mastectomy (MRM) under general anesthesia. the patients were randomly divided into two groups (P and E). Group P(N=30) received ultrasound guided modified PEC block with 30ml of 0.25% levobupivacaine. Group E(N=29) received ultrasound guided ESP block with 30 ml of 0.25% levobupivacaine. General anesthesia was then administered in both the groups. The intraoperative hemodynamics, duration of analgesia, VAS score, number of rescue analgesia, patients’ satisfaction, safety and side effects were noted and compared between the two groups”.

In their study the mean VAS score at 24 hours was 4.11 ± 0.629 in group P and the mean VAS score at 24 hours post operatively was 3.69 ± 0.679 in group E, and the difference was statistically significant (P=0.024). So they concluded that ESP block provides longer duration of pain free postoperative period. This difference may be due to the volume of local anesthetic used in their study as they used 30 ml of local anathesia in ESB block.

Our study had limitations: The small number of patients used in our study is a limitation. Also, lack of long-term assessment of the incidence of chronic pain syndromes added to the study limitations.

5. CONCLUSIONS

We can conclude that both ESB and PECSII blocks provided adequate analgesia as indicated by lowering doses of intraoperative fentanyl consumption, longer duration of postoperative analgesia, lower doses of post-operative morphine consumption compared to general anesthesia alone. However, PECS block is significantly better than ESB block regarding pain scales and morphine consumption after MRM. We recommend using PECS II block in MRM surgery due to its potent analgesic effect, its ability to improve quality of life after surgery. Other clinical randomized studies are recommended. In addition, long term assessment of chronic pain syndromes is required.

CONSENT

As per international standard or university standard, patients’ written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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