

Analgesic efficacy and opioid sparing effect of erector spinae plane block in oncologic breast surgery: An observational study

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Ethics Committee Approval

The study protocol was approved by the Ethics Committee for Clinical Studies of Marmara University Medical Faculty Istanbul Turkey (date: July 24, 2020; number: 09.2020.125).

The study was registered to ClinicalTrials.gov with identifier NCT04824300.

All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

Conflict of Interest

No conflict of interest was declared by the authors.

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Abstract

Background/Aim: Erector spinae plane block (ESPB) is a fascial plane block technique suitable for perioperative analgesia. This study aimed to evaluate the value of ESPB performed under ultrasound guidance and with ANI (Analgesia Nociception Index) monitoring in terms of intraoperative opioid need and postoperative pain management, in patients undergoing oncological breast surgery.

Methods: This prospective case-control study includes forty-two female breast cancer patients who underwent unilateral modified radical mastectomy with axillary lymph node dissection. Patients were allocated to receive (ESPB group) or not receive (controls) ultrasound guided ESPB before anesthesia induction based on patient preference, and the groups were compared in terms of total intraoperative opioid consumption (with the guidance of ANI) and postoperative pain. Visual analogue scores (VAS) were obtained during the 12-hour postoperative follow-up.

Results: Total intraoperative remifentanyl dose required was significantly lower in the ESPB group when compared to controls (361.9 (108.3) vs. 1560.0 (4), $P < 0.001$). ESPB group had significantly lower visual analogue scores at all postoperative time points. None of the patients in the ESPB group but all controls required additional analgesia during the 12-hour postoperative follow-up period.

Conclusion: Ultrasound guided ESPB together with ANI monitoring is an effective and relatively safe perioperative analgesia method in patients undergoing mastectomy. Together, they provide an effective postoperative analgesia and reduce intraoperative opioid use consumption. Further studies will shed more light on the role of ESPB in this setting.

Keywords: Erector spinae plane block (ESPB), Oncological breast surgery, Perioperative pain, Opioid

Introduction

Oncologic breast surgery is associated with significant acute and chronic postoperative pain, leading to reduced quality of life following surgery. Multimodal analgesia and regional analgesia are frequently utilized to alleviate pain after breast surgery. Pharmacological treatments to reduce pain in these patients include intra- and post-operative paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), preoperative gabapentin or pregabalin, single dose dexamethasone to reduce pain and nausea, and intraoperative opioids and postoperative opioids for rescue analgesia [1]. Other recommended pain management strategies in oncologic breast surgery include local anesthetic infiltration at the wound site, paravertebral block, pectoral nerve block (PECS1-PECS2), and erector spinae plane block (ESPB) [2].

Although local anesthetic infiltration leads to reduced postoperative pain and opioid use, its efficacy lasts for only a brief period. On the other hand, regional anesthetic administration is associated with reduced opioid use, better alleviation of postoperative nausea and vomiting, and lower postoperative pain scores, as compared to general anesthesia alone and local anesthetic infiltration at the wound site, in addition to shortened length of hospital stay [1]. Since paravertebral nerve block is performed at an anatomical site close to pleura, it is associated with the risk of pneumothorax, even if performed under ultrasound guidance [3]. Furthermore, the risk of total spinal block cannot be eliminated.

Erector spinae plane block (ESPB) is the most recently described fascial plane block technique to be utilized for analgesia in patients undergoing breast surgery [4]. There is considerable distance between the site of procedure and the pleura [5], reducing the risk of serious complications such as pneumothorax. ESPB provides all benefits associated with the gold standard thoracic epidural anesthesia for postoperative pain management, and is devoid of hemodynamic side effects [6]. Despite a surplus of studies since the first description of ESPB in 2016, most publications have reported on its effects on postoperative opioid use, with few studies examining intraoperative opioid use with ANI (Analgesia Nociception Index) monitoring. Furthermore, the increased use of opioids for postoperative pain in patients receiving general anesthesia only is associated with side effects. In recent years, we have also witnessed an alarming increase in opioid dependency and opioid-related mortality.

In the absence of a reliable monitor, the assessment of intraoperative pain intensity and opioid need is generally based on the change in hemodynamic parameters, although this approach is non-specific. In more recent years, ANI device has been introduced as an objective means for continuous perioperative pain measurement. ANI reflects the balance between nociception and analgesia using an analysis of heart rate variability against a scale of 0 to 100 and determines the intensity of pain stimuli via heart rate and arterial pressure. This allows opioid administration in accordance with the patient need [7].

The main objective of our study was to examine the effect of ESPB performed under ultrasound guidance and with

ANI monitoring on intraoperative opioid need in comparison with controls. In addition, the time to first need of analgesia postoperatively and postoperative pain scores were analyzed.

Materials and methods

Patients

A total of 42 consecutive female breast cancer patients aged between 25 and 70 years with ASA scores of 1-3 who underwent unilateral modified radical mastectomy with axillary lymph node dissection were included in this prospective non-randomized observational cohort study. Exclusion criteria were as follows: Severe respiratory or cardiac condition, hepatic or renal failure, coagulopathy, local infection at the injection site, deformity of the vertebra or chest wall, allergy against study drugs, opioid abuse, or patient unwillingness. The study protocol was approved by the Ethics Committee for Clinical Studies of Marmara University Medical Faculty Istanbul Turkey (date: July 24, 2020; number: 09.2020.125) and the study was conducted in accordance with the Declaration of Helsinki. Patients provided written informed consent prior to study entry. The study was registered to ClinicalTrials.gov with the identifier NCT04824300.

Study groups and outcome measures

Patients were allocated to receive (ESPB group) or not receive (controls) erector spinae plane block (ESPB) before anesthesia induction based on patient preference. The primary outcome measure was total intraoperative opioid consumption with the guidance of analgesia nociception index (ANI), and the secondary outcome measure was the change in postoperative pain as assessed by visual analogue scale (VAS). Sample size estimation revealed that a total of 21 patients per group would be necessary to detect a mean difference of at least 40% reduction in intraoperative opioid consumption between the two treatment groups, with an alpha error = 0.05 and beta = 0.2 (power = 0.8). Thus, 21 consecutive patients preferring and not-preferring ESPB were included in the ESPB group and controls, respectively. The study groups were compared in terms of study outcomes.

Erector spinae plane block technique

In the ESPB group, ESPB was performed by the same experienced anesthesiologist before the induction of general anesthesia. The procedure was carried out at the operation side in sitting position and under ultrasound guidance using a linear probe (6-13 MHz). Injection site was identified and marked at 3-cm lateral to the T3 spinous process. The injection was performed using in-plane technique and a 22G block needle (100mm, B-Braun, Germany). The needle was advanced in the cranio-caudal direction and 1-2 ml saline was injected to separate erector spinae muscle from the transverse process. Following the separation, 20 ml 0.5% bupivacaine and 100 mg (5 ml) lidocaine were injected. Diffusion of the drug in erector spinae plane at cranio-caudal line was ensured. No analgesic or sedative was used during the procedure.

Intraoperative management

Anesthesia induction was done with 2 mg/kg propofol and 0.6 mg/kg rocuronium and an endotracheal tube was placed. Anesthesia was maintained by propofol and remifentanyl with the guidance of ANI and BIS. Electrocardiography, non-invasive

blood pressure, bispectral index (BIS, Medtronic, Minneapolis), and ANI were monitored and recorded every 15 minutes.

ANI was monitored to objectively evaluate perioperative pain and to prevent unnecessary intraoperative opioid administration. Two ANI electrodes were placed on the sternum and at the level of left nipple (to the same places with V1 and V5 ECG electrodes, respectively). ANI was continuously displayed at 1 Hz frequency throughout the surgical procedure. Patients received a maintenance dose of 0.3 mcg/kg/h remifentanyl. Remifentanyl dose was adjusted to keep ANI values between 50 and 70. A 1 mg/kg remifentanyl dose was administered when ANI < 50, and remifentanyl infusion dose was reduced when ANI > 70. Total remifentanyl dose was recorded for each patient.

Patients were monitored with BIS (Aspect Medical Systems, Natick, Mass, ABD) to help assess anesthesia depth, which uses bispectral analysis and monitors the effect of anesthesia based on electroencephalogram (EEG). Maintenance propofol infusion dose was 6-8 mg/kg/h, which was adjusted to keep BIS value at 40±5, and the total propofol dose was recorded.

Fifteen minutes before the completion of the surgical procedure, both groups received 1 g paracetamol and the control group received 100 mg tramadol.

Postoperative assessments

Patients received instructions before the surgery on how to assess their pain postoperatively, using 0 to 10-point visual analogue scale (VAS): 0 indicated no pain, while 10 indicated the worst imaginable pain. A physician blinded to patient allocations recorded self-assessed VAS scores of all patients upon awakening and at 6 and 12 hours. In addition, the timing of the first analgesic requirement was recorded. If VAS ≥ 4, 100 mg tramadol was given as rescue analgesic.

Statistical analysis

Sample size was calculated based on changes in opioid consumption. It was determined that at least 42 (sample size calculator) patients should be included in the study, with the expectation that there would be a 40% reduction in $\alpha=0.05$, $\beta=0.2$ opioid consumption, based on significant difference.

SPSS (Statistical Package for Social Sciences) version 21 software was used for the analysis of data. Descriptive data were expressed in mean (standard deviation) or median (range), where appropriate. The normality of continuous variables was tested using both hypothesis tests and graphical methods. Intergroup comparisons of continuous variables were made using the student t test for independent samples or Mann-Whitney U test, depending on data distribution. The two-way ANOVA test for repeated measurements was used to examine the significance of differences between the groups in postoperative VAS scores and intraoperative measurements over time. Two-sided *P*-values of <0.05 were considered indication of statistical significance.

Results

Patients

A total of 42 female patients were included: 21 in the ESPB group and 21 in the control group. The patients in the ESPB group were significantly younger when compared to the controls: 45.2 (13.8) vs. 53.0 (9.4) years, respectively (*P*=0.040).

The two groups were similar regarding intraoperative changes in heart rate, mean arterial pressure, analgesia nociception index, and bispectral index over time (*P*>0.05 for all).

Analgesia requirement

None of the patients in the ESPB group required additional analgesia during the 12-hour postoperative follow-up period. All patients in the control group required analgesia following surgery after a mean duration of 3.6 (0.7) hours (median, 4; range, 2-5). At the time of analgesia requirements, the mean VAS score was 6.7 (1.1) (median, 7; range, 5-8).

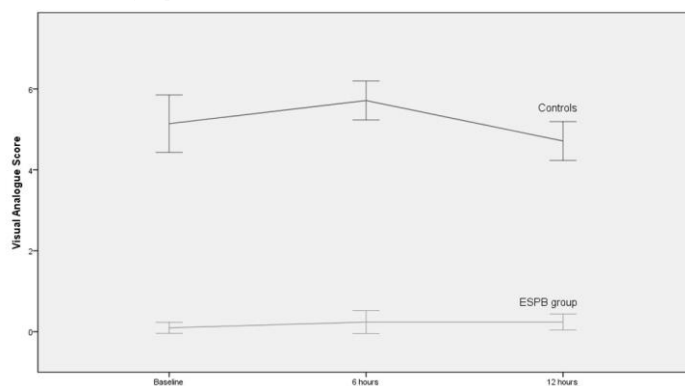
Intraoperative narcotic requirement

Total intraoperative remifentanyl dose required was significantly lower in the ESPB group, when compared to controls (361.9 (108.3) vs. 1560.0 (491.6) μ g, *P*<0.001). In addition, ESPB group required less intraoperative propofol (453.3(168.3) vs. 599.0(127.2) mg, *P*=0.001).

Changes in VAS scores

Figure 1 shows changes in postoperative VAS scores over time (at baseline when awakening, at 6 and 12 hours), where a significant difference in VAS scores was evident over time between the two groups (*P*<0.001). ESPB group had significantly lower VAS scores at all-time points (*P*<0.001 for all).

Figure 1: Changes in mean postoperative VAS scores over time. Upper line, control group; lower line, ESPB group. Error bars indicate 95% confidence intervals for the mean.



Discussion

In this study, ultrasound guided ESPB was associated with a significant reduction in the need for intraoperative opioid use and satisfactory level of pain control over a 12-hour period in patients undergoing unilateral modified radical mastectomy with axillary lymph node dissection. In patients undergoing oncological breast surgery, to the best of our knowledge, no studies have examined intraoperative opioid use and pain management with ESPB via ANI monitoring.

In our study, utilizing nociception measurement-guided analgesia monitoring, intraoperative opioid infusion settings were adjusted at an ANI of ≥ 50 . Successful analgesia could be delivered to patients using ESPB, resulting in an effective intraoperative analgesia and reduced opioid use. In routine clinical practice, analgesic administration is generally based on clinical pain symptoms elicited by the activation of the autonomous nervous system. However, this approach has been reported to lack sensitivity and specificity, due to the role of many confounders (e.g. autonomic, hormonal, or metabolic alterations) as well as due to intra-individual differences [7]. In a study by Dundar et al. [8], ANI monitoring significantly lowered

opioid consumption and could provide guidance on evaluation of blockade efficiency and determination of the need for analgesia in patients undergoing concomitant regional anesthesia and general anesthesia [8].

Also, despite the inclusion of a different group of surgical patients, Melvin et al. [9] found significantly lowered peri-operative opioid use in patients undergoing lumbosacral spine surgery when ESPB was performed at T10-T12 prior to incision.

Since the analgesic efficacy of the block continued into the postoperative period, a satisfactory level of opioid-free analgesia could be achieved. Since the recent introduction of opioid-free anesthesia, anesthesiologists have started to utilize multi-modal analgesia management in addition to general anesthesia in many surgical settings. Reduced use of opioids is associated with significant clinical benefits in terms of patient care as well as quality of life. Pain control with nerve blocks has been reported to yield superior results as compared to opioid-centered analgesia with respect to early mobilization, rapid recovery of body functions, and lack of dependency risk [10], underlining the importance of opioid-free anesthesia. In many studies exploring postoperative opioid consumption, ESPB was found to reduce the need for opioid use. For example, in Gürkan et al.'s [11] study, ESPB and control groups were compared in terms of postoperative analgesia and opioid use during the first 24 postoperative hours in patients undergoing breast surgery. Although a 65% reduction in opioid consumption was observed at postoperative 24 hours with ultrasound guided ESPB, postoperative pain scores were not significantly different [11]. Similarly, Yao et al. [12] found reduced morphine consumption and adequate analgesia with ESPB following breast surgery. In a review of 85 publications involving 242 cases undergoing ESPB, a significant proportion of patients had reduced postoperative opioid utilization [13]. A recent study from Korea included 40 patients who underwent breast-conserving surgery and received preoperative ESPB or not (controls). In the postoperative period, ESPB was associated with lower pain scores for breast but not for axilla. The two groups did not differ in terms of postoperative use of non-steroid anti-inflammatory agents [14]. ESPB has been found to provide adequate analgesia and to reduce postoperative opioid consumption in many types of surgery other than breast surgery. For instance, reduced postoperative opioid consumption with ESPB was reported following mitral valve surgery in a study by Leyva et al. [15].

In our ESPB group, patients required no additional analgesia for the first postoperative 12 hours. In contrast, control patients had a VAS score of 7 approximately 4 hours after surgery, and all subjects required additional analgesia. Postoperative VAS scores were significantly lower in the ESPB group. The stress response to postoperative pain and surgical trauma may lead to several changes in the release of hormones such as cortisol, prolactin, and adrenocorticotrophic hormone, potentially resulting in adverse metabolic and cardiovascular effects. Hence, postoperative analgesia has an important role in the stress response attenuation. As shown by Gad et al. [16], ESP block is associated with reduced stress hormone levels and pain scores. In another study, ESPB reduced pain scores significantly in breast surgery, similar to our observations [17]. In contrast to

our findings, in another study, the patients were divided into 3 groups to compare pain scores with paravertebral block, ESP block, and control treatment, and no differences were found between ESP block and control treatment [18]. Wang et al. compared postoperative pain with serratus anterior plane block, ESP block, and general anesthesia only in patients undergoing radical mastectomy and found lower VAS scores in both block groups than general anesthesia [19]. A previous meta-analysis also reported significant efficacy in providing 24 h postoperative pain control and opioid reduction with ESPB in patients undergoing breast surgery [20]. Elsabeeny et al. [21] reported better analgesia with ESPB in comparison with iv opioid analgesia in patients undergoing radical mastectomy, in addition to reduced postoperative opioid use, longer time to first dose of analgesic, and reduced number of side effects.

ESPB under ultrasound guidance provides abdominal or thoracic segmental analgesia depending on the level of injection [22]. The injected agent spreads to the thoracic paravertebral area via costa-transvers foramina; thus, ESPB blocks dorsal and ventral rami of spinal nerves [23]. In a cadaveric MRI study, it has been shown that the spread of analgesia extends to a large area from a single injection point [24]. ESPB has gained popularity as a regional anesthesia technique in several painful surgical and non-surgical conditions. In the current study, the cranio-caudal spread of the local anesthetic along the transverse process at T3 level was ascertained using ultrasound, and sensory block at T1-T6 dermatomes was confirmed with pin-prick test.

In our study, ESP blocks were performed by the same senior experienced anesthesiologist with no complications. While the use of ultrasound reduces the risk of complications, paravertebral blocks are associated with a significant risk of severe pneumothorax and pleural puncture [25]. Since ultrasound cannot fully guarantee prevention of dangerous complications, many clinicians are reluctant to utilize these blocks. ESPB, on the other hand, is associated with a lower risk of serious complications, when performed under ultrasound guidance at a tissue plane distant from potentially problematic structures [26]. It also represents a safer alternative to paravertebral block due to the use of the transverse process as a barrier, avoiding needle injury to the pleura [27]. Ueshima [5] reported only one patient developing pneumothorax following ESPB, although no clear information was provided whether patients with bullous lung disease were excluded from the study. No local toxicity due to local anesthetic was reported by Krishna et al. [28] in their patients undergoing bilateral ESPB for pain control after cardiac surgery. However, Tulgar et al. [29] administered bilateral ESPB at T9 level prior to laparoscopic umbilical hernia repair in their patient, who experienced reduced general muscle tone and loss of consciousness. The authors stated that this was likely to represent a neurological complication of local anesthetic [29]. A previous study reported stable hemodynamics following ESPB despite sympathetic block [30].

Since ANI monitoring can reduce unnecessary opioid use due to its ability to instantly reflect perioperative pain using heart rate, it may offer an additional means to lower opioid consumption in patients undergoing ESPB and to closely monitor the success of the block.

A major limitation of our study is the lack of randomization. Further randomized studies may provide more valuable information on the efficacy of ESPB performed in conjunction with ANI monitoring. Group assignment was based on patient discretion, and ESPB was preferred by younger patients, which may represent a confounding bias and reduces generalizability, although this alone may not account for the differences observed.

Conclusions

Ultrasound guided ESPB together with ANI monitoring is an effective and relatively safe perioperative analgesia method in patients undergoing mastectomy. Together, they reduce intraoperative opioid use, and provide satisfactory postoperative analgesia. Further studies will shed more light on the role of ESPB in this setting.

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