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Comparative Study between Ultrasound Guided Erector Spinae Plane Block versus Paravertebral Block for Postoperative Pain Relief in Patients Undergoing Unilateral Modified Radical Mastectomy

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ABSTRACT

Background: Breast cancer is a serious medical problem because one out of every eight women will develop the disease during her lifetime. Acute postoperative pain following breast surgery is a major risk factor for chronic postoperative pain, so good perioperative pain management is critical.

Aim of the study: The aim of the current study was to compare the efficacy of the US guided PVB and the ESPB in decreasing the intensity of postoperative pain following unilateral modified radical mastectomy (MRM).

Patients and Methods: After approved by the Ethics Committee of the Faculty of Medicine – Al-Azhar University and a written consent from each patient, a sample size of 46 patients (23 for each group) underwent unilateral MRM under GA at Al-Azhar University hospitals (ElHusseini and Sayed Galal) were enrolled in the study. All patients were randomly allocated into two equal groups by closed envelope method.

Results: There was no significant difference between both groups as regard the first use of PCA and the total dose of nalbuphine consumption in 24 hours postoperatively. There was no significant difference between both groups as regard patient satisfaction by using verbal rating scale for satisfaction. There were no recorded complications except for PONV, 1 patient in ESPB Group and 2 patients in PVB Group.

Conclusion: PVB and ESPB both considered effective in pain control following MRM, with similar analgesic effect duration, reduced postoperative opioid intake.

Keywords: Ultrasound Guided Erector Spinae Plane Block; Paravertebral Block; Postoperative Pain Relief; Modified Radical Mastectomy

Keywords: lumbar interbody cage; VAS; ODI; PLF, PLIF.

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INTRODUCTION

Breast cancer is a serious medical problem because one out of every eight women will develop the disease during her lifetime. Acute postoperative pain raises the likelihood of chronic postoperative pain, so proper perioperative pain management is critical. Breast procedures are frequently accompanied with postoperative pain, nausea, and vomiting, all of which can negatively impact the patients' perioperative experience.^{1,2}

Although opioids are commonly used to treat acute post-mastectomy pain, they can have a number of negative side effects, including drowsiness, nausea, vomiting, and respiratory depression. Despite the fact that thoracic epidural analgesia and PVB have been linked to significant complications such as pneumothorax and total spinal anaesthesia, they have

become the gold standard for breast surgery. Because of the use of ultrasound in RA, various novel blocks have been developed that can give analgesia for breast procedures with less adverse effects.^{3,4}

The dorsal and ventral rami of the thoracic and abdominal spinal nerves are blocked using ESPB, a novel regional block in which LA is injected between the ESM and TP under US guidance. A single injection at the level of the T5 caused cranio-caudal spread between C7 and T8 in a cadaver model, according to radiological imaging. This explains the widespread sensory block noted in case reports, which is at least as widespread as the spread seen with PVB. However, no previous studies compared the simplicity of this method to the gold standard PVB.⁵

The aim of the current study was to compare the efficacy of the US guided PVB and the ESPB in decreasing the intensity of postoperative pain following unilateral MRM.

PATIENTS AND METHODS

After approval of the Ethics Committee of the Faculty of Medicine – Al-Azhar University and a written consent from each patient, a sample size of 46 patients underwent unilateral MRM under GA at Al-Azhar University hospitals (ElHusseini and Sayed Galal) were enrolled in the study.

Study Design: prospective randomized controlled single blinded clinical study.

The patients were randomly divided into two equal groups using closed envelope method: Group I (ESPB) Erector Spinae Plane Block: 23 patients received preoperative ESPB with GA. Group II (PVB) Paravertebral Block: 23 patients received preoperative PVB with GA.

Group I and Group II achieve 91.250% power to detect a difference of (1) in postoperative VAS between both groups with standard deviation for both groups of (1) and a significance level (alpha) of 0.05 using a two-sided Mann-Whitney test after nonparametric adjustment.

Randomization: Patients have been allocated to one of the study groups at random using a computer-generated table, with the randomized sequence hidden in sealed opaque envelopes.

Exclusion criteria: Patients who refused to participate in the study, those with allergy to any of LA drugs or any included medications, reconstructive breast surgery, coagulopathy or patients on anti-coagulant, patients with psychiatric disorder, pregnancy, and patients less than 18 years old.

Preoperative evaluation: The patients were evaluated the day before surgery with a thorough medical history, clinical examination, and regular laboratory tests. All patients were told about the surgery and taught how to use the patient-controlled analgesia (PCA) pump (Master PCA, Fresenius vial S.A., France) and VAS, which is a 10-cm line with 0 cm indicating no pain and 10 cm indicating the most severe pain.⁶

Preanaesthesia preparation: Before the operation, all patients were present at block room, where the blocks were administered following the insertion of a peripheral IV line and the attachment of a multichannel monitor (Drager vista 120, Dragerwerk AG & Co. KGaA, Germany) that displayed heart rate (beats/min), mean non-invasive arterial blood pressure (mmHg), and oxygen saturation (%). (percent). Prior to the blocks, all of the patients were given intravenous midazolam (0.05 mg/kg) and fentanyl (25µg). 7 30 minutes following the anaesthetics, all patients were moved to the operating room (OR).

Group I: ESPB was carried out in this group with perfect aseptic method. 8 Left- or right-sided ESPB

was conducted with the patients in the sitting position, depending on the operative side, using a high-frequency (higher resolution than low-frequency) linear US probe (L25n, 13-6MHz, Sonosite S-Nerve, Sonosite Inc., USA). High-frequency probes provide a superior resolution but a lower penetration capability.⁹

Group II: PVB was carried out in this group under strict aseptic conditions. 8 PVB was conducted with a low-frequency (since more depth was needed to see the pleura) curved US probe with the patients in the sitting position, depending on the surgical side (C60n, 2-5 MHz, Sonosite S-Nerve, Sonosite Inc., USA). Low-frequency probes, on the other hand, penetrate deeper but have worse resolution.⁹

After checking for sensory dermatomes from the 2nd thoracic vertebra to the 6th, GA was induced to both groups. The anaesthetic technique in both groups was induced with fentanyl (1µg/kg) and propofol (2mg/kg), Tracheal intubation was facilitated with cisatracurium (0.15 mg/kg), anaesthesia was maintained with isoflurane (1-2%) in 100% oxygen and incremental doses of cisatracurium (0.03 mg/kg) guided by nerve stimulator (TOF-Watch SX, Organon, Ireland) train of four (TOF) was kept at 2 and fentanyl (25 µg) was given when HR and/or MABP increases more than 20% above pre-induction levels. Controlled ventilation was maintained at a tidal volume of (6 ml/kg) and at a rate of (10 breath/min), maintaining the end-tidal CO₂ at (32-35 mmHg) using the ventilator (Fabius GS- Drager-Germany). Anaesthesia was stopped at the end of the procedure, residual neuromuscular block was reversed with atropine 0.01 mg/kg and neostigmine 0.04 mg/kg, the trachea was extubated, and the patients were transported to the postoperative anaesthesia care unit (PACU) for the next 24 hours. A PCA pump (Master PCA, Fresenius vial S.A., France) was prepared by dissolving 20mg of nalbuphine in 20mL of normal saline to make 1mg/mL concentration of opioid solution. Patients were given the option of using PCA on their own. The PCA was set to a 2mL bolus with a 10-minute lockout duration. There was no infusion in the background.¹⁰

All patients were given 30mg ketorolac /8 hours IV as a standard postoperative analgesia in both groups.

All patients were subjected to:

Duration of the procedure in minutes was measured starting from administration of the LA drug (lidocaine 2%) until the complete injection of the 30 ml of 0.25% bupivacaine.

The examination of the sensory blockade was judged using an ice pack every 5 min for 20 min preoperatively as the onset of the block was identified at T4 dermatome.

The extension of the block was examined after 20 minutes and was identified as upper and lower limit of partial loss of cold sensation at dermatomes levels from T2 to T6.

Degree of sensory block was measured using an ice pack every 5 min for 20 min preoperatively by the used scale at T4 dermatome.

Duration of the block, time of first request of postoperative analgesia, total dose of consumed nalbuphine and satisfaction level.

Postoperative complications: LA toxicity, haematoma at the site of injection, pneumothorax, PONV, hypotension or bradycardia.

Statistical analysis:

The IBM SPSS software programme version 20.0 was used to analyse the data that was supplied into the computer. (IBM Corporation, Armonk, NY) Number and percent were used to describe qualitative data. The Kolmogorov-Smirnov test was employed to ensure that the distribution was normal. Range (minimum and maximum), mean, standard deviation, and median were used to characterise quantitative data. The significance of the acquired results was assessed at a 5% level. To calculate the difference between two or more sets of qualitative variables, use the Chi square test (2). The mean and standard deviation (SD) were used to express quantitative data (Standard deviation). ANOVA with repeated measures (repeated measures ANOVA): To compare more than two periods or stages of normally distributed quantitative variables, use the Post Hoc test (Bonferroni adjusted) for pairwise comparisons (HR, MABP). The Mann Whitney test is used to compare two groups with improperly distributed quantitative characteristics (VAS at rest & movement, degree of sensory block at T4, onset of the sensory block at T4, total dose of nalbuphine consumption in 24 hours).

RESULTS

Age: In group I, the age of the patients ranged between 47 and 81 years with a mean value of 62.96 ± 7.56 years, in group II, it ranged between 45 and 83 years with a mean value of 62.09 ± 10.95 years. Body weight: In group I, the weight of the patients ranged between 73 and 105 kg with a mean value of 85.35 ± 8.62 kg, in group II it ranged between 73 and 103 kg with a mean value of 86.04 ± 9.37 kg. Comparing both studied groups, there was no significant difference between the two groups regarding the age ($p = 0.756$) and the weight ($p = 0.795$) (Table 1).

The total dose of nalbuphine consumption in postoperative 24 hours in Group I ranged from 2 to 6 with a mean of 3.33 ± 1.63 mg, while it ranged from 2 to 6 with a mean of 3.14 ± 1.57 mg in Group II. There was no significant difference between both groups as regard the total dose of nalbuphine consumption in postoperative 24 hours ($p = 0.836$) (Table 2).

Satisfaction was measured using verbal rating scale for satisfaction (1-5) at the end of the study. In Group I patient verbal rating score was 3 in 2 (8.7 %) patients, 4 in 4 (17.4%) patients and 5 in 17 (73.9%) patients. While in Group II was 3 in 3 (13 %) patients, 4 in 5 (21.7%) patients and 5 in 15 (65.2%) patients. There was no significant difference between both groups as regard patient satisfaction (Table 3).

There were no complications recorded except for PONV, 1 patient in Group I and 2 patients in Group II and were treated by IV ondansetron 4mg. There was no significant difference between both groups as regard PONV (Table 4). There were no LA toxicity, haematoma at the site of injection, pneumothorax, hypotension or bradycardia.

Patient	Age (years)		Weight (kg)	
	Group I: ESP block at level of T4 with 30 ml of 0.25% bupivacaine.	Group II: TPV block at level of T4 with 30 ml of 0.25% bupivacaine.	Group I: ESP block at level of T4 with 30 ml of 0.25% bupivacaine.	Group II: TPV block at level of T4 with 30 ml of 0.25% bupivacaine.
Mean	62.96	62.09	85.35	86.04
\pm SD.	7.56	10.95	8.62	9.37
t(p)	0.313 (0.756)		0.262 (0.795)	

Table 1: Comparison between the two studied groups as regard the demographic data.

Patient	Group I: ESP block at level of T4 with 30 ml of 0.25% bupivacaine.	Group II: TPV block at level of T4 with 30 ml of 0.25% bupivacaine.
Not Received	17 (73.9%)	16 (69.6%)
Received	6 (26.1%)	7 (30.4%)
χ^2 (p)	0.107(0.743)	
Mean	3.33	3.14
\pm SD.	1.63	1.57
U(p)	19.5(0.836)	

Table 2: Comparison between the two studied groups as regard the total dose of nalbuphine (mg) consumption in 24 hours.

Degree of satisfaction	Group I (n = 23)		Group II (n = 23)		χ^2	Monte Carlo P
	No.	%	No.	%		
1	0	0.0	0	0.0	0.547	0.812
2	0	0.0	0	0.0		
3	2	8.7	3	13.0		
4	4	17.4	5	21.7		
5	17	73.9	15	65.2		

Table 3: Comparison between the two studied groups as regard patient satisfaction at the end of 24 hours.

Complications (PONV)	Group I (n = 23)		Group II (n = 23)		χ^2	Fisher Exact P
	No.	%	No.	%		
No	22	95.7	21	91.3	0.357	1.000
Yes	1	4.3	2	8.7		

Table 4: Comparison between the two studied groups regarding complications.

DISCUSSION

Regarding the demographic data (age and body weight), no significant difference was found between both groups. In both groups, in comparison with the preoperative HR and MABP there was no significant change at any of the postoperative studied times as regard HR and MABP.

This haemodynamic stability in PVB group can be illustrated by administration of single shot of 0.25% bupivacaine leading to unilateral sympathetic block. The ESPB has the same effect as It's classified as a peri-paravertebral regional procedure.⁵

In agreement to the present study, D'Ercole et al.¹¹ studied PVB in thoracic surgery and reported that compared to thoracic epidural, hypotension is uncommon after TPVB in normovolemic patients as a result of unilateral sympathetic blockade.

The haemodynamic stability of the PVB was shown in a study by Helal et al.¹² who compared thoracic epidural versus US guided TPVB in perioperative management for mastectomy. Although both techniques had comparable pain control but PVB group showed more significant haemodynamic stability in term of HR and MABP intra and post operatively when compared with the preoperative basal HR and MABP as well as a significant stability when compared to the epidural group both intraoperatively and up to 1 hour postoperatively.

Similarly, Soni et al.¹³ compared thoracic epidural and TPVB in patients underwent heart surgery with sedation, they stated that the HR and MABP were stable all through the operation and up to 2 hours postoperatively in the PVB compared to the epidural group. These results are compatible with the current results as the block was performed at T4. The cardiovascular effects of any regional block above T4 are due to high sympathetic block which will block the cardiac sympathetic outflow (T1 –T4) and accordingly lead to the bradycardia and hypotension

which lead to detrimental effect in compromised pattern.

In the current study, the total PCA nalbuphine consumption in postoperative 24 hours in ESPB group had a mean of 3.33 ± 1.63 mg.

In consistent to our results, Gurkan et al.¹⁴ found in their study that Patients who got single-shot US guided ESPB utilising 20 ml of 0.25 percent bupivacaine following breast surgery had a 65 percent reduction in total 24-hour morphine intake.

Correspondingly, Singh et al.¹⁵ studied 40 patients (20 in each group) underwent MRM. The 24-hour morphine consumption was less in US guided ESPB group when compared with the control group who received no block and it was statistically significant (1.95 ± 2.01 mg vs 9.3 ± 2.36 mg, $P = 0.01$).

To find all ESPB-related publications, a pooled review of 242 cases was done. Reports of ESPB single shot, continuous infusion, and intermittent bolus, as well as human and cadaveric trials, were all considered. This study stated that there was a reduction in opioid use in 76% of the cases which agreed with the present study.¹⁶

Meanwhile the total PCA nalbuphine consumption was of mean 3.14 ± 1.57 mg in PVB group.

Similarly, Wahba et al.¹⁷ and Abdel-Halim¹⁸ both found in their studies reduction in postoperative morphine consumption in patients who received PVB.

Comparing both groups, there was no significant difference between them as regard total PCA nalbuphine consumption ($p = 0.836$).

In agreement to the current study, Moustafa et al.¹⁹ in their study showed no significant difference between ESPB and PVB in MRM regarding the total dose of opioids in the first 24 hours postoperatively

(in ESPB group the mean amount of morphine was 6.17 ± 2.08 mg while PVB group the mean amount of morphine was 6.22 ± 2.09 mg).

Also El Ghamry et al.²⁰ in their study showed that no significant difference was observed regarding 24 hours postoperative morphine consumption between both groups which agreed with the present study.

In the current study, no significant difference between both groups as regard the recession of sensory block as in ESPB group the mean was 19.48 ± 2.5 hours while in PVB group, the mean was 18.96 ± 2.16 hours.

In agreement to the current study, Kumar et al.²¹ in their study showed that duration of action of ESPB was limited to 12–24 hours with traditional LA. However, they succeeded to increase the duration of ESPB over 72 hours by adding liposomal bupivacaine.

Similarly, Qian et al.²² in their study reported that the effective duration of single-injection PVB is <24 hours.

In addition, Parikh et al.²³ studied PVB to control Postoperative pain in patients underwent autologous breast reconstruction after mastectomy. They concluded that patients receiving a PVB showed a marked improvement in pain control at 2 hours and 24 hours postoperatively.

In ESPB group only one patient suffered from PONV while in PVB group only two patients suffered from PONV and they were treated by IV ondansetron 4 mg.

In agreement to the current study, El Ayoubi et al.²⁴ and Singh et al.¹⁵ studied ESPB in MRM and showed that no cases of PONV were noted after US guided ESPB.

Similarly, Fahy et al.²⁵ reported that patients who received PVB needed less postoperative anti-emetic drugs after mastectomy.

Comparing both groups, there was no significant difference between them as regard PONV. The decrease in PONV can be explained by the reduction in the amount of opioids needed after the block.

El Ghamry et al.²⁰ in their study recorded that there was no significant difference in PONV between ESPB and PVB groups after MRM which agreed with the present study.

In the current study no other complications were recorded such as pneumothorax or systemic toxicity as both blocks were performed under US guidance and only a concentration of 0.25% bupivacaine was used.

In consistent to the current study, Pace et al.²⁶ studied 1427 patients receiving PVB and found that

there was no incidence of pneumothorax due to the use of US which led to very few complications.

On the contrary, Naja et al.²⁷ discussed the failure rate and complications after thoracic and lumbar PVB performed in 620 adults and 42 children. And found that the incidence of pleural puncture was 0.8% and pneumothorax was 0.5% after PVB. This might be due to performing PVB using nerve stimulation approach not under the guidance of US.

López et al.²⁸ concluded that ESPB carries lower risk for critical complications as the LA deposit in the tissue plane, is away from the pleura.

On the contrary, Ueshima²⁹ recorded only one case developed pneumothorax 3 minutes following the administration of ESPB, without any information about the type and length of the needle used and without exclusion of patients with bullous lung disease.

On the other hand, Barrington and Kluger³⁰ showed that PVB is the most common cause of LAST, followed by upper extremity and trunk/lower extremity blocks. This might be due to the highly vascular muscle tissue surrounding the block area leading to fast spread of LA to the systemic circulation. They reported that using US guidance decreased the risk of LAST as it reduced the risk of intravascular and intramuscular injection and decreased the amount of LA used.

Correspondingly, Tulgar and Balaban³¹ in their retrospective study on 182 patients who had ESPB, observed LAST symptoms in three patients. No cardiovascular toxicity was reported. They explained this toxicity after ESPB by the spread of the LA to paravertebral and intercostal spaces. The highly vascular muscle tissue surrounding the block area leading to fast spread of LA to the systemic circulation.

There was no significant difference between both groups as regard the satisfaction. This can be explained by good pain control, easier access to postoperative analgesia using the PCA, less PONV and tolerable block relatively without complications.

In agreement to the present study, El Ayoubi et al.²⁴ in their pilot study recorded that in ESPB the overall satisfaction with analgesia had a median of 8.5 / 10.

Similarly, Arunakul and Ruksa³² reported that patients with PVB had lower incidence of postoperative pain, PONV and other serious complications. None of patients in this study was unsatisfied with anaesthetic techniques.

CONCLUSION

After (MRM) Modified Radical Mastectomy, Both (PVB) Paravertebral Block and (ESPB) Erector Spinae Plane Block provide effective pain control with a similar duration of analgesic effect, lower

postoperative opioid intake. Because it is a straightforward approach with a clear sonographic picture, US guided ESPB could be considered a safe and effective alternative to US guided PVB.

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