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ORIGINAL ARTICLE

Comparison of postoperative analgesic efficacy between erector spinae plane block and rhomboid intercostal block in breast-conserving surgery and sentinel lymph node biopsy: A randomized non-inferiority clinical trial

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SUMMARY

Objectives: Breast-conserving surgery is a common breast operation type in the world. Patients may feel severe postoperative pain after the surgery. Several regional anesthesia methods are used for postoperative pain control as a part of multimodal analgesia management after breast surgery. Erector spinae plane block (ESPB) and rhomboid intercostal plane block (RIB) are commonly used techniques for this purpose. The studies that compare these methods are limited. Therefore, we aimed to compare the efficacy of ESPB and RIB.

Methods: This prospective, randomized study included sixty female patients with ASA class I-II physical status in the study. All patients underwent general anesthesia. We performed the blocks at the end of the surgery before extubation. Participants were randomized into two groups between the operation: the Group ESPB (n=30) and the Group RIB (n=30). We performed 30 ml volume of 0.25% bupivacaine for the blocks. 400 mg ibuprofen 3x1 was ordered postoperatively, and a fentanyl PCA device (2 ml bolus, 0 ml infusion, 20 min lock time, 4 hour limit) was attached intravenously to the participants. If the pain score was ≥4, meperidine (0.5 mg/kg) was performed.

Results: There were no differences in terms of demographical data. The postoperative opioid use, pain scores, adverse events, and the need for rescue analgesia were similar between groups.

Conclusion: Both RIB and ESPB are effective regional anesthesia techniques following breast surgery. They are simple and safe methods. Anesthesiologists may prefer one or the other based on their clinical experience.

Keywords: Erector spinae plane block; mastectomy; postoperative analgesia; rhomboid intercostal block.

Introduction

The incidence of breast cancer in women is more than 25% worldwide, making breast surgery one of the most performed types of surgery.[1] In terms of cosmetic conditions, several surgical procedures are available to prevent breast deformity.[1,2] Breast-conserving surgery (BCS) is a common breast surgery procedure.[3] 30–50% of patients report moderate to severe acute postoperative pain after BCS.[4] Severe postoperative pain leads to poor recovery, delayed discharge, delayed mobilization, and discomfort for patients.[4,5] Several techniques are used in multimodal analgesic management for pain relief after BCS.[6,7]

Regional anesthesia methods are commonly used due to the efficiency of ultrasound (US) in pinpointing the location of anatomical landmarks. Erector spinae plane block (ESPB) and rhomboid intercostal block (RIB) are effective analgesic techniques, and they are preferable because distance can be maintained from the surgical field to reduce breast analgesia.[8] ESPB was first described in 2016, and many papers on its efficacy for several indications and breast surgery have been published to date.[9–15] RIB was first described in 2016.[16] It targets the dorsal ramus and intercostal nerves and is more predictable than ESPB due to its consistent spread toward the dorsal ramus in a focused and narrow auscultation

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triangle.[17] Both ESPB and RIB are used for analgesic management after breast surgery. Thoracic paraspinal blocks are a very popular topic in the field of regional anesthesia, but comparative studies in the literature are few.

The aim of this randomized prospective trial was to evaluate and compare the analgesic efficacy of ESPB and RIB after breast surgery and thus address the research gap. The hypothesis was that ESPB and RIB would have similar analgesic efficacy levels following BCS.

Material and Methods

Study Design

A single-center, prospective, randomized design was adopted for this study. Ethical approval was obtained from the Istanbul Medipol University Ethics and Research Committee (November 12, 2022, decision no: 859), following which the study was registered and recorded on ClinicalTrials.gov (12/02/2021, NCT04752150). Patients with ASA I-II classes and aged 18–65 years who underwent elective BCS and sentinel lymph node biopsy were included in the trial. The exclusion criteria: infection in the thoracic paraspinal region, coagulation abnormalities, ongoing anticoagulant therapy, refusal to follow the study procedure, allergies related to the study drugs, or inability to use the pain scoring and patient-controlled analgesia (PCA) device. Written informed consent for the study was obtained from all participants. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. The study was conducted at Medipol Mega University Hospital from April 2021 to January 2022.

General Anesthesia Induction and Maintenance and Perioperative Analgesia Management

Patients underwent classical ASA monitoring upon arrival at the operating room. The same general anesthesia induction (propofol 2–2.5 mg/kg, fentanyl 1–1.5 µg/kg, and rocuronium 0.6 mg/kg intravenously) and maintenance (sevoflurane, remifentanil infusion 0.05–2 µg/kg/min) were performed on the patients. All patients underwent BCS and sentinel lymph node biopsy by the same surgical team. Ondansetron (4 mg) was administered intravenously for postoperative nausea and vomiting prophylaxis.

Randomization/Groups

We used the Research Randomizer software program for randomization. There were two groups in our trial: Group ESPB and Group RIB. There were 30 participants in each group. Randomization was performed before the surgery. Patients did not know which group they were in. The outcomes assessor was blinded to the grouping and recorded the postoperative pain scores, opioid agent usage, and adverse events.

Block Procedures

Both ESPB and RIB were administrated at the end of the operation, before termination of anesthesia with US (Vivid Q, GE Healthcare, USA). A linear transducer (11–12 MHz) was used for the procedure. The patients were placed in a lateral decubitus position with the surgical side up for the block procedures. A 22G, 80 mm needle was used for injection.

ESPB Procedure

The transducer was placed 2–3 cm away from the midline at the level of the T4 spinous process. Hyperechoic shadows of the transverse process (TP) and the erector spinae muscle (ESM) were seen (Fig. 1a). The block needle was punctured in the craniocaudal way with in-plane technique. Five ml normal isotonic saline was administrated between the TP and ESM for correction. Following this, thirty ml 0.25% bupivacaine was administrated deep into ESM.

RIB Procedure

The US probe was placed near the medial border of the scapula on the ribs, corresponding to the T5–6 level. The rhomboid major muscle (RMm) and ribs were visualized (Fig. 1b). The block needle was punctured in the craniocaudal way (in-plane). Normal isotonic saline (5 ml) was administrated between the RMm and ICM for correction. Following this, the local anesthetic was administrated (30 ml volume of 0.25% bupivacaine).

Analgesia Management After Surgery and Evaluation of Outcomes

We administered 400 mg ibuprofen + 100 mg tramadol IV to all participants intraoperatively, as per our protocol. In the postoperative period, intravenous 400 mg ibuprofen 3x1 was routinely ordered. A PCA device with 10 mcg/ml fentanyl was at-

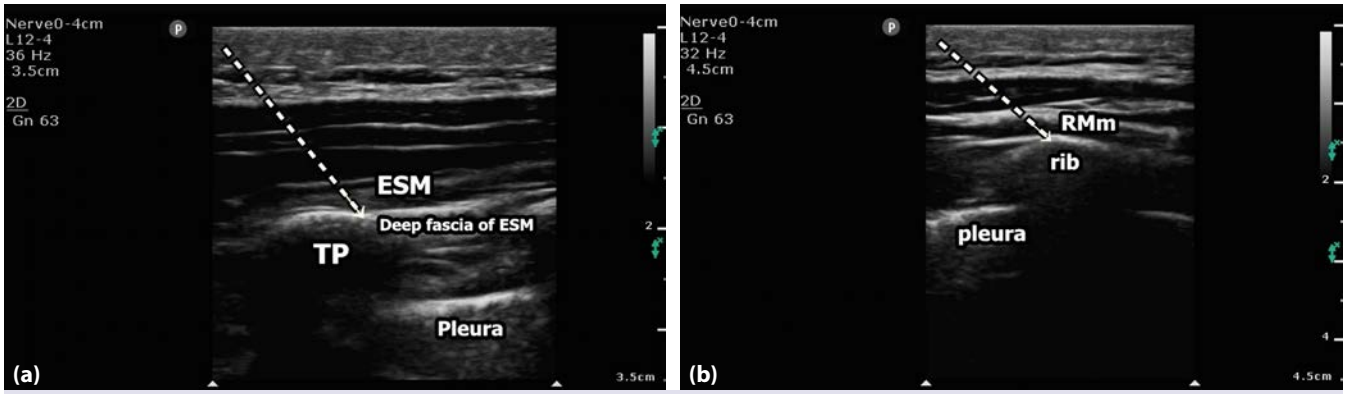

Figure 1. (a) Sonographic anatomy of the ESPB at the level of T4 vertebrae. ESM; erector spinae muscle, TP; transverse process. White arrow indicates the cranio-caudal needle direction. **(b)** Sonographic anatomy of the RIB at the level of T5-T6. RMm; rhomboid major muscle. White arrow indicates the cranio-caudal needle direction.

tached intravenously to the participants (2 ml bolus, without infusion, 20 min lock time, 4 hour limit). We used the Numerical Rating Scale (NRS static and dynamic) for pain evaluation. If the NRS score was ≥4 despite the ibuprofen and PCA bolus, meperidine (0.5 mg/kg) was performed intravenously. Opioid-related adverse effects were recorded.

Outcomes

Primary aim: The median changes in the first-hour NRS (static) between Group ESPB and RIB.

Secondary aims: Static/dynamic NRS, postoperative total PCA volume consumption, and the rate of adverse events.

Sample Size Calculation

Hodges-Lehmann was used to calculate the 95% CI of the median differences in NRS. The hypothesis was that RIB and ESPB (RIB compared with ESPB/non-inferiority) would have similar analgesic efficacy levels (NRS) one hour after operation. Our trial design was a non-inferiority design. We described a non-inferiority margin as 1.0 in accordance with the study by Jiang et al.[18] A sample size of 60 cases (30 for each group) was needed to give a power of 0.8 and a one-sided α of 0.025 with a 10% contingence of dropout (to accomplish 80% power and illustrate non-inferiority). p values <0.025 were admired to be considerable.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows (Version 22.0; IBM Corp., Armonk, NY, USA) and R statistical software package (V 4.0.2, R Foundation for Statistical Computing, Vienna, Austria). The Shapiro-Wilk test was used to analyze the data distribution. Continuous variables were expressed as mean±standard deviation, and median (25^{th}–75^{th} percentiles). Pearson chi-square test was performed to compare the categorical data. Student's t-test was performed to control for the normally distributed continuous variables. One-sided Wilcoxon rank-sum test was used to compare the median difference in NRS score and PCA volume.

Table 1. Demographic data and duration times of surgery and anesthesia

	Group ESPB (n=30)	Group RIB (n=30)	p
Age (years)	43±11	45±12	0.529*
ASA (I/II)	17/13	16/14	1†
Height (cm)	161±5	163±5	0.18*
Weight (kg)	69±8	70±7	0.733*
Anesthesia time (min)	95±8	90±10	0.094*
Surgical time (min)	80±6	75±8	0.051*

Values are expressed mean±standart deviation or number. ESPB: Erector spinae plane block; RIB: Rhomboid intercostal block; kg: Kilogram; cm: Centimeter; M: Male; F: Female; min: Minutes; ASA: American Society of Anesthesiologist; *: P value is obtained with t-test. (mean±standard deviation). †: P value is obtained with Pearson's χ^2 test (n).

Results

We used the CONSORT flow diagram for enrolling patients in our trial (Fig. 2). A total of 79 patients underwent breast surgery for several indications during the study period. Nineteen patients were excluded; among them, 10 patients underwent different breast surgery procedures (modified radical mas-

Table 2. The average Numerical Rating Scale scores during postoperative first 24 h

Hour	Group ESPB (n=30)	Group RIB (n=30)	p*†	Difference in NRS (ESPB-RIB)‡	
				Median	95% CI
NRS static					
1	2 (1–3)	2 (1–3)	0.715	0	-1–1
2	2 (1–2)	2 (1–2)	0.393	0	-1–0
4	1 (1–2)	2 (1–2)	0.411	0	-1–0
8	1(1–2)	1 (1–2)	0.955	0	0–0
16	1 (0–1)	1 (1–2)	**0.010**	**0**	-1–0
24	0 (0–1)	0 (0–1)	1	0	0–0
NRS dynamic					
1	2 (2–4)	3 (2–4)	0.304	0	-1–0
2	2 (2–3)	2 (2–3)	0.372	0	0–0
4	2 (1–2)	2 (2–3)	0.160	0	-1–0
8	1 (1–2)	2 (1–2)	0.091	0	-1–0
16	1 (1–2)	1 (1–2)	0.080	0	-1–0
24	0 (0–1)	0 (0–1)	0.884	0	0–0

Data are expressed as median (percentiles 25–75). p values that are written in bold represent statistical significance. Difference of NRS=NRS of ESPB minus NRS of RIB. *: P value compares the RIB group and the ESPB group; †: Wilcoxon rank-sumtest used to compare medians between the groups; ‡: Hodges–Lehman estimator used to calculate 95% CI of the median differences; NRS: Numerical rating scale; RIB: Rhomboid intercostal block; ESPB: Erector spinae plane block; CI: Confidence interval.

Table 3. Comparison of opioid (fentanyl) consumption form PCA device between groups

Hour	Group ESPB (n=30)	Group RIB (n=30)	p*†	Median differance (ESPB-RIB)‡	
				Median	95% CI
0–8 (mcg)	20 (20–20)	20 (20–20)	0.640	0	-20–0
8–16 (mcg)	0 (0–20)	0 (0–20)	0.578	0	0–0
16–24 (mcg)	0 (0–0)	0 (0–20)	0.476	0	0–0
Total (mcg)	40 (20–40)	40 (20–45)	0.707	0	20–0

Data are expressed as median (percentiles 25–75). Difference of PCA volume = PCA volume of ESPB minus PCA volume of RIB. PCA: Patient-controlled analgesia; *: P value compares the RIB group and the ESPB group; †: Wilcoxon rank-sum test used to compare medians between the groups; ‡: Hodges–Lehman estimator used to calculate 95% CI of the median differences; RIB: Rhomboid intercostal block; ESPB: Erector spinae plane block; CI: Confidence interval.

tectomy, segmental mastectomy, etc.), four patients were under anticoagulant therapy, and five patients' (three in Group ESPB, two in Group RIB) PCA got disconnected due to technical problems after surgery.

The demographic data were similar between Group ESPB and Group RIB (Table 1).

Static/dynamic NRS are seen in Table 2. Group ESPB and Group RIB were not superior to each other in terms of NRS.

The 95% CI of the median differences in static NRS scores postoperatively was <1. This demonstrated the non-inferiority of the ESPB group (Fig. 3). There was no difference in terms of dynamic pain scores.

The fentanyl consumption from the PCA device after surgery was similar between groups (Table 3). There were no differences in terms of the rate of adverse events (nausea, vomiting, and itching) and the meperidine usage amount (Table 4).

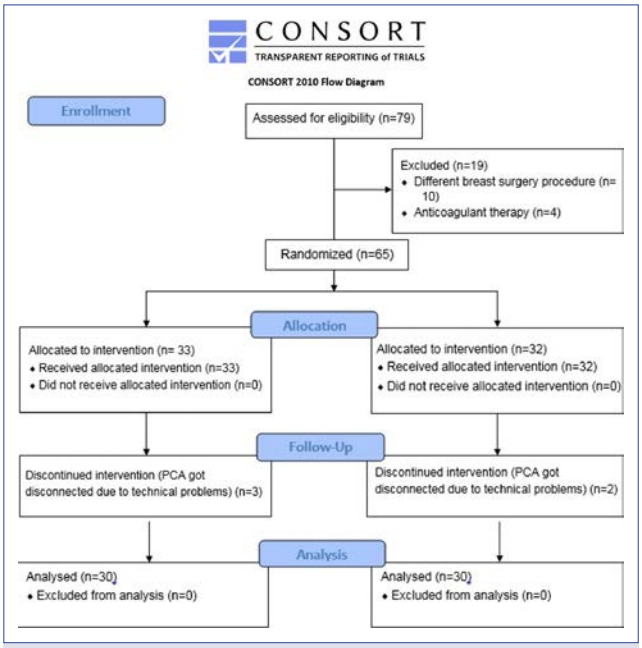

Figure 2. Consort flow diagram of the study.

Discussion

According to the results of our non-inferiority study, ESPB and RIB had similar analgesic efficacy levels after BCS. The postoperative 24-hour opioid consumption rate, pain scores, and adverse effect rates did not differ between the groups.

Pain management after breast surgery is important. Several methods such as regional techniques, local infiltration, and opioids may be used to this end.[6] After its first description, ESPB has been performed for a wide range of indications. One of its application areas is breast surgery.[10,11] Local anesthetic (LA) injected deep into the ESM spreads anteriorly through the costotransverse foramen at the origin of the dorsal and ventral rami.[11] It has also been reported that ESPB shows epidural and paravertebral spread patterns.[15] Thus, ESPB results in hemithoracic analgesia that includes the breast and axilla.[19]

However, there is still controversy about the mechanism of ESPB. Earlier cadaveric and radiologic studies have reported that it leads to extensive craniocaudal spread in the deep fascia of the ESM and into the epidural, paravertebral, and intercostal spaces.[9,19,20] However, another cadaveric study reported that anterior spread occurred in only two cadavers out of 10 specimens.[21] Additionally, a recent cadaveric study reported that no dye spread to the axillary region via the area under the scapula.[22] Despite inconsistent reports regarding its mechanism, ESPB has been shown to provide effective analgesia after breast surgery.[8]

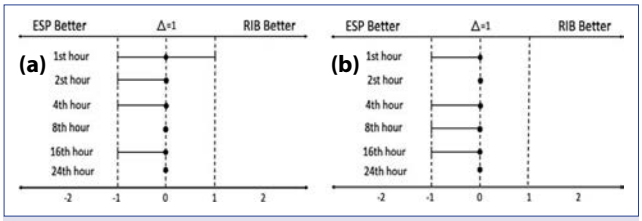

Figure 3. Median differences for NRS scores at rest **(a)** and dynamic **(b)**. Error bars representing 95% CIs.

Δ: Margin of non- inferiority margin; ESPB: Erector spinae plane block; RIB: Rhomboid intercostal block.

Table 4. Incidence of adverse effects, and the need of rescue analgesia (meperidine)

	Group ESPB (n=30)	Group RIB (n=30)	p†
Nausea (Y/N)	6/24	7/23	1
Vomiting (Y/N)	4/26	6/24	0.731
Itching (Y/N)	4/26	5/25	1
The need of rescue analgesia (Y/N)	9/21	10/20	1

ESPB: Erector spinae plane block; RIB: Rhomboid intercostal block; †: P value is obtained with Pearson's χ^2 test (n); Y: Yes; N: No.

Aksu et al.[12] performed bi-level ESPB in patients who underwent breast surgery. In their randomized controlled trial, unlike the classic single-shot approach, they performed bi-level ESPB at T2 and T4 levels. They used 10 ml 0.25% bupivacaine for each level (a total of 20 ml), and they compared bi-level ESPB with the control group. They reported that bi-level ESPB provided effective analgesia management after breast surgery.

Unlike this study, we performed single-shot ESPB at one level (T4) with 30 ml volume. Abdella et al.[13] evaluated the analgesia and spread of ESPB in patients who underwent breast cancer surgery in their randomized controlled trial. They performed ESPB with 20 ml and 40 ml volumes and compared it with the control group. They evaluated the spread of ESPB with radiologic imaging. They reported that both 20 ml and 40 ml ESPB provided effective analgesia compared to the control group.

In addition, according to their results, ESPB with 40 ml volume enhanced the craniocaudal spread compared to 20 ml volume of ESPB. However, there was no difference in terms of analgesic efficacy or patient satisfaction between 20 ml and 40 ml volume of ESPB. Abdella reported that there was no further spread to the paravertebral and epidural spaces.[13]

Genc et al.[14] compared the pectoserratus plane block and ESPB in terms of acute and chronic pain after breast cancer surgery. In their randomized controlled study, they performed 30 ml volume for the blocks. They reported that both pectoserratus plane block and ESPB provided effective acute and chronic pain control compared to the control group after surgery.

According to their results, the analgesic efficacy of pectoserratus plane block and ESPB were similar in terms of acute and chronic pain management after surgery. In our study, we performed 30 ml volume for ESPB, and we evaluated only acute pain after surgery.

RIB was first described by Elsharkawy et al.[16] It is performed by injecting LA between the RMM and ICM. RIB has been performed for several indications, including thoracoscopic and breast surgeries.[23,24] In a descriptive cadaveric study of RIB, the authors reported that the dye spread from T2 to T9.[16] One important feature of RIB for breast and axilla analgesia is its spread to the axilla via the clavipectoral fascia.[17] RIB provides pain relief after various breast surgeries, such as modified radical mastectomy with axillary curettage and breast reconstruction surgery.[25,26]

Altıparmak et al.[8] performed the first prospective randomized study to evaluate the efficacy of RIB after breast surgery and reported that RIB improved patient recovery scores and reduced postoperative pain scores/opioid consumption. Based on a randomized study comparing RIB vs. Pectoral nerve block type-II (PECS-II block) vs. control group, the authors reported that RIB provided analgesic effects similar to PECS-II and superior to the IV-fentanyl PCA group.[27]

A recent meta-analysis evaluating the efficacy and safety of RIB in breast and thoracoscopic surgery revealed that RIB provides better pain control than general anesthesia.[23] In addition, the authors emphasized that RIB may be an effective and safe technique for such surgeries.

The literature on studies that compared the efficacy of RIB and ESPB is limited. Jiang et al.[18] compared RIB, ESPB, and serratus plane block (SPB) for pain management after modified radical mastectomy surgery. In their double-blind clinical trial involving 90 patients, the authors performed each block with 20 ml of 0.5% ropivacaine. They reported that RIB and ESPB effectively reduced opioid consumption and provided better pain relief than SPB.

In another randomized prospective trial, Zhang et al.[28] compared RIB, ESPB, and SPB for analgesia after thoracoscopic surgery. They administered 20 ml of 0.4% ropivacaine to three groups of 30 patients (90 patients in total). Similar to Jiang et al.,[18] they concluded that ESPB and RIB reduced opioid (sufentanil) consumption and pain scores compared to SPB within 24 h after surgery.

Our results showed that RIB and ESPB provided equal levels of pain relief 24 h after breast surgery.

Both ESPB and RIB provide effective analgesia for patients who have undergone breast surgery. The injection area of RIB is more peripheral than the action region of ESPB. Therefore, the LA spreads through the lateral branches of the intercostal nerves more than the epidural and paravertebral spaces during RIB.[23] Due to this spread pattern, RIB may provide more focused breast and axilla analgesia than ESPB.

Piraccini reported that RIB may be preferred over ESPB for breast surgery when a bilateral block is needed, due to the peripheral spread of LA. Since there is no spread to the epidural and paravertebral spaces, RIB poses a low risk of hypotension compared to ESPB.[23,29]

The present study has some limitations. First, 30 ml of LA was used, and the results may vary with lower or higher volumes. Second, dermatome levels were not evaluated; only opioid consumption and pain scores were used to evaluate the efficacy of the blocks. A block catheter was not used either; a single-shot RIB or ESPB was performed. Finally, the sample consisted of 60 patients; further studies with larger patient numbers are needed.

Conclusion

In sum, both RIB and ESPB are effective regional anesthesia techniques following breast surgery. They are simple and, with US guidance, safe methods. Anesthesiologists may prefer one or the other for analgesia management after breast surgery.

Ethics Committee Approval: The İstanbul Medipol University Clinical Research Ethics Committee granted approval for this study (date: 12.11.2020, number: 859).

Authorship Contributions: Concept – BÇ, PB, HG, SA, BEG, YOA; Design – BÇ, PB, HG, SA, BEG, YOA; Supervision – BÇ, PB, HG, SA, BEG, YOA; Materials – BÇ, PB, HG, SA, YOA; Data collection and/or processing – BÇ, PB, HG, SA, YOA; Analysis and/or interpretation – BÇ, BEG; Literature review – BÇ, YOA; Writing – BÇ; Critical review – BÇ, BEG, YOA.

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