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Erector spinae plane block to reduces numeric rating scale, neutrophil-lymphocyte ratio and opioid consumption in post-operative modified radical mastectomy: A randomized, single-blind study

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Abstract

Background: Acute pain after surgery can result in an increased incidence of persistent pain, so analgesia techniques and pain medications are used in the perioperative period. Uncontrolled acute pain after surgery leads to impaired functional recovery, increased opioid use, and prolongation of treatment. Erector spinae plane block (ESPB) is used to manage pain for thoracic procedures. This study aimed to determine the effect of ultrasound-guided ESPB on pain score, opioid consumption, and inflammatory stress response of surgical wounds expressed by lymphocyte neutrophil ratio (NLR) after MRM surgery.

Patients and Methods: Twenty-eight female patients (18-60 years) undergoing MRM were divided into 2 groups of 14 each and were given general anesthesia and ESPB with 0.4 mL/kgBW of 0.125% levobupivacaine or control.

Results: The results showed that the NRS was significantly lower in the ESPB group up to the 24th hour post-operatively ($p<0.050$). The p values of NLR at the 12^{th} h ($p=0.007$) and 24^{th} h ($p=0.001$) after surgery. The NLR of the ESPB group was more stable. The decrease in opioid consumption was 63.26% in the ESPB group. The LOS in the ESPB group was shorter ($p=0.019$).

Conclusion: General anesthesia (GA) combined with ESPB in patients who underwent unilateral MRM surgery lowered NRS and NLR, lowered opioid consumption, and shortened patient length of stay in the hospital.

Keywords: ESPB, NRS, NLR, Opioid, LOS, MRM.

Introduction

Breast cancer is the most common type of cancer worldwide, making breast surgery one of the most frequent types of surgery performed today.[1] Patients who have undergone breast surgery have reported moderate to severe pain after breast surgery.(Leong et al., 2021) Acute pain after surgery can result in an increased incidence of persistent pain, so analgesia techniques and pain medications are used in the perioperative period.(Yuksel et al., 2022)

Uncontrolled acute pain after surgery is always associated with impaired functional recovery, delayed discharge from the post-anesthesia care unit, reduced patient satisfaction, increased morbidity and

mortality, prolonged length of stay in the hospital, and imposes a financial burden on patient families and healthcare systems.(Canikli Adıgüzel et al., 2023) To find out the mortality and morbidity of patients with breast cancer is to explore diagnostic markers for early diagnosis and prognosis.(Wei et al., 2016) The NLR is a good reflection of inflammation, which plays an important role in tumor progression and metastasis. NLR is a biomarker that conjugates two faces of the immune system.(Howard et al., 2019; Ishihara et al., 2021) NLR is an inflammatory immune response and stress response from the body to cancer.(Buonacera et al., 2022) An increase in neutrophils indicates an acute or chronic inflammatory response. An increase of neutrophils in the blood, related to inflammation that promotes tumors. Lymphocytes generate an adaptive immune response to eliminate incoming pathogens, infected cells, and, in reaction to malignant cells.(Song et al., 2021) Lymphocytes are well-known for their anti-tumor role. Therefore, a low number of lymphocytes may indicate low cell-mediated immunity.(Naszai et al., 2021) NLR is a simple marker of inflammatory response and has grown in popularity in recent years as a marker of emerging disease.(Buonacera et al., 2022; Canikli Adıgüzel et al., 2023; Naszai et al., 2021)

Regional anesthesia techniques not only reduce postoperative pain and reduce opioid use but also reduce the inflammatory response due to surgical wounds through the immune system mechanism.(Aykut, 2023) ESPB is a relatively new regional anesthesia technique for managing pain for acute or chronic pain after surgery. ESPB was first described by Forero et al. in 2016 for two patients with rib-related neuropathic pain.(Forero et al., 2016)

This study aimed to determine the effect of ultrasound-guided ESPB on pain score, opioid consumption, and inflammatory stress response of surgical wounds expressed by lymphocyte neutrophil ratio (NLR) after MRM surgery.

Patients and Methods

This was a prospective, single-blinded, randomized controlled trial in two groups. The study protocol was carried out in accordance with relevant guidelines and regulations and was approved by the Ethics Committee of the Faculty of Medicine, Gunung Jati University, Cirebon, no: 182/EC/FKUGJ/IX/2023 dated September 4, 2023, with the number of Research Protocol 00232132742122720230703000001. This research was carried out at the Waled Hospital Cirebon from April to October 2024. Informed consent for study participation was obtained from all patients and/or their legal guardians. No violation of the Helsinki Declaration occurred during the informed consent and data filling period.

The required sample size was calculated using the Harry King Normogram. The calculation of an adequate sample size was determined by the Harry King Normogram with an error rate of 5%. Based on Nomogram Harry King, the number of samples used was 28 people, or 90% of the population, divided into 2 groups. Female patients with American Society of Anesthesiologists (ASA) scores of 1-3, aged 18-60 years, undergoing unilateral MRM with general anesthesia, had no contraindications to peripheral regional anesthesia block and gave written informed consent were included in this study. Patients with pre-existing infection at the site of block injection, contraindications for regional anesthesia, history of drug abuse, pre-existing chronic pain, body mass index >25 kgBW/m2, sensitivity to the drugs to be given, presence of coagulopathic disorders, uncontrolled hypertension, ischemic heart disease, renal dysfunction, pre-existing neurological deficits, psychiatric diseases were excluded from the study. Patients were randomly allocated to groups A and B undergoing the applicable elective surgery preparation procedures.

Participants were fasted for at least 6 h, and oral premedication was administered with paracetamol 500 mg, dexketoprofen 50 mg, and pregabalin 75 mg orally 2 h prior to surgery. For Group A, ESPB installation was performed on patients in a sitting position. After aseptic action, a linear high-frequency (Philips) ultrasound probe (6-15 MHz) was placed in a longitudinal orientation, 3 cm lateral from the 6^{th} and 7^{th} spinosus processes of vertebrae thoracales.

The trapezius muscle, major rhomboid muscle, and erector spinae were identified on the surface of the transversus process that showed a hyperechoic. The puncture site was local anesthesia of 1 ml of 2% lidocaine, and using an in-plane ultrasound approach, the PlexoLong NanoLine 19 G x 100 mm was inserted from the caudal to cranial direction until the catheter tip was placed between the erector spinae muscle and the Vertebra Thoracal 4-5 procesus transversus. Patients were monitored for complications including intravascular injections, pneumothorax, hypotension, and bradycardia. All subjects were given general anesthesia (GA). Extubation after the surgery was completed, and the patient is transferred to the recovery room. Group A would receive dexketoprofen 50 mg/8 h, paracetamol 500 mg/4 h of infusion, and administration of local anesthetic drugs through ESPB PlexoLong catheters. In this study,

0.125% Levobupivacaine 0.4 mL/kgBW was used intermittently every 4 h. The maximum daily dose was 400 mg (320 ml 0.125% Levobupivacaine).(Merjavy, n.d.) Group B would receive dexketoprofen 50 mg/8 h and paracetamol 500 mg/4 h of infusion as analgesics. Furthermore, NRS, NLR, and opioid consumption (fentanyl) up to 24 h after surgery were recorded. When the patient entered the recovery room, it was recorded at 0 h, then recorded every 4 h for 24 h after surgery. Vital signs, NRS, and NLR were recorded, and intravenous (IV) fentanyl 0.5 μg/kgBW was used for rescue analgesia. Rescue analgesic was given to the subjects if the intensity of pain was obtained with an NRS value of ≥4. The time of first administration of rescue and the total need for opioids in the patient were recorded.

Univariate analysis aimed to explain or describe the characteristics of each group. Each group was tested for normality from Shapiro Wilk. The value of data normality is $p>0.05$. Quantitative variables were compared using an independent sample t-test or a Mann-Whitney test (if the data are not normally distributed between the 2 groups). The chi-square test was applied to analyze the relationship between categorical variables that are non-parametric. A significant correlation was concluded if $p<0.05$. The International Business Machines Statistical Package for the Social Sciences version 29 software (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

Results

There were 28 eligible subjects, with 14 subjects in each group (Fig. 1). Data on demographic characteristics, age, weight, height, mean arterial pressure, ASA physical status, resting and activity NRS, neutrophil, lymphocyte, and NLR levels, and duration of surgery showed similar results in both groups ($p>0.050$). The baseline demographic characteristics of the subjects are presented in Table 1. There was no significant difference between the two groups of NRS rest ($p=0.200$) or NRS active ($p=0.105$) before surgery. After surgery, the NRS of the two groups differed significantly, except for the 8^{th} h active NRS ($p=0.057$). The NLR preoperative of the two groups was not significantly different ($p=0.097$). The post-operative NLR at 12^{th} h ($p=0.007$) and 24^{th} h ($p=0.001$) had significant differences in both groups. The NLR in group A was calmer and more stable in fluctuations compared to the control group. Table 2.

The use of opioids for rescue analgesic (fentanyl 0.5 μg/kgBW IV) in both groups had significant differences. In the ESPB group, there were 9 times of rescue analgesic administration (18.37%), while in the control group, there were 40 times of rescue analgesic administration (81.63%). Time required by the subject to leave the ward in group A was shorter than control, with a significant difference ($p=0.019$). The length of treatment days after surgery was calculated from the time the patient enters the recovery room until the surgeon declared that they can go home. Table 3.

Discussion

In this study, patients with mammary carcinoma who underwent MRM surgery with GA and ESPB showed changes in the NRS scale. NRS was assessed at rest, and active showed a significant decrease. The pain score on the NRS scale in this study was found to be significantly lower in the ESPB group compared to the control group at 0, 4, 8, 16, 20, and 24 h after surgery ($p<0.050$). Only at the 8^{th} h of active NRS between the ESPB group and the control group was there no significant difference. This might be because the NRS examination at 8^{th} h was carried out on subjects who had just woken up from a night's sleep so that the subject was more likely to feel pain if moved in the upper limb. However, overall the 24 h NRS value was lower in the ESPB group than in the control group, both in the NRS assessment at rest and when the patient moved the upper arm parallel to the area after surgery. Figure 2 and 3.

A study by Nair et al. found lower pain scores (VAS=1) at 1^{st}, 3^{rd}, and 6^{th} h after surgery in five patients undergoing mastectomy.(Nair et al., 2018) Bonvicini et al., also reported NRS scores of <3 at up to 24 h of surgery in patients undergoing breast cancer surgery.(Bonvicini et al., 2018) Xin et al.'s research showed that the results of pain score after operative within 24 hours showed a significant

difference (p=0.036) between the GA group and ESPB compared to the GA group alone.(Xin et al., 2022)

Score NRS rest and active in the ESPB group were significantly lower than in the control group at 1, 6, 12, 24, and 48 h after surgery ($p<0.05$) and ESPB group consumed rescue analgesics less than the control group ($p<0.001$).(He et al., 2020)

A systematic review and meta-analysis of 11 randomized controlled trials conducted by Zhang et al. involved 679 patients. The study's results showed that compared to the GA group, the ESPB group showed a decrease in morphine use in the first 24 hours after surgery ($p<0.01$). In addition, the ESPB group showed lower NRS scores than the GA group in four time periods (1, 6, 12, and 24 h after surgery). The conclusion stated that ESPB was more effective in reducing morphine use and pain intensity in the first 24 hours after MRM surgery compared to GA alone.(Zhang et al., 2021)

Both groups had VAS scores at both rest and cough, which were the same at 0 h, 3 h, 6 h, and 12 h ($p>0.05$). However, the epidural group had a higher VAS score, which was statistically more significant than the ESPB group ($p\leq0.05$) at 24 hours, 36 hours, and 48 hours, but the mean VAS in the epidural group was ≤ 4 both at rest and during coughing.(Nagaraja et al., 2018)

The use of an ESPB catheter fitted in the 8^{th} thoracic vertebra could provide effective perioperative analgesia for major surgery of the lower abdomen. Another advantage of continuous ESPB is the lack of hypotension and minimal risk of serious complications such as epidural hematomas or epidural abscesses. This suggests that this technique might be an alternative option for thoracic section surgery analgesia.(Restrepo-Garces et al., 2017)

Table 2 shows that preoperative NLR had no significant difference between the two groups. The NLR in the ESPB group at 12^{th} h and 24^{th} h was lower than that of the control. Lower NLR is usually associated with prognostic factors that reflect maintained immune balance. NLR is often characterized by increased neutrophils and/or decreased lymphocytes. Increased NLR generally occurs < 6 hours after physiological stress; NLR acts as a marker of acute stress earlier than laboratory parameters. Lower NLR is usually associated with immune balance.(Buonacera et al., 2022) In cancer patients, higher NLR has been associated with poorer prognosis.(Li et al., 2023) Li et al. in China studied 584 patients with rectal cancer who had undergone primary tumor resection. Patients were divided into two groups, high and low NLR. It was found that the high NLR group had a survival rate of 41%, and in the lower NLR group, the survival rate was 74.4% ($p < 0.001$). Howard et al. retrospectively studied 5,363 patients with cancer. The results mentioned that patients with stage IV cancer showed much higher neutrophils and much lower lymphocytes than all other stages ($p < 0.00001$), hence a much higher NLR.

We found that the use of rescue analgetic fentanyl 0.5 μg/kgBW in the ESPB group was 9 times (18.37%) and as many as 36 times (81.63%) of rescue analgetic administration in the control. Where

the provision of analgetic rescue is given after the subject's NRS is assessed every 4 hours. The Mann-Whitney test found that at all monitoring hours, there was a significant difference in the use of analgesic rescue between the two groups. In the ESPB group, the use of analgetic rescue decreased by 63.26%. A study by Sahrma et al. showed a 42% decrease in 24-hour morphine consumption in the block group.(Sharma et al., 2020) Similarly, a randomized controlled trial by Gurkan et al. found a 65% reduction in 24-hour morphine consumption in the ESP group compared to the control ($p<0.001$).(Gürkan et al., 2018) The difference in the consumption of 24-hour rescue analgesics in our study compared to other studies could be due to different analgesic regimens. In this study, a fentanyl 0.5 μg/kgBW bolus was used while Sharma used morphine via a patient control analgesia (PCA) device (1.5 mg bolus, 20-minute lock interval) in the postoperative period.(Sharma et al., 2020) Gurkan et al. used morphine via PCA device (1 mg bolus, 8-minute lock interval, maximum 6 mg/hour) after surgery.(Gürkan et al., 2018) Aksu et al. also reported a 75% reduction in 24-hour morphine consumption in the ESPB group compared to the placebo group. Morphine consumption was 3.02±2.06 mg in the block group and 13.2±4.98 mg in the control group. This can be explained by the fact that patients received bilevel blocks, in thoracal-2 and 4 vertebrae resulting in lower postoperative NRS scores at 12 and 24 hours postoperatively and lower morphine consumption.(Aksu et al., 2019) Of the 60 patients, the average morphine consumption during the post anesthesia care unit (PACU) period in the ESPB group and in the placebo group ($p=0.004$) were included. The mean VAS during the first 24 hours was 3,944 in the ESPB group and 5,193 in the placebo group ($p=0.046$).(Holas et al., 2023)

This study also compared the length of hospital stay of the two groups, where the result was that the ESPB group (3.14±0.36) had a shorter duration of stay in the hospital compared to the control group (3.38±0.70) with a significant difference of 0.019 ($p<0.05$). Yao et al. also reported a lower average time to exit the recovery room after anesthesia in the ESPB group at 17.2 (±2.7) minutes compared to 28.4 (±2.9) minutes in the control group.(Yao et al., 2020) Patients usually need high doses of opioids for the first 3 days after surgery to relieve pain, resulting in a longer hospital stay.(Liu et al., 2021)

In this study, several limitations were observed, one of which was that a larger sample size was needed to obtain statistically stronger data. The follow-up period, where in this study only short-term measurements were made, namely up to 24 hours after surgery. By extending the follow-up time to 72 hours, it can be used to determine the long-term effects of ESPB. The examination of the NRS scale at night when the subject is sleeping can be biased in the NRS assessment.

In conclusion, this study has shown that ESPB-guided ultrasound can prove to be a safe and effective analgesia technique for analgetics after MRM surgery. ESPB is effective for postoperative analgesics and can significantly reduce opioid consumption and accelerate functional recovery in patients undergoing MRM surgery. The importance of NLR as a predictor of inflammatory response in cancer

patients and with ESPB can lower NLR, thereby reducing stress response. Therefore, authors strongly recommend this technique as part of the multimodal analgesia protocol in MRM surgery or even for surgery on the abdomen and surrounding area; even normal delivery, it is possible that ESPB will have the same effect. Further studies comparing this technique with other regional techniques are needed to identify the most appropriate technique in MRM.

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Conflicts of interest

Authors declare no conflicts of interest.

Authors' contributions

Conceptualization: MRA, AAAH.

Data collection: DPP, LT.

Data analysis: MRA, AAH, BB, RP.

First draft of manuscript: MRA, AAAH, AMTM, MDD, CWT.

All authors significantly contributed to and approved the submission of this manuscript.

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Tables

Table 1. Baseline Characteristics

Variables	Group A (n=14)	Group B (n=14)	p
Age (years), mean±SD	49.1±7.3	47.4±9.5	0.298
Weigth (kg), mean±SD	55.6±6.6	54.6±7.6	0.334
Heigth (cm)	153.2±5.8	153.8±4.2	0.384
BMI (kgBW/m^2)	23.7±2.3	23.0±2.6	0.143
ASA physical status			0.411
1, n (%)	6 (42.9%)	6 (42.9%)	
2, n (%)	5 (35.7%)	4 (28.6%)	
3, n (%)	3 (21.4%)	4 (28.6%)	
Pre-operative NRS, median (min-max)			
At rest	4 (3-6)	4 (2-6)	0.201
At active	5 (4-7)	4.5 (2-6)	0.105
NLR, mean±SD	3.6±1.1	4.4±1.9	0.097
Duration of Surgery (min)	105.4±10.6	107.1±13.8	0.352

Data are expressed as mean±SD or number.
SD, standard deviation; BMI, Body Mass Index; NRS, Numeric Rating Scale; SBP, Systolic Blood Pressure; DBP, Dyastolic Blood Pressure; MAP, Mean Arterial Pressure; HR, Heart Rate; NLR, neutrophil Lymphocyte Ratio; ASA, American Society of Anaesthesiologists.

Table 2. Primary study outcomes.

Variables	Group A (n=14)	Group B (n=14)	p
NRS in RR, median (min-max)	3 (2-5)	4 (3-6)	0.020
NRS at 4 h, median (min-max)			
At rest	3 (2-4)	4 (2-6)	0.006
At active	3 (2-4)	4 (2-7)	0.020
NRS at 8 h, median (min-max)			
At rest	2 (1-4)	3 (2-5)	0.020
At active	3 (1-4)	3 (2-6)	0.057
NRS at 12 h, median (min-max)			
At rest	2 (1-3)	3 (2-5)	0.031
At active	2.5 (2-4)	3.5 (2-6)	0.047
NRS at 16 h, median (min-max)			
At rest	2 (1-3)	3 (2-4)	0.005
At active	2 (1-3)	3 (2-4)	0.002
NRS at 20 h, median (min-max)			
At rest	2 (1-3)	3 (2-3)	0.001
At active	2 (1-3)	3 (2-4)	0.001
NRS at 24 h, median (min-max)			
At rest	1 (1-2)	2 (2-4)	0.001
At active	1 (1-2)	2.5 (2-5)	0.001
NLR, mean±SD			
Pre-operative	3.6±1.1	4.4±1.9	0.097
12 h	7.7±1.5	15.3±3.5	0.007
24 h	4.2±1.0	7.8±1.7	0.001

Variable data are expressed as median (range minimal – maximal); SD, standard deviation; NRS, numeric rating scale; NLR, neutrophil lymphocyte ratio; LOS, length of stay.

Table 3. Secondary study outcomes.

Variables	Group A (n=14)	Group B (n=14)	p
Analgetic Rescue, n (%)	9 (18.4)	40 (81.4)	0.027
LOS after surgery (days), mean±SD	3.1±0.4	3.4±0.7	0.019