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Meme Kanseri Cerrahisi Geçiren Hastalarda Erektör Spina Plan Bloğunun İntravenöz Opioid Tüketimi ve Postoperatif Ağrı Üzerine Etkisi: Retrospektif Bir Kohort Çalışması

Effect of Erector Spinae Plane Block on Intravenous Opioid Consumption and Postoperative Pain in Patients Undergoing Breast Cancer Surgery: A Retrospective Cohort Study

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ÖZ

Giriş: Meme cerrahisi geçiren hastalarda ameliyat öncesi ve sonrası ağrı yönetimi büyük önem taşımaktadır. Erector spinae plane bloğu (ESPB), torasik ve abdominal cerrahi girişimlerde postoperatif analjezi amacıyla uygulanmaktadır. Bu çalışmada, meme kanseri cerrahisi geçiren hastalarda ESPB'nin postoperatif ağrı ve intravenöz (IV) opioid tüketimi üzerine etkisinin değerlendirilmesi amaçlanmıştır.

Yöntem: Bu retrospektif kohort çalışma, etik kurul onayı sonrasında gerçekleştirilmiştir. 15 Ekim 2020 ile 30 Nisan 2022 tarihleri arasında meme kanseri cerrahisi uygulanan hastaların verileri analiz edilmiştir. ESPB ile birlikte IV hasta kontrollü analjezi (PCA) uygulanan hastalar Grup 1, yalnızca IV PCA uygulanan hastalar ise Grup 2 olarak sınıflandırılmıştır. Her iki grupta postoperatif 1., 6., 12. ve 24. saatlerde IV morfin tüketimi ve ağrı skorları kaydedilmiştir.

Bulgular: Çalışmaya toplam 172 hasta dahil edilmiştir. Morfin tüketimi 1., 6., 12. ve 24. saatlerde Grup 1'de anlamlı olarak daha düşüktü (1. saat p=0,042; 6., 12. ve 24. saatlerde p<0,001). Grup 1'deki postoperatif ağrı skorları sırasıyla 4,68 ± 2,18, 3,79 ± 2,00, 3,51 ± 1,88 ve 2,65 ± 1,68 iken, Grup 2'de 6,09 ± 1,91, 4,78 ± 1,58, 4,14 ± 1,53 ve 3,19 ± 1,36 idi. Ağrı skorları Grup 1'de anlamlı olarak daha düşüktü (1. ve 6. saat p<0,001; 12. saat p=0,017; 24. saat p=0,006).

Sonuç: Meme kanseri cerrahisi geçiren hastalarda, ESPB uygulaması postoperatif opioid tüketimini anlamlı düzeyde azaltmakta ve ağrı skorlarını düşürmektedir.

Anahtar Kelimeler: erektör spina plan bloğu, hasta kontrollü analjezi, meme kanseri, postoperatif analjezi, opioid

ABSTRACT

Objective: Pain management before and after surgery is crucial for patients undergoing breast surgery. The erector spinae plane block (ESPB) is applied for postoperative analgesia in thoracic and abdominal surgical procedures. This study aimed to evaluate the effect of ESPB on postoperative pain and intravenous (IV) opioid consumption in patients undergoing breast cancer surgery.

Method: This retrospective cohort study was conducted following ethics committee approval. Data from patients who underwent breast cancer surgery between October 15, 2020, and April 30, 2022, were analyzed. Patients who received ESPB along with IV patient-controlled analgesia (PCA) were classified as Group 1, while those who received only IV PCA were classified as Group 2. IV morphine consumption and pain scores at postoperative 1st, 6th, 12th, and 24th hours were recorded in each group.

Results: A total of 172 patients were included in the study. Morphine consumption at postoperative 1st, 6th, 12th, and 24th hours was significantly lower in Group 1 (1st hour p = 0.042; 6th, 12th, and 24th hours p < 0.001). Postoperative pain scores at postoperative 1st, 6th, 12th, and 24th hours were 4.68 ± 2.18, 3.79 ± 2.00, 3.51 ± 1.88, and 2.65 ± 1.68 in Group 1, compared with 6.09 ± 1.91, 4.78 ± 1.58, 4.14 ± 1.53, and 3.19 ± 1.36 in Group 2, respectively. Pain scores were significantly lower in Group 1 (1st and 6th hours p < 0.001; 12th hour p = 0.017; 24th hour p = 0.006).

Conclusion: ESPB significantly reduced postoperative opioid consumption and lowered postoperative pain scores compared to IV PCA in patients undergoing breast cancer surgery.

Keywords: erector spinae plane block, patient-controlled analgesia, breast cancer, postoperative analgesia, opioid

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INTRODUCTION

Breast cancer is the most commonly diagnosed cancer in women. Almost 2.3 million new cases were diagnosed in 2020 according to the latest global estimates from the International Agency for Research on Cancer. The number of surgical procedures performed is also increasing due to the increasing incidence of breast cancer.

Patients undergoing breast cancer surgery may experience postoperative acute pain which has an incidence of up to 40%, and the incidence of chronic pain after breast surgery ranges from 25% to 60% (1,2). Providing effective analgesia in breast surgery can be challenging due to the complexity of breast innervation and the variety of surgical procedures performed (3). Regional anesthetic techniques such as thoracic epidural and paravertebral blocks are effective for pain relief in breast cancer surgery (4). However, serious complications such as nerve damage and pneumothorax concern clinicians (5).

The erector spinae plane block (ESPB) has become popular in recent years, after described by Forero et al. in 2016 (6). Local anesthetic is injected into the fascial area between the transverse process and the erector spinae muscle to perform an ESPB (7). Since the erector spinae fascia stretches from the nuchal fascia cranially to the sacrum caudally, the local anesthetic spreads across multiple levels, making the block effective over a wide area (6). Effective results have been observed in studies of analgesia in breast surgery (8,9).

The aim of this retrospective cohort study is to evaluate the analgesic effectiveness of ESPB in patients with elective breast cancer surgery. Our hypothesis is that the administration of ESPB in patients undergoing breast cancer surgery will reduce postoperative opioid consumption and postoperative pain scores compared to patients who were administered only intravenous (IV) analgesia. The primary outcome was 24-hour opioid consumption, and the secondary outcome was the evaluation of postoperative pain scores.

MATERIALS AND METHODS

This retrospective cohort study was commenced after obtaining ethical approval from the Ethics Committee of Sakarya University Faculty of Medicine, with approval number 197, dated June 15, 2022. This study was conducted in accordance with the Declaration of Helsinki. The patients' data records were evaluated between October 15, 2020 and April 30, 2022, through the institutional patient information and management system of a tertiary university hospital. A total of 172 patients aged between 18 and 75, classified under the American Society of Anesthesiologists (ASA) risk groups I, II, III, and undergoing elective breast cancer surgery, were identified. Inclusion Criteria were patients undergoing breast cancer surgery between the ages of 18-75 and patients who received IV patient controlled analgesia (PCA) or IV PCA in conjunction with ESPB.

The surgical procedures included Breast-Conserving Surgery with Sentinel Lymph Node Biopsy (BCS + SLNB), Breast-Conserving Surgery with Axillary Lymph Node Dissection (BCS + ALND), Simple Mastectomy with Sentinel Lymph Node Biopsy (SM + SLNB), Simple Mastectomy with Axillary Lymph Node Dissection (SM + ALND), and excision for fibroadenoma.

Exclusion criteria included patients who underwent bilateral breast surgery (simultaneous operations on both breasts), patients who had recurrent (revision) surgery, patients using preoperative opioid analgesics, and those with a history of chronic pain.

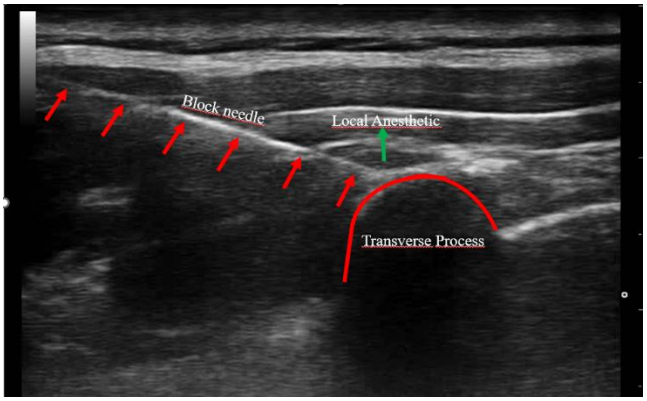
The following variables were collected from patient records: age (years), height (m), weight (kg), body mass index (BMI, kg/m²), ASA physical status classification, presence of additional diseases, history of chemotherapy, and type of surgical procedure.

Intraoperative data included operation duration and presence of axillary pain.

Postoperative data consisted of Numerical Rating Scale (NRS) scores at the 1st, 6th, 12th, and 24th hours, and total morphine consumption (mg) at the corresponding time points.

The requirement for rescue analgesics was also recorded.

In our clinic, the ESPB procedure is routinely performed using a standardized ultrasound-guided technique. The patient is placed in sitting position. The 4th thoracic vertebra level is identified by ultrasonography scan. The block site is sterilized with povidone-iodine solution and a sterile camera cover is applied to a 15 MHz linear probe (MyLab, Esaote, Genoa, Italy). The ultrasound probe is placed on the spinous process (midline) in the parasagittal plane and the injection is performed unilaterally over the 4th vertebra transverse process. The local anesthetic solution is injected using an echogenic block needle (stimuplex®D plus, Braun, Germany) which is inserted from cranial to caudal. Bupivacaine 20 ml in 0.25% concentration is administered to the interfascial plane between the erector spinae muscle and the transverse processes (Picture 1). The block procedure is performed preoperatively. An IV PCA device was prepared containing 0.4 mg/ml of morphine. The PCA device was programmed to give 2 mg bolus dose in 30 min intervals with 6 mg 4-hour limit. Our goal is to achieve a Numerical Rating Scale (NRS) score below 4.



Picture-1. The Visualization of the Block Needle on the Ultrasound Image During ESPB Procedure and the Distribution of the Injectate within the Interfascial Plane.(ESPB: ERECTOR SPINAE PLANE BLOCK)

If the patient's pain was not adequately relieved by either ESPB or IV PCA, and the Numerical Rating Scale (NRS) score was ≥ 4, rescue analgesia was administered with the goal of reducing pain to NRS < 4. Rescue analgesics were administered sequentially as follows: paracetamol

10 mg/kg IV, dexketoprofen 50 mg IV, and tramadol 1 mg/kg IV, each given at 4-hour intervals if the previous step was insufficient. All rescue analgesic administrations, along with postoperative NRS scores (at 1st, 6th, 12th, and 24th hours) and total morphine consumption, were recorded in standardized pain assessment forms.

The patients who underwent an ESPB were named Group 1 and the patients who only received IV PCA and an ESPB was not performed were named Group 2.

Statistical Analysis

Statistical analyses were performed using SPSS version 20.0. Descriptive statistics were presented as mean ± standard deviation, frequency, and percentage (n, %). The distribution of variables was assessed using the Kolmogorov–Smirnov test. For the analysis of non-normally distributed independent numerical variables, the Mann-Whitney U test was used, and the results were expressed as median. For independent categorical variables, Pearson's chi-squared test, Pearson's chi-squared test with Yates's continuity correction, and Fisher's exact test were applied. Categorical data were presented as frequency and percentage. P-value <0.05 was considered statistically significant.

RESULTS

No statistically significant differences were observed among groups regarding demographic variables (p-value >0.05). Administration of chemotherapy, duration of the operations, ASA classification, comorbidities, presence of axillary pain, and the requirement for rescue analgesia were also found similar between the groups (p-value >0.05) (Table 1, Table 2, Table 3).

The NRS scores at postoperative 1st, 6th, 12th, and 24th hours were found to be lower in Group-1 which was statistically significant (respectively, $p < 0.001$, $p < 0.001$, $p = 0.017$, and $p = 0.006$) (Table 4) (Figure 1). Postoperative IV morphine consumption at 1st, 6th, 12th, and 4th hours was found lower in favor of Group-1 and this was also statistically significant (respectively, $p = 0.042$, $p < 0.001$, $p < 0.001$, and $p < 0.001$) (Table 5) (Figure 2).

Within Group-1, NRS scores and morphine consumptions were evaluated based on surgical types. NRS scores at postoperative 1st, 12th, and 24th hours were significantly lower in the Breast Conservation Surgery (BCS)+ Sentinel lymph node biopsy (SLNB) group compared to the BCS+ Axillary lymph node dissection (ALND) group (respectively, $p = 0.037$, $p = 0.006$, and $p = 0.008$) (Table 6). The postoperative morphine consumption at 6th, 12th, and 24th hours in the BCS+ALND group was significantly higher compared to the BCS+SLNB group (respectively, $p = 0.039$, $p = 0.004$, and $p = 0.001$) (Table 6).

No statistically significant difference was found in the NRS scores at postoperative 1st, 6th, 12th, and 24th hours between the groups undergoing Simple Mastectomy (SM)+SLNB and SM+ALND operations ($p > 0.05$) (Table 7). However, in the SM+ALND group, postoperative morphine consumption at 1st, 6th, and 12th hours was significantly higher compared to the SM+SLNB group (respectively, $p = 0.016$, $p = 0.004$, and $p = 0.046$) (Table 7).

Table 1. Comparison of Demographic Data of Patients Between Groups

Parameters	Group 1 (n=94)	Group 2 (n=78)	p value
Age (Years)	51.31±11.51	52.76 ± 12.43	0.394[t]
Height (m)	1.60 ± 0.06	1.60 ± 0.07	0.582[t]
Weight (kg)	67.36 ± 9.81	69.88 ± 12.01	0.233[t]
BMI (kg/m^2)	26.46 ± 3.75	27.20 ± 4.42	0.241[t]

Data are presented as mean ± standard deviation.
[t]Student's t-test.

Table 2. Comparison of Patients' Characteristics, Operation Duration and Performed Surgical Procedures Between Groups

Parameters		Group 1 (n=94)	Group 2 (n=78)	p value*
Chemotherapy	Present	26 (%27.7)	46 (%59)	0.065[x]
	Absent	68 (%72.3)	32 (%41)	
ASA	2	68 (%72.3)	53 (%67.9)	0.645[y]
	3	26 (%27.7)	25 (%32.1)	
Additional diseases	Present	40 (%42.6)	42 (%53.8)	0.140[x]
	Absent	54 (%57.4)	36 (%46.2)	
Surgical procedure type	BCS + SLNB	52 (%55.3)	51 (%65.4)	**0.006[z]***
	BCS + ALND	12 (%12.8)	7 (%9)	
	SM + SLNB	15 (%16)	10 (%12.8)	
	SM + ALND	15 (%16)	4 (%5.1)	
	FIBROADENOMA	0 (%0)	6 (%7.7)	
Operation duration	Minutes	115.37 ± 28.74	107.63 ± 20.71	0.129[t]

Data are presented as number (%) or mean ± standard deviation. *p-value < 0.05 was considered statistically significant. [t]Student's t-test; [x]Pearson's chi-squared test; [z]Fisher's exact test; [y]Pearson's chi-squared test with Yates's continuity correction.
BCS: Breast Conservation Surgery. SLNB: Sentinel lymph node biopsy. ALND: Axillary lymph node dissection. SM: Simple Mastectomy.

Table 3. The Comparison of Inter-group Additional Analgesic Needs and Axillary Pain

Parameters		Group 1 (n=94)	Group 2 (n=78)	P value
Axillary pain	PRESENT	32(%34)	18(%23.1)	0.159[y]
	ABSENT	62(%66)	60(%76.9)	
Additional analgesic	PRESENT	43(%45.7)	49(%62.8)	0.257[x]
	ABSENT	51(%54.3)	29(%37.2)	

Data are presented as number (%). [x]Pearson's chi-squared test; [y]Pearson's chi-squared test with Yates's continuity correction.

Table 4. The Comparison of NRS Scores Between Groups for Patients Participating in the Study at Postoperative 1st, 6th, 12th, and 24th Hours

Postoperative Durations	Group 1 (n=94)	Group 2 (n=78)	P value*
1st Hour	4.68 ± 2.18	6.09 ± 1.91	**0.001[t]***
6th Hour	3.79 ± 2.00	4.78 ± 1.58	**<0.001[t]***
12th Hour	3.51 ± 1.88	4.14 ± 1.53	**0.017[t]***
24th Hour	2.65 ± 1.68	3.19 ± 1.36	**0.006[t]***

Data are presented as mean ± standard deviation. [t]Student's t-test. *p < 0.05 is considered statistically significant.

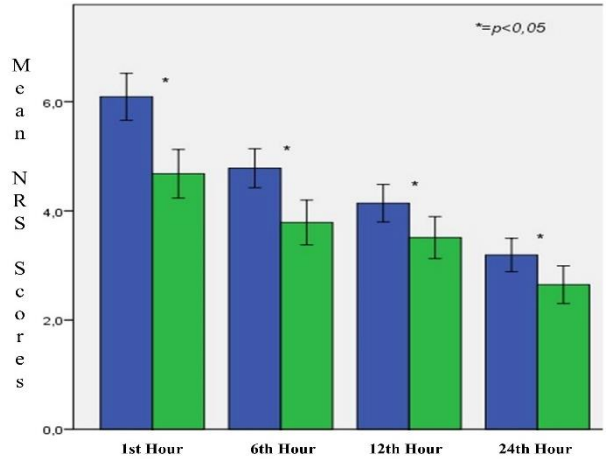


Figure 1. Comparison of NRS scores between groups at postoperative 1st, 6th, 12th, and 24th hours (green bars indicate Group 1 and blue bars indicate Group 2). *= p < 0.05 is considered statistically significant. NRS: Numerical Rating Scale

Table 5. The Comparison of Intravenous Morphine Consumption (mg) Between Groups in Postoperative 1st, 6th, 12th, and 24th Hours

Postoperative durations	Group 1 (n=94)	Group 2 (n=78)	P value*
1st Hour	3.51 ± 0.91	3.77 ± 0.64	**0.042[t*]**
6th Hour	6.77 ± 2.67	8.38 ± 2.66	**<0.001[t]***
12th Hour	9.87 ± 4.55	12.15 ± 4.21	**<0.001[t]***
24th Hour	11.98 ± 6.23	15.13 ± 5.80	**<0.001[t]***

Data are presented as mean ± standard deviation. [t]Student's t-test. *p < 0.05 is considered statistically significant.

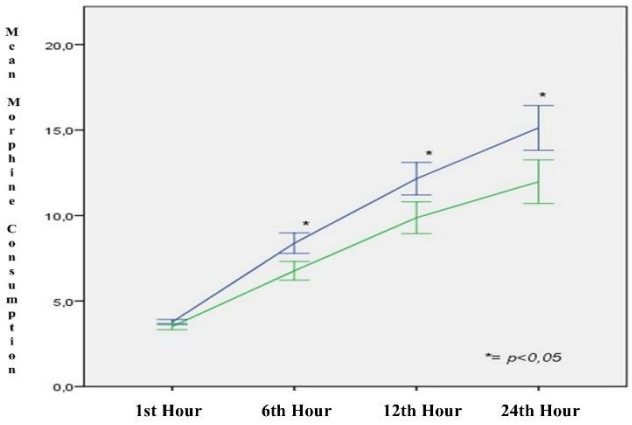


Figure 2. Comparison of Morphine Consumption (mg) Between in Postoperative 1st, 6th, 12th, and 24th Hours (Green Line Represents Group 1, and Blue Line Represents Group 2). *= p < 0.05 is considered statistically significant

Table 6. The comparison of Intravenous Morphine Consumption (mg) and NRS Scores Between Patients Undergoing BCS+SLNB and BCS+ALND Surgeries in Group 1 at postoperative 1st, 6th, 12th, and 24th hours

	Performed Operation		
	BCS+SLNB	**BCS+ALND**	**p-value**
Postoperative NRS Scores			
1st Hour	5 (0-9)	6.5 (2-8)	**0.037[m]***
6th Hour	4 (0-8)	5.5 (0-7)	0.115[m]
12th Hour	3 (0-7)	6 (0-7)	**0.006[m]***
24th Hour	2 (0-6)	4.5 (0-6)	**0.008[m]***
Postoperative Morphine Consumption (mg)			
1st Hour	4 (0-4)	4 (2-4)	0.114[m]
6th Hour	6 (2-12)	9 (4-12)	**0.039[m]***
12th Hour	10 (2-20)	15 (6-20)	**0.004[m]***
24th Hour	10 (2-22)	19 (10-30)	**0.001[m]***

Data are presented as median (minimum-maximum). [m] Mann-Whitney U test. *p-value <0.05 was considered statistically significant. BCS: Breast Conservation Surgery. SLNB: Sentinel lymph node biopsy. ALND: Axillary lymph node dissection

Table 7. The Comparison of Intravenous Morphine Consumption (mg) and NRS Scores Between Patients Undergoing SM+SLNB and SM+ALND Surgeries in Group 1 at postoperative 1st, 6th, 12th, and 24th hours

	Performed Operation		
	SM+SLNB	**SM+ALND**	**p-value**
Postoperative NRS Scores			
1st Hour	4 (2-7)	4 (1-9)	0.720[m]
6th Hour	3 (1-6)	4 (0-8)	0.528[m]
12th Hour	3 (1-6)	4 (0-7)	0.658[m]
24th Hour	2 (1-5)	2 (0-6)	0.495[m]
Postoperative Morphine Consumption (mg)			
1st Hour	4 (2-4)	4 (4-4)	**0.016[m]***
6th Hour	4 (2-8)	8 (4-12)	**0.004[m]***
12th Hour	8 (2-14)	10 (6-16)	**0.046[m]***
24th Hour	10 (2-16)	14 (6-20)	0.079[m]

Data are presented median (minimum-maximum). [m] Mann-Whitney U test. *p < 0.05 is considered statistically significant. SLNB: Sentinel lymph node biopsy. ALND: Axillary lymph node dissection. SM: Simple Mastectomy

DISCUSSION

This study demonstrated that ESPB significantly reduced postoperative IV morphine consumption and pain scores in patients undergoing unilateral breast cancer surgery compared to IV PCA alone. A statistically significant decrease was observed in morphine consumption in 1st, 6th, 12th, and 24th hours postoperatively. ESPB application resulted in an approximate 20% reduction in 24-hour postoperative morphine consumption. Additionally, a statistically significant decrease was observed in NRS scores in 1st, 6th, 12th, and 24th hours postoperatively in the ESPB group.

Consistent with the findings of the present study, ESPB reduced the postoperative pain in breast surgery which was reported in many studies.

Gürkan et al. reported that in patients undergoing breast cancer surgery, the 24-hour morphine consumption was 5.76 ± 3.8 mg in the ESPB group and 16.6 ± 6.92 mg in the control group. They also observed significantly lower NRS scores at the 1st, 6th, 12th, and 24th postoperative hours in the ESPB group(8).

In a similar study, Sharma et al. evaluated patients undergoing total mastectomy and found that the 24-hour morphine consumption was 2.9 ± 2.5 mg in the ESPB group and 5 ± 2.1 mg in the non-ESPB group, resulting in a 42% decrease. NRS scores in the ESPB group were also significantly lower at all postoperative time points(10).

In a study conducted by Singh and colleagues on patients undergoing modified radical mastectomy, the 24-hour morphine consumption was 1.95 ± 2.01 mg in the ESPB group and 9.3 ± 2.36 mg in the non-ESPB group. A significant reduction in NRS scores was also observed in the ESPB group at postoperative 0, 2, 4, 6, 8, 10, 12, and 24 hours(11). Leong et al. also reported a significant decrease in 24-hour postoperative morphine consumption in the ESPB group and a significant reduction in postoperative NRS scores in patients undergoing breast surgery(12).

Unlike previous studies, different surgical methods were compared in the present study to evaluate the effectiveness of ESPB. BCS+SLNB operations was compared to BCS+ALND and SM+SLNB operations were compared to SM+ALND regarding postoperative NRS scores and

morphine consumption. The results of the present study show that the NRS scores and morphine consumption were higher in the ALND operations. In this context, it indicates that the analgesic efficacy of ESPB in the axillary region may be insufficient. It is noticeable that the 24-hour morphine consumption in the present study was higher than that reported in similar studies (8,10,11). There may be various reasons for this. The analgesic drugs used in PCA devices and the protocols applied, the levels of the blocks, the local anesthetic concentrations used for the block are some of these reasons. Altiparmak et al. investigated the effect of ESPB on pain using different doses of local anesthetics. In this study, patients were randomly assigned to two groups, receiving either 0.375% or 0.25% bupivacaine for ESPB. At 24 hours postoperatively, tramadol consumption in the group receiving 0.375% bupivacaine was significantly lower compared to the group receiving 0.25% bupivacaine. Furthermore, pain scores evaluated at different time points were lower in the group receiving 0.375% bupivacaine (13).

The intercostobrachial nerve (ICNS) contributes to the innervation of the axilla, lateral chest wall and upper arm. Because of its close neighborhood with the lymph nodes, there is a risk of injury to this nerve during ALND. Retraction, transection with electrocautery or sharp dissection, surgical clips, scar tissue, infection, prolonged pressure, chemotherapy and radiotherapy can cause damage to this nerve (14,15). Injury to sensory nerves, including the ICNS, can cause severe pain in the early postoperative period. We think that interventions especially in the axillary region may increase postoperative pain intensity and morphine consumption. In a meta-analysis, the ALND procedure was reported to increase the severity of pain compared to SLNB procedures (16). However, this situation alone may not be the only cause of pain. The number of lymph nodes removed during ALND and whether the ICBS is damaged during the procedure also affect the severity of pain. Johansen et al. found a positive correlation between the number of lymph nodes removed and the development of postoperative refractory chronic pain after breast cancer surgery (18). In light of these findings, the use of ESPB may be considered according to the planned extent of lymph node dissection, as its analgesic efficacy could vary depending on the involvement of the axillary region.

This study has several limitations. First, its retrospective design limits the ability to establish causal relationships, and some degree of data recording bias may be unavoidable. Second, although the same anesthetic and analgesic protocols were used, differences in surgical types (e.g., BCS + SLNB, SM + ALND, etc.) may have influenced postoperative pain and morphine consumption, potentially affecting the initial intergroup comparisons. Third, pain assessment was based solely on subjective NRS scores, without the use of objective pain scales or functional recovery measures. Fourth, minor variations in clinical practice among anesthesiologists and nurses could not be completely excluded. Finally, as this was a single-center study with a limited sample size, the generalizability of the findings may be restricted.

In conclusion, the findings of the present study demonstrate that ESPB provides a significant analgesic effect in patients undergoing breast cancer surgery. The ESPB also provided significant decrease in opioid consumption in these patients. In the intergroup comparison, axillary lymph node excision resulted in more severe pain compared to other procedures, thus a more comprehensive postoperative analgesia including additional blocks may be necessary.

Ethics Committee Approval: This retrospective cohort study was commenced after obtaining ethical approval from the Ethics Committee of Sakarya University Faculty of Medicine, with approval number 197, dated June 15, 2022. Throughout the study, the principles of the Declaration of Helsinki were complied with.

Author Contributions: All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by Bedirhan Günel and Büşra Eren Okumuş. The first draft of the manuscript was written by Onur Balaban, and all authors commented on previous versions of the manuscript. Additional suggestions and comments were provided by Havva Belma Koçer and Ali Fuat Erdem. Havva Belma Koçer offered valuable feedback particularly on data analysis and interpretation of results, while Ali Fuat Erdem provided recommendations regarding methodology and the discussion section. All authors read and approved the final manuscript.

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Informed Consent: Informed consent was not obtained because of the retrospective nature of the study.

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