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ORIGINAL RESEARCH REGIONAL ANESTHESIA

Analgesic efficacy of ultrasound-guided retrolaminar block and erector spinae plane block in modified radical mastectomy: a randomized controlled study

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ABSTRACT

Background & objective: Modified radical mastectomy (MRM) is the most commonly performed surgical procedure in breast cancer patients and is usually associated with severe postoperative pain. The peripheral nerve block techniques have been suggested in addition to the traditional opioid and non-opioid analgesics to manage acute post-mastectomy pain. We compared the analgesic efficacy of retrolaminar block (RLB) with erector spinae plane block (ESPB) in patients undergoing MRM, with an aim to establish the efficacy of one over the other.

Methods: This randomized single-blind study included 60 female patients scheduled for MRM under general anesthesia and randomized into two equal groups. The RLB Group (n = 30) received a preoperative ultrasound-guided RLB with 20 ml levobupivacaine 0.25%. The ESPB Group (n = 30) received an ESPB with 20 ml levobupivacaine 0.25%. The primary outcome measure was the total postoperative morphine consumption. Secondary outcomes were total intraoperative fentanyl consumption, duration of analgesia, pain intensity (NPRS score), hemodynamic changes, and adverse effects.

Results: The intraoperative fentanyl and postoperative morphine consumption were lower in the ESPB group than the RLB group, but the difference was near statistical significance (P = 0.066 and 0.058, respectively). Pain intensity at rest and on movement was comparable in both groups in the postoperative period, except that NPRS on movement was significantly lower in the ESPB group compared to RLB group (P = 0.039). Both techniques offered hemodynamic stability and there was no significant difference in the occurrence of PONV (P = 0.559).

Conclusion: Ultrasound-guided single-point retrolaminar block and erector spinae plane block are safe and effective postoperative analgesic techniques for patients undergoing modified radical mastectomy with comparable effects in terms of opioid consumption, duration of analgesia, pain intensity, and occurrence of PONV.

Abbreviations: BMI - body mass index; ESPB - erector spinae plane block; ESM - erector spinae muscle; MRM - Modified radical mastectomy; NPRS - Numerical pain rating scale; RLB - retrolaminar block;

Keywords: Analgesics; Opioids; Breast Neoplasms; Postoperative Pain; Mastectomy; Nerve block

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1. INTRODUCTION

Globally, breast cancer remains the most prevalent cancer among females, with an estimated incidence of 31% and mortality of 15%.[1] Surgery is the foremost treatment in managing breast cancer, where modified radical mastectomy (MRM) is the most commonly performed procedure.[2] This procedure implicates vigorous tissue dissection and seroma formation with many postoperative complications. Pain is the main complaint following MRM, affecting up to 50% of women,[3] and 25-60% develop persistent chronic postmastectomy pain.[4]

Therefore, adequate pain control is crucial to postoperative management after MRM. Numerous analgesic methods have been suggested to reduce acute post-mastectomy pain. Opioid-related adverse events include nausea and vomiting, respiratory depression, sedation, and dizziness.[5]

Most mastectomy-related pain originates from the chest wall's sensory nerves.[6] The peripheral nerve block techniques have gained increased interest in treating postoperative pain. The erector spinae plane block (ESPB) is one of these techniques that proved effective in various surgical procedures, including breast surgery.[7,8] It encompasses injecting the local anesthetic (LA) solution deep into the erector spinae muscle (ESM), which eventually spreads through the paravertebral space.[9] Ultrasound-guided retrolaminar block (RLB) is another approach that was found to be effective for pain relief after thoracic surgery.[10,11] In RLB, LA is injected into the space between the ESM and the lamina of the thoracic vertebra.[12]

Both techniques are considered variants of paravertebral block; however, prospective studies comparing RLB and ESPB are limited. Therefore, this study was designed to compare the analgesic efficacy of ultrasound-guided retrolaminar block and erector spinae plane block in patients undergoing modified radical mastectomy.

2. METHODOLOGY

This randomized single-blinded study was conducted at the National Cancer Institute (NCI), Cairo University, Cairo, from October 2022 to March 2023. The study was approved by the institutional review board and the scientific committee of the anesthesia department of the NCI and Faculty of Medicine, Cairo University. All participants provided written informed consent before enrollment in the study after fully explaining the procedures and possible complications.

The study involved 60 female patients scheduled for MRM under general anesthesia (GA) with the following inclusion criteria: age 18 to 65, ASA class II or III, and body mass index (BMI) of 20-35 kg/m^2. Patients with known sensitivity or contraindication to the drugs used in the study, history of psychological disorders or chronic pain syndromes, contraindication to regional anesthesia (local sepsis, pre-existing peripheral neuropathies, coagulopathy), severe respiratory or cardiac conditions, or advanced liver or kidney disease were excluded.

Preoperative assessment included thorough history taking, physical examination, and laboratory and radiological investigations. The patients were instructed to report pain using the Numeric Pain Rating Scale (NPRS), where 0 = no pain and 10 = worst imaginable pain. All patients were premedicated with IV midazolam 0.01-0.02 mg/kg 30 minutes before surgery.

The patients were randomly allocated into one of the two equal groups using computer-generated random numbers in opaque closed envelopes. An independent statistician performed the randomization. The grouping was revealed only when the patient was transferred to the pre-anesthetic room. The RLB Group (n = 30) received a preoperative ultrasound-guided retrolaminar block using 20 ml of levobupivacaine 0.25%. The ESPB Group (n = 30) received a preoperative ultrasound-guided erector spinae plane block using 20 ml of levobupivacaine 0.25%. In both blocks, a Fujifilm Sonosite M-Turbo Ultrasound system linear probe was used (SN.04RQZ6). After performing blocks lung ultrasound was performed to exclude pneumothorax.

2.1. Retrolaminar block technique

The block was performed under complete aseptic conditions. The ultrasound probe was placed on the back in a transverse orientation on the lateral side of the posterior median line to identify the lamina of the 5th thoracic vertebra, ESM, and transversospinalis muscles of the target segment. A skin wheal was raised with 3 ml of 1% lidocaine 2-3 cm medial to the transducer. A 38-mm 22-gauge regional block needle 'B Braun PERIFIX®'was advanced in an in-plane technique. When the puncture needle touched the lamina, with no blood, gas, or cerebrospinal fluid observed on aspiration, 20 mL of 0.25% levobupivacaine was administered between the transversospinalis muscle and the lamina. The LA spread between the lamina and the ESM indicated a successful block.

2.2. Erector spinae plane block

The ultrasound probe was placed on the back in a transverse orientation to identify the tip of the T5 transverse process as flat, squared-off acoustic shadow with a faint image of the pleura visible. When the tip of the transverse process is centered on the ultrasound screen, the probe was rotated to a longitudinal

orientation. In the parasagittal view, the following layers were visible superficial to the acoustic shadows of the transverse processes: skin and subcutaneous tissue, trapezius, ESM, and T5 transverse process. A skin wheal was made using 3 ml of 1% lidocaine; then, the block needle was inserted in-plane in a cranial-to-caudal direction until contact was made with the T5 transverse process. The correct location of the needle tip in the fascial plane deep to the ESM was confirmed by injecting 0.5-1.0 ml of normal saline and seeing the fluid lifting the ESM off the transverse process without distending the muscle. After aspiration to avoid intravascular injection, levobupivacaine 0.25% 20 ml was injected.

2.3. Anesthetic management

All patients were monitored continuously including electrocardiography, non-invasive blood pressure, peripheral O_2 saturation, and end-tidal CO_2 throughout the surgical procedure. Anesthesia was induced with fentanyl 2 μg/kg and propofol 2 mg/kg IV. Tracheal intubation was facilitated with rocuronium 0.5 mg/kg IV. Anesthesia was maintained with inhaled sevoflurane 2.0-2.5% in oxygen-enriched air (FiO_2 = 0.5). Maintenance doses of rocuronium 0.1 mg/kg were provided every 30 min. Inj. paracetamol 500 mg and ketorolac 30 mg were injected as a part of multimodal analgesia. Rescue analgesia of fentanyl 1 μg/kg was given if the mean arterial blood pressure (MAP) or heart rate (HR) rose above 20% of the baseline values. The patients were mechanically ventilated at appropriate settings to keep end-tidal CO_2 at 30-35 mmHg.

The first reading of MAP and HR was taken before induction of GA as a baseline reading. Second reading was taken immediately before incision and then at 30-min intervals intraoperatively. Hypotension (reduction > 20% of baseline reading) was treated with normal saline and/or inj. ephedrine 5 mg in incremental doses to maintain MAP above 70 mmHg. The residual neuromuscular blockade was reversed using neostigmine 0.05 mg/kg and atropine 0.02 mg/kg. Extubation was done after complete recovery of the airway reflexes.

Postoperatively the pain score, MAP, and HR were noted immediately on arrival to PACU and every 2 h. Multimodal analgesia was provided as paracetamol infusion and ketorolac 30 mg/8 h IV. Rescue analgesia was provided as morphine 3 mg IV boluses when the pain score ≥ 4. Maximum dose of 0.5 mg/kg/24 h of morphine was allowed. Side effects such as nausea, vomiting, sedation, hallucinations, and respiratory depression (respiratory rate < 10/min) were recorded. Moderate or severe postoperative nausea and vomiting (PONV) was treated with inj. ondansetron 0.1 mg/kg IV.

The primary outcome measure was the total morphine consumed postoperatively for 24 h. Secondary outcome measures were the total intraoperative fentanyl consumption, duration of analgesia, pain intensity, hemodynamic changes, PONV, block-related complications, and patient satisfaction. Duration of analgesia was defined as the time from the block performance to the first postoperative rescue analgesic administrated upon patient request.

2.4. Sample size

Assuming an actual difference in mean morphine consumption between the two groups of 2 mg (i.e., 12-10 mg), and a pooled standard deviation of 10 mg, the study requires a sample size of 26 for each group (i.e., a total sample size of 52, assuming equal group sizes), to achieve a power of 80% and a level of significance of 5%, for declaring that RLB is not inferior to the ESPB at -5 mg margin of non-inferiority (assuming that a larger mean is desirable). The sample is increased to 30 patients per group to accommodate non-parametric testing.

2.5. Statistical analysis

We used IBM© SPSS© Statistics version 23 (IBM© Corp., Armonk, NY, USA) for statistical analysis. Numerical data were expressed as means and standard deviations or median and ranges as appropriate. Qualitative data were expressed as frequency and percentage. Chi-square test was used to examine the

relation between qualitative variables. The groups were compared for quantitative data using independent sample t-test or Mann-Whitney test. Comparison of repeated measures was made using ANOVA for repeated measures. A $P < 0.05$ was considered significant.

3. RESULTS

There were no significant differences between the two groups in age, weight, height, BMI, side of MRM, and ASA physical status (Table 1).

Table 2 shows that apparently, the intraoperative fentanyl and postoperative morphine consumption were lower in the ESPB group compared to the RLB group; however, the difference was only near statistical significance ($P = 0.066$ and 0.058, respectively). Throughout the postoperative period, the pain scores at rest and on movement were comparable in both groups, except that score on movement was significantly lower in the ESPB than in RLB ($P = 0.039$).

The heart rate and blood pressure showed slight changes during the pre and postoperative periods. However, all readings were within the clinically accepted ranges (Figure 1, 2).

Table 1: Baseline characteristics of the two studied groups

Variables	RLB Group (n = 30)	ESPB Group (n = 30)	P-value
Age (y)	54.9 ± 7.4	47.3 ± 11.05	0.106
Body weight (kg)	81.9 ± 1.5	76.6 ± 2.42	0.071
Height (m)	1.66 ± 0.8	1.65 ± 0.05	0.856
Body mass index (kg/m^2)	29.9 ± 4.4	27.8 ± 4.4	0.076
Side of surgery (Right/Left)	17/13	11/19	0.121
ASA class (II/III)	26/4	27/3	0.688

Data are expressed as mean ± SD

Table 2: Analgesic profile of the two studied groups

Parameter	RLB Group (n = 30)	ESPB Group (n = 30)	P-value
Intraoperative fentanyl (µg)	164.0 ± 42.6	140.0 ± 48.1	0.066
Duration of analgesia (h)	10.9 ± 3.0	8.5 ± 2.3	0.477
No. of patients requiring morphine	25 (83.3)	20 (66.7)	0.136
Postoperative morphine (mg)	7.0 ± 2.1	5.6 ± 2.6	0.058
NPRS at rest			
Immediate	2 (0-6)	2 (0-4)	0.299
After 2 h	2 (0-5)	2 (0-5)	0.206
After 4 h	2 (0-5)	2 (0-6)	0.476
After 8 h	2 (0-5)	2 (0-7)	0.479
After 12 h	2 (0-6)	2 (0-4)	0.269
After 24 h	2 (0-6)	2 (0-5)	0.793
NPRS with movement			
Immediate	2 (0-7)	1 (0-3)	0.039
After 2 h	2 (0-6)	2 (0-5)	0.090
After 4 h	3 (0-6)	2 (0-6)	0.075
After 8 h	3 (0-6)	3 (0-7)	0.243
After 12 h	3 (1-7)	2 (1-6)	0.063
After 24 h	3 (1-6)	3 (1-7)	0.870

Data are expressed as mean ± SD, number (%), or median (range)

Seven patients in the ESPB group and nine in the RLB group experienced mild to moderate PONV with no significant difference between the two groups (P = 0.559).

4. DISCUSSION

This study demonstrated that RLB and ESPB have comparable analgesic efficacy in patients subjected to MRM for breast cancer management. There were no significant differences between the two techniques in postoperative morphine consumption, as well as intraoperative fentanyl consumption, duration and analgesia, pain intensity for 24 h postoperatively, and frequency of PONV.

The RLB was introduced as a new alternative to paravertebral block (PVB) and proposed to be an easier and more direct substitute to the classical PVB. The RLB needle injects the LA after contacting the lamina of the vertebra.[13] ESPB was suggested as another alternative to PVB, where the needle is inserted more laterally to reach the tip of the transverse process. The needle tip is advanced to a more superficial point than PVB to inject the local anesthetic between the transverse process and the erector spinae muscle.[14]

So far, the mechanism of the analgesic effects of RLB and ESPB has not been clarified. Despite the few centimeters difference in injection sites of both techniques, RLB may act via deep dispersion as PVB, whereas ESPB primarily affects the lateral cutaneous branch and small branches of the intercostal nerve through a transverse distribution to provide the analgesic effect.[15,16]

The lateral cutaneous and anterior branches of the intercostal nerves play a critical role in conducting postoperative pain signals in breast cancer surgery.[17] Elsharkawy et al. illustrated that the retrolaminar space is connected laterally to the interfacial plane between the serratus anterior and external intercostal muscles, where the lateral cutaneous branch runs.[18] Therefore, blocking the lateral cutaneous branch by RLB could contribute to the postoperative analgesia following breast cancer surgery.

Previous cadaveric studies reported inconclusive

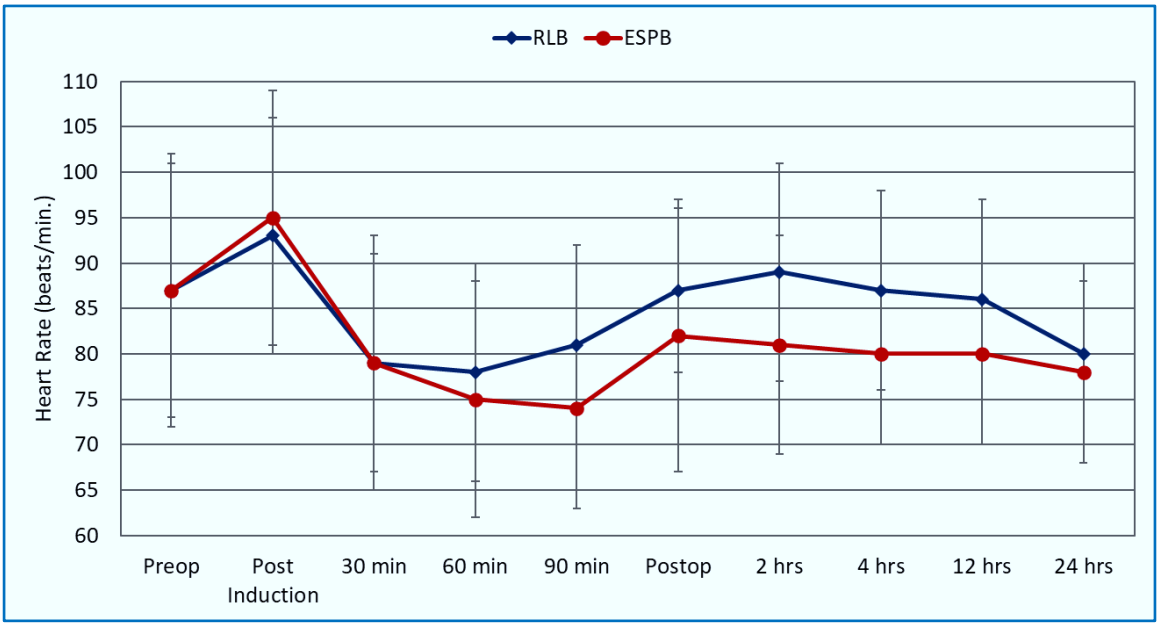

Figure 1: Changes in heart rate during the intra- and postoperative periods in the two studied groups

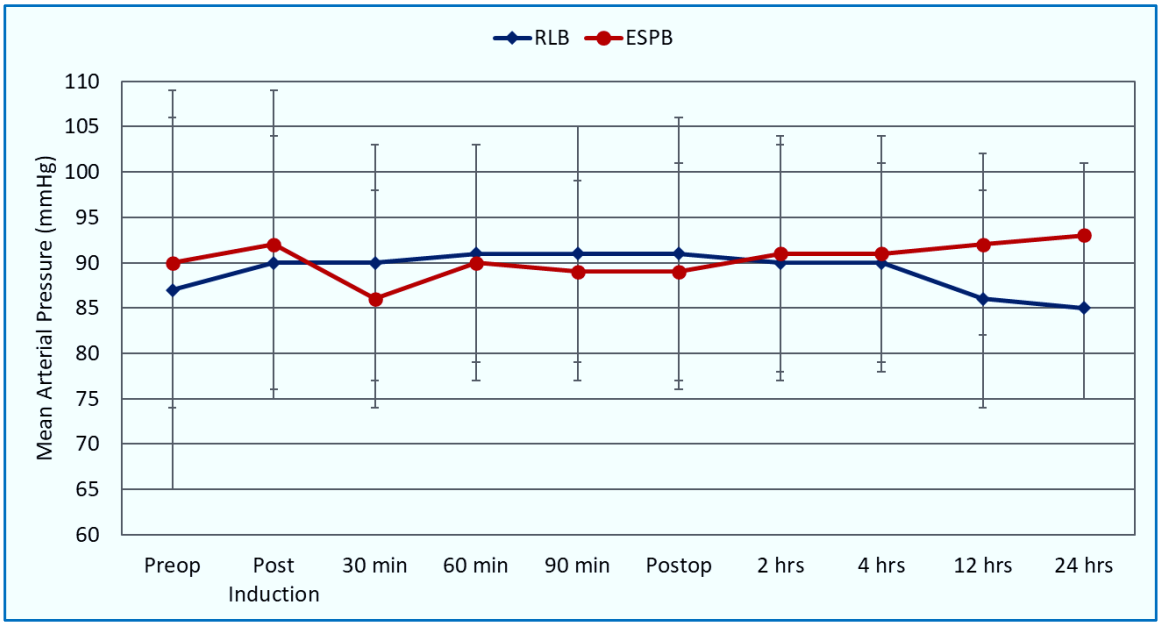

Figure 2: Changes in mean arterial pressure during the intra- and postoperative periods in the two studied groups

findings. Adhikary et al. demonstrated contrast dye diffusion to intercostal spaces over 5 to 9 levels after 20 mL in ESPB but to one segment only following RLB.[19]

n another study, the dye injected for ESPB did not enter the paravertebral space or stain the intercostal nerves.[20] On the contrary, Onishi et al. confirmed lateral distribution following ESPB, but the diffusion into the paravertebral space was limited in ESPB and RLB.[16] On the other hand, Yang et al. demonstrated more lateral dye distribution after ESPB compared to RLB.[21]

A recent prospective, randomized, controlled clinical trial demonstrated equivalent analgesic efficacy of RLB and ESPB after breast surgery.[22] They injected 20 mL of 0.375% levobupivacaine at the fourth thoracic vertebra. The authors found no significant difference between the

two approaches in the duration of analgesia, intraoperative remifentanil consumption, or pain intensity. In the current study, 20 mL of 0.25% levobupivacaine was administered in both blocks. There is no consensus about the appropriate volume and concentration of local anesthetic required for ESPB. It has been performed using 10-40 ml of ropivacaine, levobupivacaine, or bupivacaine at concentrations of 0.5%, 0.25%, or 0.375%.[23] It has been shown that RLB with 20 mL is more satisfactory than 10-15 mL and that 25 ml did not make a difference.[12]

Despite being a more recent technique, ESPB has been repeatedly investigated in breast surgery. A meta-analysis including 11 randomized controlled trials involving 679 patients examined the analgesic efficacy of ESPB after breast cancer surgery. The authors concluded that ESPB effectively reduced postoperative morphine consumption and pain intensity within the first 24 h compared with GA alone.[24] On the other hand, reports about the effectiveness of RLB in breast surgery are limited. It was found to prolong the analgesic duration of analgesia after breast cancer surgery with significant pain reduction.[15] On the contrary, Hwang et al. showed that single injection RLB did not reduce postoperative analgesic requirements or pain intensity after breast surgery.[25] A prospective, randomized, double-blinded study compared the analgesic profile of continuous RLB and PVB after MRM under GA. Continuous RLB was satisfactory after mastectomy and was not inferior to PVB except for the first 24 h.[12]

5. LIMITATIONS

The study was a single-center and small-sample one. Multicenter large-sample clinical trials are required to confirm the conclusions of this study. We calculated the sample size based on the assumption that postoperative analgesia of RLB was non-inferior to ESPB, which might weaken the statistical power to detect the difference. We used a particular volume and concentration of one type of LA. Thus, we cannot generalize the results for other types and different volumes of LAs. In fact, the optimal dose of LA and the method of RLB (one-shot or continuous injection, single-level or multi-level) need additional investigations.

5. CONCLUSION

Ultrasound-guided single-point retrolaminar block and erector spinae plane block are safe and effective postoperative analgesic techniques for patients with breast cancer subjected to modified radical mastectomy. There is no difference between the two approaches in terms of opioid consumption, duration of analgesia, pain intensity, and occurrence of PONV. The two techniques were hemodynamically stable during surgery. Future research is recommended to verify the anatomical mechanisms of action of both blocks, the ideal volume and concentration of local anesthetics required for adequate effect, and the appropriate method of retrolaminar block.

7. Data availability

The numerical data generated during this research is available with the authors.

8. Conflict of interest

The study utilized the hospital resources only, and no external or industry funding was involved.

9. Ethical considerations

The study was approved by institutional ethical committee vide their letter No. MS-492-2022.

The study was registered with ClinialTrials.gov No.: NCT06322316.

Written informed consent was obtained from every participant of the study.

10. Authors' contribution

AMS: Corresponding author, Final Approval

AZ: Scientific literature search, Data collection, Manuscript writing, Editing, Final Approval

MSM: Scientific literature search

MBA: Conduct of study

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