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Comparative study between the analgesic effect of erector spinae plane block and thoracic paravertebral block in patients undergoing modified radical mastectomy

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Abstract
Background: Various pain relief choices are available for breast surgeries, comprising opioids, and nerve blocks like pectoralis block, serratus block, thoracic paravertebral block (PVB), and erector spinae plain block.
Objectives: The current investigation evaluated the pain-relieving effects of erector spinae plane block (ESPB) compared to thoracic PVB in patients who underwent modified radical mastectomy.
Methods: Participants ranged in age from 18 to 70 years and were part of a prospective, randomized, double-blind trial, those whose BMI is between the range of 18.5 to 29.9and classified as American Society of Anesthesiologists (ASA) class I-II, who were undergoing modified radical mastectomy. Participants differed into two equal groups: Group A got unilateral ultrasound-guided PVB by 0.25% Bupivacaine 30 ml, while Group B got unilateral ESPB by 0.25% Bupivacaine 30 ml under ultrasound guidance. Mean arterial pressure (MAP) and heart rate (HR) measurements were taken upon patient arrival as baseline, after 10 minutes of performing the block, and subsequently after the skin incision several periods throughout the operation. Additionally, intraoperative consumption of Fentanyl was noted. Visual Analogue Scale (VAS) was used to assess the pain severity by 15 minutes after admission to the recovery room, and subsequently at regular intervals for up to 24 hours post-admission.
Results: No significant differences were found between the two groups regarding intraoperative MAP, HR, fentanyl requirement, VAS scores, or pethidine usage metrics (time of first use, requirement, number of patients, total usage) and complication incidence ($p > 0.05$ for all).
Conclusions: ESPB under the guidance of ultrasound shows similar effectiveness to PVB under the guidance of ultrasound for modified radical mastectomy. No significant differences were observed in intraoperative MAP, HR, fentanyl use, VAS scores post-operation, time to 1st rescue analgesia, or pethidine consumption amongst both techniques.

Keywords: Analgesic effect, erector spinae plane block, modified radical mastectomy, pain score, thoracic paravertebral block

Introduction

Breast cancer stands as the prevailing cancer diagnosis within the female population. One of the most common surgical procedures used to treat breast cancer is the modified radical mastectomy [1].

Ensuring effective pain management represents a paramount concern in contemporary healthcare. The significance of adequate pain relief is underscored by its profound impact on clinical outcomes and immediate postoperative patient recovery. Research has illuminated the adverse consequences of inadequate pain management, encompassing reductions alveolar ventilation and capacity of lung, heightened risks of hypertension, myocardial infarction, myocardial ischemia, pneumonia, tachycardia, as well as the potential for chronic pain development, compromised wound healing, and sleep disturbances [2].

Breast surgeries offer a range of analgesic choices, involving non-steroidal anti-inflammatory drugs (NSAIDs), opioids, and nerve blocks such as pectoralis block, serratus block, paravertebral block (PVB), and erector spinae plane block (ESPB) [3].

The ESPB presents a novel approach to regional anesthesia for pain related to thorax (acute

and chronic). This technique involves administering deep local anesthetic within the erector spinae muscle and superficial to the tips of the thoracic transverse processes, targeting a paraspinal fascial plane. Compared to thoracic epidural anesthesia and thoracic PVB, ESPB is considered less complex and associated with fewer complications as introduced in 2016 by Ferrero *et al*. [4]. The utilization of PVB dates to its initial performance in 1905, marking its emergence as a favored method for administering analgesia in the early decades of the twentieth century. Nevertheless, its application experienced a decline over time until a pivotal publication by Eason and Wyatt in 1979 sparked a revival of interest. Presently, PVB stands as a firmly established regional anesthetic technique, owing to its resurgence and subsequent adoption within clinical practice [5].

The current investigation evaluated the pain-relieving effects of ESPB compared to thoracic PVB in patients who underwent modified radical mastectomy.

Materials and Methods

This study was a prospective randomized double-blinded trial that lasted for one year, from June 2021 to June 2022, at Tanta University Hospital, Egypt following approval from the local ethical committee (approval code: 33826/5/20). The study enrolled 70 patients aged between 18 to 70 years, had 18.5 to 29.9 BMI, and was classified as American Society of Anesthesiologists (ASA) class I-II, who were undergoing modified radical mastectomy. Each patient provided informed written consent before participation.

Exclusion criteria encompassed coagulopathy, liver dysfunction, local infections, obesity, (BMI > 30), renal dysfunction, sensitivity to local anesthetics, and the presence of distant metastasis particularly involving the thoracic vertebrae.

Randomization and blindness

Utilizing computer-generated random numbers and sealed envelopes, individuals were allocated into two equivalent groups. Group A (PVB) underwent unilateral paravertebral block (PVB) under the guidance of ultrasound using 0.25% Bupivacaine 30 ml, while Group B (ESPB) underwent unilateral erector spinae plane block (ESPB) under the guidance ultrasound using 0.25% Bupivacaine 30 ml.

All patients underwent a comprehensive assessment, including past medical records, physical assessment, and diagnostic testing, such as coagulation profile comprising bleeding time, coagulation time, prothrombin concentration, and international normalized ratio (INR), Liver and kidney function tests, Complete blood count (CBC) in addition to Electrocardiogram (ECG), Echocardiography.

The collection of data was performed by anesthesiologists who were separated from the ones responsible for administering the blocks.

Intraoperative management

Upon entering the operating suite, patients received a peripheral intravenous line and were connected to standard monitoring devices. Preoperative medication involved the administration of intravenous midazolam at a dosage of 0.05 mg/kg. Either ESPB or thoracic PVB under the guidance of ultrasound was executed with the individual in a seated situation. Induction of general anesthesia using 2 mg/kg propofol IV, 1 µg/kg fentanyl, and 0.4 mg/kg atracurium besylate, followed by endotracheal intubation and the start of mechanical ventilation to regulate end-tidal carbon dioxide levels between 35 and 45 mmHg. Anesthesia was sustained with isoflurane at concentrations of 1% to 1.5% in an oxygen and air mixture (50%/50%), with additional doses of atracurium besylate administered every twenty minutes at 0.1 mg/kg. In cases of inadequate analgesia, manifested by a 20% increase in HR or MAP above baseline without explanation, intravenous fentanyl at 1 µg/kg was administered. Following completion of the surgical procedure, patients were extubated after successfully reversing neuromuscular blockade with 0.05 mg/kg neostigmine and 0.1 mg/kg atropine.

PVB technique

The ultrasound probe was aligned longitudinally over the midline spinous process at the fourth thoracic vertebra (T4) level. Then, it was shifted laterally to visualize the transverse process, where the intersection with the rib marked the lateral boundary of the paravertebral space. A Tuohy needle, 18-20 gauge, was inserted towards the cephalic direction. With direct ultrasound guidance, the needle tip was advanced until it pierced the superior costotransverse ligament and entered the paravertebral space, just above the pleural line. Once the desired position was achieved, the needle was aspirated to ensure no blood or air was present. After confirming negative aspiration, 30 ml of 0.25% bupivacaine was injected incrementally in 3-4 ml aliquots [6].

ESPB technique

Following sterile precautions and local anesthesia with 2% lidocaine infiltration, a Tuohy needle (18-gauge) was injected using ultrasound guidance in an in-plane, craniocaudal orientation. The needle advanced until it reached the transverse process of the T4 vertebra. Hydro dissection was performed using 2 ml of normal saline to confirm the separation of the erector spinae muscle from the T4 transverse process. Then, inject 30 ml 0.25% bupivacaine in 5 ml increments under direct ultrasound visualization after ensuring negative aspiration. The diffusion of the local anesthetic solution was monitored within the erector spinae plane, extending both cephalad and caudad [7].

Hemodynamic metrics, comprising MAP and HR, were documented upon the patient's arrival to establish a baseline. These metrics were then noted again 10 minutes post-block administration, 5 minutes following skin incision, and subsequently at 15 minutes, 30 minutes, 1 hour, and upon completion of the surgical procedure. Additionally, intraoperative fentanyl usage was recorded.

Postoperative management

Visual Analog Scale (VAS) was utilized to assess the levels pain at specific time points: 15 minutes post-admission to the recovery room, then at (1, 2, 6, 12, 18, 24) hours after admission to the recovery room [8].

Following the surgical procedure's conclusion, postoperative analgesia commenced with the administration of 1 gram of paracetamol. Subsequent doses were administered every 8 hours. In cases where the Visual Analog Scale (VAS) score surpassed 3, rescue analgesia was administered using 0.5 mg/kg pethidine.

The primary outcome measure was the time taken until the first postoperative rescue analgesia was required. Secondary outcomes included the number of patients necessitating rescue analgesia within the initial 24 hours following surgery in each group, patient satisfaction levels, onset, and duration of the blocks, intra and postoperative opioid consumption, and incidence of postoperative complications.

Sample Size Calculation

The determination of sample size and power analysis was conducted utilizing the Epi-Info software statistical package developed jointly by the World Health Organization and the Centers for Disease Control and Prevention, located in Atlanta, Georgia, USA, version 2002. The parameters employed for sample size calculation included a confidence level of 95% and a study power of 80%. Anticipated outcomes were set at a favorable treatment group rate of 90% compared to a least favorable treatment group rate of 60%. The determined sample size per study group was established at N>33. To enhance result validity, the sample size was subsequently augmented to 35.

Statistical analysis

Data analysis was conducted using SPSS version 26 (IBM Inc., Chicago, IL, USA). Quantitative data were expressed as mean ± standard deviation (SD), and qualitative data were shown as frequency and percentage (%). Statistical significance was defined as a two-tailed P value of less than 0.05.

Results

The study initially evaluated 80 patients for potential enrollment. However, 10 patients were deemed ineligible for inclusion: two failed to meet the specified criteria, while eight declined participations. Consequently, 70 patients comprised the final cohort, equally divided into two groups (35 individuals each). Subsequently, all 70 patients were subject to follow-up and underwent statistical analysis.

No significant demographic difference between the two groups observed (p >0.05).

There is no significant difference between the two groups regarding intraoperative MAP, HR (figure 1), intra-operative fentanyl, postoperative VAS score, time of 1st use of pethidine (table 2), pethidine need, number of patients who needed pethidine, total pethidine (table 3) and patient complications (table 4). (p-value >.05)

Discussion

Breast cancer stands as a widespread malignancy worldwide, demanding surgical attention for a significant portion of afflicted women. Managing postoperative pain after breast surgery poses a notable obstacle given the intricate procedure and the complex nerve distribution in breast tissue [8].

Our study findings indicated no statistically significant distinction in HR and MAP among both groups throughout the intraoperative phase. This observation aligns with Moustafa *et al.*'s findings, who similarly found no statistically significant variations in MAP and HR in the ESPB group and the PVB group at baseline and (5, 10, 15) minutes following incision (p>0.05) [9, 10].

Our findings differ from those presented by Sivrikoz *et al.* [11] who assess the effectiveness of ESPB under the guidance of ultrasound with PVB for managing pain after surgery in patients underwent modified radical mastectomy, the PVB group (Group P) demonstrated superior analgesic efficacy compared to the ESBP group (Group E). Group P (19.2±2.9 mg) had significantly lower morphine consumption vs (21±3.1 mg) in group E, a greater number of dermatomes with complete sensory loss, and consistently lower pain scores. However, there was no significant difference in complications or adverse events between the two groups, suggesting that both techniques were well-tolerated and safe.

For this investigation, no significant difference in fentanyl uses through the operation in groups (P value >0.001). Supporting these findings, Gürkan *et al.* [12] reported no significant difference in 24-hour morphine consumption between ESPB and PVB groups (p>0.05). However, both groups significantly reduced morphine needs at 6-, 12-, and 24-hours following surgery compared to the control group (p<0.001 for each interval), with no statistical differences between the two block groups at any time interval. In contrast to the aforementioned study, Eldemrdash and colleagues [13] observed ESPB group had a significantly longer duration until the first analgesic dose (416 ± 68 min) compared to the PVB group (371 ± 67 min) and the control group (343.5 ± 54.7 min).

For this investigation, no significant difference was observed in VAS scores post-operatively. Corroborating our findings, Gürkan *et al.* [12] asserted that the comparative analyses between groups did not reveal any statistically significant variation in numeric rating scale (NRS) pain scores across different time intervals concerning the ESPB and PVB groups (p > 0.05 for each time interval). Conversely, Eldemrdash *et al.* [13] illustrated that postoperative VAS scores were lower in the ESPB group compared to both the PVB and serratus anterior plane block (SAPB) groups at 4, 6, 12, and 24 hours (P < 0.05). This difference might be attributed to the differing local anesthetic agents utilized. Additionally, our findings contrast with those of Richardson *et al.* [14] discovered that VAS values were statistically lower in the PVB group compared to the ESPB group (p = 0.02) with low consumption of morphine. The larger sample size in their study may account for this disparity. Moreover, Swisher *et al.* [15] reported higher pain scores in subjects receiving ESPBs compared to PVBs (median NRS 3 vs 0, p=0.0011). Variations in sample size or dosing regimens might have contributed to this inconsistency.

In our current investigation, the occurrence of obstacles such as bradycardia, nausea, pneumonia, vascular injury, and vomiting did not demonstrate a statistically significant variance between the two groups. In Group A, 4 (11.4%) patients experienced nausea, 5 (14.3%) experienced vomiting, 5 (5.7%) experienced bradycardia, none (0%) experienced pneumothorax, and 2 (2.9%) had vascular injury. Conversely, in Group B, 5 (14.3%) patients experienced nausea, 4 (11.4%) experienced vomiting, 5 (14.3%) experienced bradycardia, none (0.0%) had pneumothorax, and none (0.0%) had vascular injury. Despite the theoretical likelihood of pneumothorax being higher with PVB than ESPB, no instances occurred in our study cohort. The observed reduction in postoperative nausea and vomiting (PONV) with ESPB can be attributed to the decreased opioid requirements after the block. Our results align with those reported by Eskandr *et al.* [16] who noted no complications other than PONV, with (one case in

the ESPB group) and (two cases in the PVB group) receiving intravenous ondansetron 4 mg. No difference in PONV incidence between groups. Additionally, they documented no local anesthetic toxicity or injection site hematoma, pneumothorax, hypotension, or bradycardia, as both blocks were conducted under ultrasound guidance.
Similarly, Gürkan *et al*. [12] observed nausea after surgery occurred in 7 ESPB patients, 2 PVB patients, and 12 control patients (p=0.008). However, there was no significant difference in vomiting after surgery within groups (p=0.920).

Limitations of our study: The sample size was relatively small. The study was in a single center and the results may differ elsewhere. A control group was not included due to ethical issues.

Table 1: Comparison between the two studied groups according to demographic data and physical status

		Group (A) (n=35)	Group (B) (n=35)	P
Age (years)		44.51±13.369	50.26±11.184	0.055
Weight (Kg)		76.89±12.043	77.69±12.073	0.855
Height (m)		167.94±8.007	169.23±7.211	0.483
BMI (kg/m^2)		27.48±5.288	27.35±5.247	0.930
ASA	I	16(45.7%)	14(40.0%)	0.629
	II	19(54.3%)	21(60.0%)	

Data are presented as mean ± SD or frequency (%). *Significant p value <0.05, BMI: Body mass index, ASA: American Society of Anesthesiologists.

Table 2: Comparison between the two studied groups as regard intra operative fentanyl (more than usual induction dose), VAS score post operatively and time of 1st use of pethidine

	Group (A) (n=35)	Group (B) (n=35)	P
Intra operative fentanyl			
Number of patients requiring intra operative fentanyl	19 (54.2%)	17 (48.5%)	0.293
Dose (µg/kg)	74.74 ± 15.41	69.41 ± 14.35	
VAS score			
One-hour post-operative	1-3	1-3	0.244
After 2 hours	2-3	3-4	0.133
After 6 hours	2-3	2-3	0.741
After 12 hours	2-3	2-3	0.754
After 18 hours	2-3	2-3	0.126
After 24 hours	1-2	1-2	0.708
Time of pethidine	1.40±4.28	1.14±4.04	0.797

Data presented as range or mean ± SD or frequeny (%). * Significant p value <0.05, VAS: visual analogue scale.

Table 3: Comparison between the two studied groups according to number of patients who needed pethidine and total pethidine

	Group (A) (n=35)	Group (B) (n=35)	P
Number of patients who needed pethidine	10(28.6%)	9 (25.7%)	0.788
Total pethidine (mg)	115.14 ± 41.44	123.71±46.89	0.421

Data are presented as Mean ± SD or frequency (%). * Significant p value <0.05.

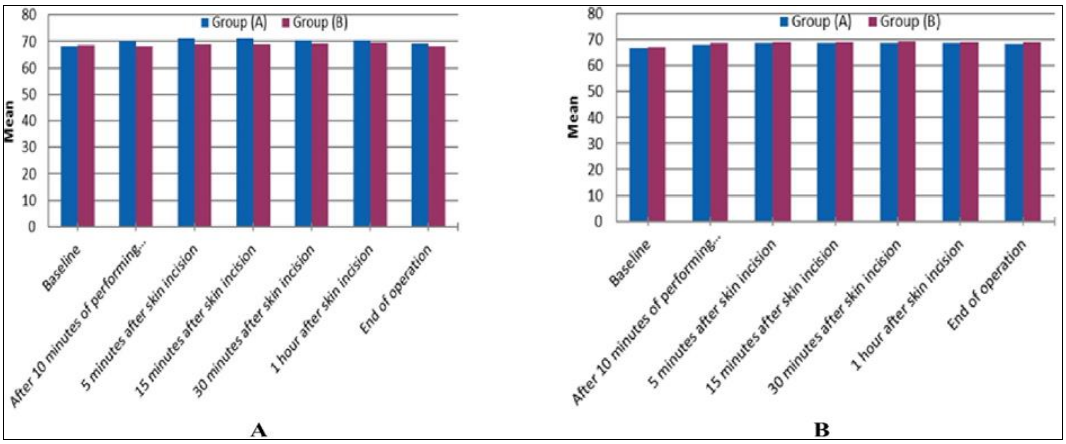

Fig 1: Comparison between two studied groups as regard patient's intra operative A) mean arterial blood pressure (MAP) and B) heart rate (HR)

Conclusion

Ultrasound-guided ESPB offers favorable outcomes for elective mastectomy patients, decreasing intraoperative fentanyl and postoperative pethidine usage, baseline, and postoperative VAS scores, while enhancing satisfaction and reducing complications compared to TPVB. It serves as a simple and safe multimodal postoperative analgesic approach.

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Conflict of Interest: Nil

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