Comparative study between Ultrasound guidance and blind technique for thoracic erector spinae plane block in post mastectomy pain control; a randomized controlled study

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Abstract

Background: Erector spinae plane block (ESPB) is commonly done under ultrasound guidance (US) but not all physicians have US and not all of them well trained on it. Therefore, the aim of the work is to compare the analgesic efficiency of both blind and US of thoracic ESPB in post mastectomy pain control.

Methods: This prospective, randomized, double-blinded was conducted on 90 female patients between 20 and 70 years of age and ASA physical status (I & II) scheduled for elective breast cancer surgery. Patients were randomly allocated into two equal groups, Group B received blind ESPB and Group U received US guided ESPB.

Results: There was no statistically significant difference between both groups regarding VAS, morphine consumption, heart rate, mean arterial pressure, postoperative nausea and vomiting, block performance, ease of performance and duration of surgery. Duration of anaesthesia was statistically significant lower in the blind group than US group. Satisfaction was statistically significant difference between both groups.

Conclusions: Blind ESPB could be done safely and easily, and it was not be inferior to US guided ESPB.

Keywords: Erector spinae plane block, ultrasound, blind, post mastectomy pain

1. Introduction

Breast surgery is one of the most common surgeries among female population [1].Uncontrolled postoperative pain control remains a common problem for that type of surgeries which may lead to endocrine, metabolic, inflammatory, and immune consequences, longer hospital stays and development of chronic pain [2].

The main problem after surgical management of breast cancer is neuropathic pain in the chest wall, armpit, and/or arm which could last for a long time causing post-mastectomy pain syndrome (PMPS). This syndrome can also happen after other types of breast-conserving surgery (such as a lumpectomy) [3]. The classic symptoms of PMPS are pain and tingling in the chest wall, armpit and arm. Pain may also be felt in the shoulder or surgical scar. Other common complaints include: numbness, shooting or pricking pain, or unbearable itching [3, 4].

Opioid analgesics, non-steroidal anti-inflammatory, pregabalins all has been used alone or in-combination for treatment of such problem. Function by reducing the perception of pain signals in the central nervous system [4, 5]. Moreover, The analgesia ladder is a useful paradigm in addressing pain in the patient by using non-steroidal anti-inflammatory drugs, paracetamol, and adjuvant medications in conjunction with opioid [6, 7].

The Use of the N-methyl-D- aspartate (NMDA) receptor antagonist (ketamine) and calcium

channel blocker (Magnesium sulphate) to control pain refractory to high dose of opioids is described in a number of clinical trials [8, 9].

A lot of interventional technique has been used to control postoperative pain such as Serratus Anterior Blocks, high thoracic epidural anesthesia, thoracic paravertebral block. However, these are particularly challenging, techniques, because of the anatomic proximity of the pleura and central neuraxial system [2, 10].

Ultrasound (US) guided erector spinae plane block (ESPB) is a safe, innovative strategy that is easy to perform and ensures good postoperative analgesia in radical mastectomy with high success rate, reducing opioid requirements. It was first described for the treatment of thoracic neuropathic pain. It has later been used as a postoperative analgesia method in many surgical procedures from shoulder to hip surgeries [10, 11].

ESPB is commonly done under US guidance but not all physicians have US and not all of them well trained on it. Therefore, we speculate that blind ESPB could be done safely and easily and it may not be inferior to US guided ESPB. The aim of the work is to compare the analgesic efficiency of both blind and US guided technique of thoracic erector spinae plane block in post mastectomy pain control.

Patients and Methods:

This is a prospective, randomized, double-blinded conducted on 90 female patients, between 20 and 70 years of age and ASA physical status (I & II) scheduled for elective breast cancer surgery. The study was done at Kasr Alaini Hospital, Cairo, Egypt.

The study was approved by the Ethics Committee of Cairo university hospital. Informed consent was obtained from each patient.

Exclusion criteria included body mass index > 35, patients with previous difficulty in evaluating their level of pain, contraindications for local anesthesia as patient refusal of local anesthesia, coagulopathy (thrombocytopenia (platelet count below 100000 platelets per microliter), prothrombin time greater than 14 seconds), therapeutic anticoagulation and skin infection or hematoma in the vicinity of the puncture site, allergy to any of the study drugs, infection at surgical site, previous breast surgeries, hepatic or renal impairment and history of psychological disorders.

Patients were randomly allocated into two equal groups, Group B received blind technique for thoracic erector spinae plane block and Group U received US guided technique of ESPB.

The preoperative assessment included training of the patients about VAS for postoperative pain.

US group

The patients were placed in a sitting position for the ESP block interventions. The US probe (8-14 MHz) straight probe (Siemens ACUSON X300 Ultrasound System) were placed in a longitudinal orientation at the level of the T4 spinous process, then placed the probe 2–3 cm laterally from the midline. After the identification of the T4 transverse process and overlying trapezius, rhomboideus, and erector spinae muscles, the targeted injection site was anesthetized with 1–2 ml of 2% lidocaine. An 80mm 21- gauge block needle was inserted using the in-plane technique following the same injection point in the cranial to caudal direction until the tip is contacted to the T4 lamina. Then the correct needle tip position was confirmed by hydro-location with 1–2 ml of isotonic saline solution separating the erector spinae muscle and the transverse process. Local anesthetic solution was injected 30 mL (15 xlyocaine + 15 Marcaine) local anesthetic was injected slowly. Patients were placed in a supine position after the completion of injection of LA.

Blind group:

The patients were placed in a sitting position, the tip of spinous process of thoracic vertebrae was felt and identified, and a point 1.5 cm lateral to spinous process was marked. At this point spinal needle was inserted in perpendicular orientation till hitting bone. This noticeable bone is the lamina and injection at this point is under the erector spinae muscle and therefore it was considered as ESPB. If we insert our spinal needle and severe resistance to injection is met, we rotate the spinal needle 90 degrees until free flow of injectate is applicable. Then 30 mL (15 xlyocaine + 15 Marcaine) of local anesthetic was injected slowly.

In both groups, assessment of block success was done after 15 minutes from the end of block. (After introducing both techniques successful block was assessed using hot/cold discrimination with icepack). Patients with failed block or partial block were excluded from the study. Failed block is defined as no sensory loss along the thoracic cage (area supplied by intercostal nerves) after 20 minutes of doing block or severe increase in heart rate more than 20% of baseline or if the patient requires more than two doses of rescue analgesia in the first hour postoperatively.

General anesthesia started at 20 minutes after the end of block (after assessment of block success). All patients in the study received general anesthesia in the form of propofol 2mg/kg,atracurium0.5ml/kg, fentanyl 1.5 microgram/ Kg in the induction with endotracheal tube and mechanical ventilation, full monitoring with electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry and capnography were applied. Maintenance anesthetic drugs with isoflurane with minimum alveolar concentration (MAC 1.2%) and atracurium 10 mg every 20 minutes. The residual neuromuscular blockade was reversed using neostigmine (0.05mg/kg) and atropine (0.02 mg/kg), and intubation was removed upon complete recovery of reflexes. After completion of surgical procedure and emergence from anesthesia the patient was referred to the post-anesthesia care unit (PACU). When the VAS level increases to more than 3, paracetamol 1 gm intravenous infusion was used (Maximum daily dose of 4 g / 24 hour), and morphine (2 mg intravenous) every hour and maximum 24 hour dose could be 48 mg. The total dose of analgesic was recorded in all groups after 24 hours.

Total morphine taken by intermittent boluses during the first 24hour postoperatively was recorded. Visual Analogue Scale for pain was measured and recorded postoperative after 30 min., 2, 4, 6, 8, 12 and 24 hours. Failure rate of the block was calculated, where the block considered a failed block if the patient requires more than two doses of rescue analgesia in the first hour postoperatively. Duration of surgery (from skin incision till skin closure) and general anesthesia (from induction of GA till extubation) was recorded. Incidence of complications, such as: Hematoma formation and pneumothorax and incidence of postoperative nausea and vomiting were recorded.

Sample size

Based on a previous study [12] and the assumption that there was no statistically significant difference in the mean value of morphine consumption 24 hours postoperatively between blind technique (56.87 ± 9.31) and U/S guided technique (59.86 ± 9.83) taking local lidocaine anesthetics (30 ml, 2%=600 mg), with α=0.05, two tailed, power of 80%, and an effect size of 0.6. So, a sample size of 45 patients/group would be required (G Power 301 http: www.psycho.uni-duesseldorf.de). If the duration of block in the blind technique 10% or less than 10% of the duration of U/S guided technique were considered the non- inferiority margin of the study.

Statistical analysis

SPSS (version 19 windows) was used for data analysis. Results were expressed as mean ± standard deviation (SD) or number (%). Comparison between categorical data [number (%)] was done using Chi square test or Fisher exact test instead if cell count is less than 5. Test of normality, Kolmogorov-Smirnov test, was used to measure the distribution of data measured. Accordingly, comparison between normally distributed variables in the two groups was performed using unpaired t test. Repeated measures factorial ANOVA test was used to study the interaction between groups and different time of measurements. In not normally distributed data, comparison between variables in the two groups was performed using Mann Whitney test. Comparison between T0 (30 minutes) and different times of measurement (T1, T2, T3, T4, T5 and T6) within the same group was performed using Friedman test and if significant result was recorded, Wilcoxon Signed Ranks test was used as a post hoc test for pairwise comparison. P value ≤ 0.05 was considered significant.

Results:

CONSORT

There was a statistically significant difference between both groups regarding ASA and duration of general anesthesia was statistically significant lower in group B compared to group U. No statistically significant difference was observed between both groups regarding age and duration of surgery. (table 1)

Table (1): General characteristics of the two studied groups.

	Group U (n= 45)	**Group B (n= 45)**	**P value ##**
Age (yrs.)	50.98 ± 10.78	53.67 ± 11.66	0.259
ASA (I/II)	34/11 (75.6%/24.4%)	22/23 (48.9%/51.1%)	χ^2= 0.009*
Duration of surgery (min)	134.78 ± 14.50	132.11 ± 9.86	0.311
Duration of general anesthesia (min)	156.89 ± 11.88	147.89 ± 22.47	0.020*

Data were expressed as mean ± standard deviation or number (percent). ##= Unpaired t test; χ2= Chi square test.

p> 0.05= not significant; *p≤ 0.05= significant.

There was no statistically significant difference between both groups regarding VAS however, measurements within each group were statistically significant different at different times. There was no statistically significant difference in morphine consumption between both groups. (Table 2)

Table (2): Comparison between values of VAS measured at different times of measurement in

the two studied groups

	Group U. (n= 45)	**Group B (n= 45)**	**P value[#]**
VAS T0 (30 min.)	0.64 ± 0.77	0.42 ± 0.78	0.079
VAS T1 (2 hrs.)	1.56 ± 1.25 **	1.91 ± 1.79 **	0.503
VAS T2 (4 hrs.)	2.56 ± 1.85 **	3.33 ±2.14 **	0.083
VAS T3 (6 hrs.)	3.67 ± 1.95 **	3.82 ± 2.15 **	0.667
VAS T4 (8 hrs.)	3.62 ± 2.14 **	3.36 ± 2.72 **	0.409
VAS T5 (12 hrs.)	2.33 ± 1.61 **	2.24 ± 1.71 **	0.790
VAS T6 (24 hrs.)	1.40 ± 0.81 **	1.49 ± 1.22 **	0.848
Friedman ANOVA test (p value)	0.001*	0.001*	
Total 24 hrs morphine consumption dose (mg)	3.60 ± 3.43	4.53 ± 3.80	0.247

Data were expressed as mean ± standard deviation.

[#]= Non parametric statistics (Mann Whitney test).

**= p≤ 0.05 relative to T0 (30 minutes) within the same group using Wilcoxon Signed Ranks test.

No statistically significant difference was found between both groups in MAP and HR. (figures 1&2)

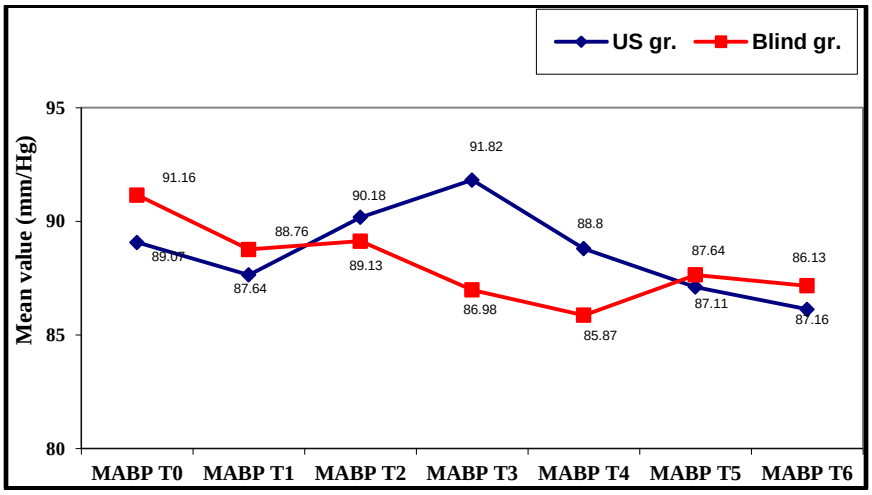

Figure (1): Mean values of mean arterial blood pressure (mm/Hg) measured at different times of measurement in the two studied groups.

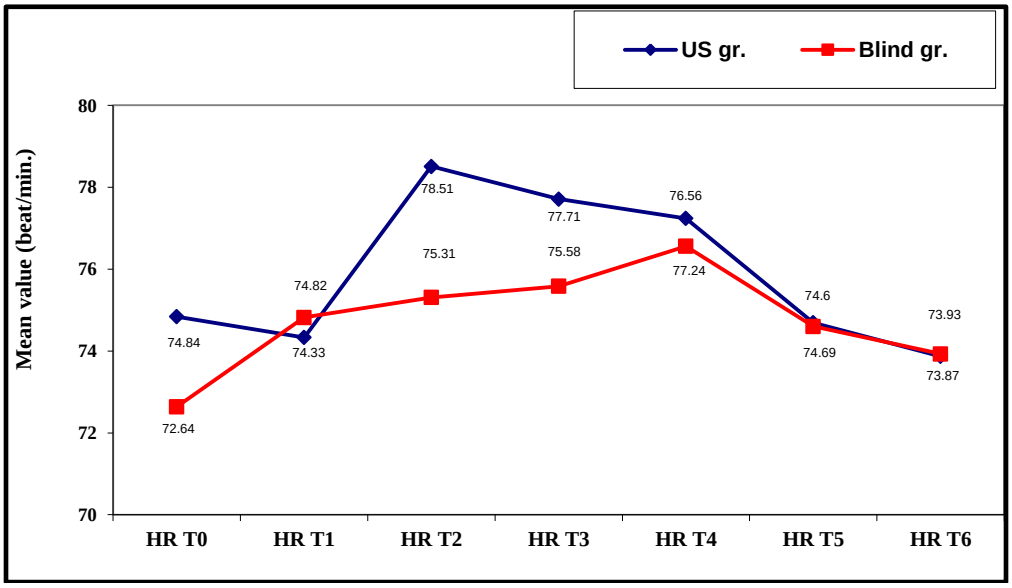

Figure (2): Mean values of heart rate (beat/minute) measured at different times of measurement in the two studied groups.

There was no statistically significant difference between both groups in the postoperative nausea and vomiting. (Table 3)

Table (3): Postoperative nausea and vomiting in the two studied groups

	Group U (n= 45)	**Group B (n= 45)**	**P value[#]**
PONV T0 (yes)	3 (6.7%)	5 (11.1%)	0.459
PONV T1 (yes)	4 (8.9%)	6 (13.3%)	0.502
PONV T2 (yes)	4 (8.9%)	3 (6.7%)	0.694
PONV T3 (yes)	2 (4.4%)	1 (2.2%)	0.557
PONV T4 (yes)	1 (2.2%)	1 (2.2%)	1.000
PONV T5 (yes)	1 (2.2%)	0 (0.0%)	0.315
PONV T6 (yes)	0 (0.0%)	0 (0.0%)	----

Data were expressed as number (%). [#]= Chi square test, *p< 0.05= significant

No statistically significant difference was observed between two groups regarding ease of performance technique, block performance time, and adverse effects however there was statistically significant difference regarding patients' satisfaction. (Table 4)

Table (4): Mean value of different data in the two studied groups.

	US gr. (n= 45)	**Blind gr. (n= 45)**	**P value ##**
Ease of performance of the technique			
Difficult	0 (0.0%)	4 (8.9%)	
Moderately difficult	15 (33.3%)	13 (28.9%)	0.122
Easy	30 (66.7%)	28 (62.2%)	
Block performance time (min.)	11.11 ± 2.10	12.22 ± 3.62	0.080
Adverse effects (yes)	0 (0.0%)	0 (0.0%)	-----

Patients' satisfaction			
Not very satisfied	5 (11.1%)	0 (0.0%)	0.006*
Satisfied	11 (24.4%)	23 (51.1%)	
Very satisfied	29 (64.4%)	22 (48.9%)	

Data were expressed as mean ± standard deviation or number (percent).

##= Unpaired t test; χ^2= Chi square test, $p \leq 0.05$= significant.

Discussion

ESP has been described as a technically simpler alternative to US guided paravertebral block with a similar mechanism of action [13]. Part of the appeal of the ESP block could be that it is gaining indirect access to the paravertebral space and providing analgesia without the potential for needle- pleura interaction and consequent risk of pneumothorax. There are no structures at risk of needle injury in the immediate vicinity, such as, neuroaxis, pleura, and any major vascular structures. It permits the block to be performed by experienced practitioners in anticoagulated patients with a reasonable safety margin [13]. Similarly, some authors believe that injection into a fascial plane and lack of needle proximity to neural structures make it reasonable to perform the ESP block under general anesthesia if necessary [14].

In our study, regarding VAS there was insignificantly different between the two groups (US guided group and blind group). With our study jian-wen et al who explore the effect of a single preoperative US guided thoracic paravertebral nerve block (TPVB) and ESPB for perioperative analgesia in thoracoscopic pulmonary lobectomy, regarding VAS at 1, 6, 12, 24, and 48 h postoperatively there was insignificantly different among the groups t 24 hour after surgery ($p > 0.05$) [15].

Against our result regarding VAS, Ismail ahmed and hesham said there was significantly different, The pain score (VAS) was significantly better in group erector spinea as compared to group thoracic epidural ($p<0.001$) in postmastectomy analgesia [16].

In our study, regarding total morphine consumption in 24 hour there was insignificantly different between the two groups ($P> 0.05$). With our study Gürkan et al [17] ,morphine consumption at postoperative hours 1, 6, 12 and 24 decreased significantly in the ESP group ($p < 0.05$ for each time interval). Total morphine consumption decreased by 65% at 24 h compared to the control group (5.76 ± 3.8 mg vs 16.6 ± 6.92 mg). Regarding total morphine consumption in 24 hour, there was no statistically significant difference between the groups in terms of numeric rating scale(NRS) scores [17].

Eleven randomized controlled trials involving 679 patients met the study inclusion criteria and were included in this study. In comparison to general anesthesia group (GA, the ESPB group showed a significant reduction in morphine consumption at the first 24 h after surgery by a mean difference (MD) of − 7.67 mg [95% confidence interval (CI) − 10.35 to − 5.00] ($P < 0.01$) [18].

Also, our study showed that regarding the mean arterial blood pressure(MABP) there was no statistically significant difference between the two groups at different time of measurements (T0, T1, T2, T3, T4, T5 and T6),P value more than 0,05. In US group, repeated measures showed that there was no statistically significant difference between different time of measurements (T0, T1,

T2, T3, T4, T5 and T6). In blind group, repeated showed that there was no statistically significant difference between different time of measurements (T0, T1, T2, T3, T4, T5 and T6). The interaction between groups and different times of measurement was not significant. That to say that there was no statistically significant difference between the two groups across different times of measurement.

Similar to our result regarding mean arterial pressure Malawat et al [19] showed that there was no statistically significant difference in their study .

Also, our study showed that regarding the heart rate there was no statistically significant difference between the two groups. With our study regarding heart rate, Wasfy et al [20] found that there was no statistically significant difference in heart rate between group A (IV) (n = 20) who received multimodal intravenous analgesia or group B (ES) (n = 20) who had continuous erector spinae block.

Against our results, Seelam et al [21] found that there was no statistically significance difference in baseline parameters and immediate postoperative parameters (heart rate, systolic, diastolic, and mean arterial pressure).

In our results incidence of post-operative nausea and vomiting (PONV) was minimal and showed insignificantly different between the two groups. In accordance with our study Zhang et al [22] stated that ESPB decreases post-operative nausea and vomiting.

Also, our study showed that the incidence of regional anesthesia complications such as local anesthetics toxicity, hematoma ,nerve injury and intravascular injection were absent in all patients in both groups.

Against our result regarding the heart rate Fang et al [23] found that there was statistically Significance difference in heart rate in the study provides comparison between US guided preoperative single-dose ESPB and TPVB following thoracotomy. Ninety-four patients scheduled for thoracotomy lung surgeries were randomly allocated to an ESPB or TPVB group. Patients in both groups were provided with an intravenous patient-controlled analgesia (PCA) device containing sufentanil. Visual analogue scale (VAS) pain scores under the status of rest and cough were recorded at 1, 6, 12, and 24 h postoperatively. In addition, total press times of PCA were read from the PCA memory. The adverse effects, puncture time and success rate of one puncture were also recorded. There was significantly bradycardia (0 vs. 8.7%, P=0.04) [23].

Against our results regarding PONV Park et al [24] stated that the ESPB did not significantly reduce the incidence of PONV, although it significantly reduced postoperative opioid use, perhaps because in their study there were other risk factors for PONV, such as gender, a prophylactic antiemetic regimen, and use of volatile anesthetics.

Against our study El-Boghdadly et al [25] reported that local anaesthetic systemic toxicity (LAST) is typically manifested as central nervous system (CNS) toxicity (tinnitus, disorientation, and ultimately, seizures) or cardiovascular toxicity (hypotension, dysrhythmias, and cardiac arrest). The dose capable of causing CNS symptoms is typically lower than the dose and concentration result in cardiovascular toxicity. This is because the CNS is more susceptible to local anaesthetic toxicity than the cardiovascular system.

Also, Tulgar et al [26] found that motor weakness may occur when the LA spreads to the lumbar plexus when performed from the lower thoracic or lumbar areas. Our report of ESPB from L4 being used for effective postoperative analgesia in hip, femur, and knee surgery is of clinical significance. Limitations include small sample size and being a single-centered study shows a difference among other centers so we recommend further studies with large sample size and being multicenter to be compared to our results. Further studies are required to determine the

relationship between volume and the LA spread, if one exists.

Conclusions:

The total morphine consumption in both blind technique and US guided technique of ESPB is decreased in successful block and there is no significant difference between two groups but not all physicians have US and not all of them well trained on it. Therefore, we speculate that blind ESPB could be done safely and easily and it wasn't inferior to US guided ESPB.

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Conflict of Interest: Nil

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