

# Ultrasound-Guided Erector Spinae Plane Block Versus Paravertebral Block for Perioperative Analgesia in Patients Undergoing Open Splenectomy: A Randomized Controlled Trial

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## Abstract

**Background:** The preferred anesthetic technique for upper abdominal surgeries, including splenectomy, is general anesthesia (GA). However, these procedures frequently result in severe postoperative pain, necessitating a greater need for efficient pain management. Regional analgesic blocks like the paravertebral block (PVB) and erector spinae plane blocks (ESPB) offer better postoperative pain management.

**Materials and Methods:** Following the induction of GA, 99 patients were randomly assigned to receive bilateral ESPB (n=33) or bilateral PVB (n=33), and a control group (n=33) received traditional analgesia. Time to first analgesic request was the primary outcome, and total morphine consumption and pain scores over the first 24 hours were the secondary outcomes. Postoperative side effects related to the block technique, such as pneumothorax or drug side effects, including postoperative nausea and vomiting (PONV), hypotension, bradycardia, pruritus, shivering, and respiratory depression, were recorded.

**Results:** Patients in the ESPB and PVB groups experienced a significantly prolonged time of postoperative analgesia, lower total intra and postoperative opioid consumption, and lower pain scores (NRS) than patients in the control group ( $P < 0.001$ ). Patients in both ESPB and PVB groups showed a significantly lower intraoperative heart rate and mean blood pressure ( $P < 0.001$ ) after 10 minutes of block. Regarding adverse events, Pruritus, Shivering, Nausea and vomiting, Urine retention, and Respiratory depression ( $P < 0.001$ ) were more frequent in the control group.

**Conclusion:** After an open splenectomy, ultrasound-guided ESPB and PVB provided comparable postoperative analgesia, reduced the need for overall opioid intake, and lessened the side effects of opioid use. However, ESPB was technically easier.

**Keywords:** Bupivacaine, Erector spinae plane block, Paravertebral block, Splenectomy

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## Introduction

Splenectomy is the removal of one of the body's important organs in the immune system, mostly due to traumatic injury, idiopathic thrombocytopenic purpura, hereditary spherocytosis, splenic infarction, tumors, hypersplenism, splenomegaly (1).

Laparoscopic splenectomy (LS) and open splenectomy (OS) are currently used for splenectomy. Although there are many benefits to laparoscopic surgery, including a smaller incision and a shorter hospital stay, it was once believed that the complexity of blood vessels, the presence of peritoneal appendages, and the challenge of locating the accessory spleen prevented LS from being used in clinical practice (2).

Various upper abdominal incisions (left subcostal, left subcostal with midline extension, or supraumbilical midline incision) are used to perform OS (3). Upper abdominal wall incisions are associated with moderate to severe postoperative pain, which can negatively affect postoperative recovery, with a delayed return to normal activities (4, 5).

General anesthesia (GA) is the most popular anesthetic method used for OS. Moreover, these procedures under GA are frequently accompanied by excruciating postoperative pain. Severe pain after OS restricts the ability to cough and minimizes functional residual capacity, leading to atelectasis, hypoxemia, ventilation-perfusion abnormalities, and an increased risk of pulmonary complications. Adequate analgesia may lessen the risk of these complications, encourage intestinal peristalsis, and improve recovery (6).

Many pain management techniques have been investigated and documented to administer analgesia. As a vital component of multimodal analgesia, peripheral regional analgesia has grown in popularity (7).

The paravertebral block (PVB) requires injecting a local anesthetic into the paravertebral space. This technique can satisfy postoperative analgesia during breast, thoracic, and abdominal surgeries, depending on where the local anesthetic was placed. It is also included in enhanced recovery pathways but is challenging because of its anatomic proximity to the pleura and the central neuraxial system (8, 9). Pneumothorax, epidural spread, hypotension, bradycardia, and possible toxicity from intravascular

injections are possible complications during PVB.

Newer fascial plane blocks, such as erector spinae plane block (ESPB), could provide an alternative to PVB. The US-guided ESPB could be a useful alternative to PVB for surgery involving the thoracoabdominal wall (10, 11).

The ESPB aims to inject a large volume of local anesthetic in the plane deep to the erector spinae muscles, between the muscle and transverse process with subsequent craniocaudal spread; as a result, it may eventually replace other regional techniques because it is efficient, safe, and simple (12).

Our study aimed to compare the efficacy of the perioperative analgesic effect of US-guided PVB and US-guided ESPB in OS regarding the duration of postoperative analgesia, total opioid consumption, hemodynamic profile, and postoperative complications.

## Methods

**Ethical approval:** This prospective randomized controlled trial was authorized by the Research Ethics Committee, Faculty of Medicine, Ain-Shams University (FMASU R 77/2022); the protocol was registered at [clinicaltrials.gov](https://clinicaltrials.gov) on 07.07.2022: <https://clinicaltrials.gov/show/NCT05448469> before patient enrollment, started on 10.07.2022, and ended on 10.12.2022. The principles of the Declaration of Helsinki were followed for this study. The study was conducted at the Department of General Surgery at Ain Shams University Hospital.

99 Adult Patients were enrolled in the study with ages ranging from 18–65 years, both genders, with a score of physical status American Society of Anesthesiologists (ASA-ps) II and III, who were scheduled for open splenectomy. All patients who were enrolled provided written, fully informed consent.

Patients were not eligible to participate in the study if they refused to share or they had a body mass index (BMI) >35 kg/m<sup>2</sup>, uncorrected coagulopathy, severe thrombocytopenia with platelet count <75×10<sup>3</sup>/mm<sup>3</sup>, polytrauma patients with a dorsal spine fracture, urgent abdominal exploration for splenectomy in hemodynamically unstable patients, spine deformity, a history of opiate addiction, a history of opiate or local



**Figure 1.** A - US-guided erector spinae plane block, TP transverse process, ES erector spinae. B. US-guided paravertebral block, TP transverse process, PVS paravertebral space.

anesthetic allergies, and infection at the injection site.

Three groups of patients were randomly assigned using computer-generated random numbers. After enrolling the patients, a sealed envelope containing the group allocation number was cracked open. The blocks were performed by a consultant anesthesiologist with a 5-year of experience in regional nerve blocks.

The 1<sup>st</sup> group (ESPB) experienced ESPB (n=33) in which patients received a combination of GA and bilateral US-guided ESPB with 20 ml bupivacaine 0.20% on each side at the T9 level, while patients in the 2<sup>nd</sup> group (PVB) (n=33) undergone a combination of GA and a bilateral US-guided-PVB at T8 and T10 levels with 7ml bupivacaine 0.20% in each injection. Patients in the 3<sup>rd</sup> group (control) received GA with conventional perioperative analgesia (n=33).

#### **Anesthetic technique:**

After entering the operating room, anesthesia monitoring, including electrocardiography (ECG), noninvasive blood pressure (NIBP), and pulse oximetry (SpO<sub>2</sub>), was applied. Baseline heart rate (HR), mean blood pressure (MAP), and SpO<sub>2</sub> values were recorded. An intravenous (IV) access was established, and then ringer's acetate was infused for all patients.

After Pre-oxygenation with O<sub>2</sub>/Air mixture (FiO<sub>2</sub> =0.8) for 3-5min, GA was induced with IV Fentanyl 1-2µg/kg, then Propofol (1.5-2 mg/kg), atracurium was administered (0.5mg/kg) to facilitate tracheal intubation. After securing the endotracheal tube, end-tidal CO<sub>2</sub> monitoring was established using capnography, and mechanical ventilation was initiated with pressure-regulating volume-target mode (PRVC).

#### **Regional analgesic blocks**

##### **Technique of ESPB**

After induction of GA, bilateral ESPB guided by ultrasound at the level of thoracic vertebrae (T 9) was done after the patient was carefully and gradually put in the lateral position. The skin was disinfected first by Chlorhexidine with alcohol, then a 7–12 MHz linear ultrasound transducer covered with a sterile Tegaderm™ film (model USAP-770A; Toshiba, Tokyo, Japan) was placed in the parasagittal plane to identify the 12<sup>th</sup> rib, then counting ribs cephalad as the probe was moved cranially till the ninth rib. The intercostal muscles appeared gray between the ribs, and the pleura appeared bright (hyperechoic) beneath them. The probe was turned medially until the transverse process was visualized with the erector spinae muscle superficial to the acoustic shadow. A 20-gauge, echogenic needle (Pajunk, 120mm, Germany) was inserted cephalad to the probe and advanced caudally. The needle was directed in an in-plane technique to reach the transverse process. After hydro-dissecting the plane with 1.5 mL of normal saline, 20 ml bupivacaine, 0.20%, was injected bilaterally and slowly after careful aspiration (Figure 1A).

##### **Technique of PVB**

In the same steps as ESPB, the US probe was placed in the parasagittal plane to identify the 12<sup>th</sup> rib, then counted ribs cephalad as the probe moved cranially until the 8<sup>th</sup> rib. The intercostal muscles appeared gray between the ribs, and the pleura appeared bright (hyperechoic) beneath them. The probe was turned medially until the costotransverse ligament, pleura, and transverse process were visualized. A 20-gauge, echogenic needle was inserted

cephalad into the probe and advanced caudally. The needle was directed in an in-plane technique to reach the transverse process. The ideal image is to visualize the paravertebral space between two transverse processes; once the view was obtained, sliding the probe caudally was done to bring the target space closer to the cephalad edge of the probe. The needle was inserted in the plane from cranial to caudal and advanced 1 cm deep to the dorsal surface of the transverse process and just superior to the pleura. Injection of 1.5 mL of saline was done to confirm the correct placement by deflection of the pleura downwards on injecting, then 7ml bupivacaine 0.20% was injected. The same technique was used at the T-10 level. Fig 1B

#### **Intraoperative events**

After performing either block technique, patients were returned carefully to the supine position. Intraoperatively, the depth of anesthesia was monitored by the bispectral index (BIS), which was maintained within 40 to 60 by regulating isoflurane concentration in O<sub>2</sub>/Air mixture (FiO<sub>2</sub>=0.4), intermittent boluses of atracurium (0.15 mg/kg) according to nerve stimulator were given to provide balanced general anesthesia, and fentanyl was used in the maintenance of anesthesia to maintain appropriate hemodynamics, if MAP or HR exceeded 20% of baseline values, Fentanyl 0.5 µg/kg bolus was given as rescue analgesia. A fluid bolus and, if necessary, a dose of 6–9 mg of ephedrine was administered to treat hypotension (MAP <20% of baseline). Blood products were prepared and administered if the transfusion trigger was reached. Neostigmine 0.05 mg/kg and Atropine 0.01 mg/kg were used to reverse the neuromuscular blockade, and extubation was done after fulfilling the extubation criteria.

#### **Assessment in PACU**

After full recovery, all patients received an IV – patient-controlled analgesia (PCA) system (Accufuser M8P, 100 mL; Woo Young Meditech Co, S. Korea). PCA was prepared with 60 mL of isotonic saline containing 60 mg morphine, and the selected system was adjusted to infuse a 1 mL bolus dose with a lockout interval of 15 minutes while the basal flow rate was switched off. Breakthrough pain was managed with 2mg morphine. PCA was disconnected after 24 hours from surgery, where oral analgesics were prescribed.

After complete recovery, each patient was moved to the post-anesthesia care unit (PACU), where they were all observed by an anesthetist who had been blinded to the study's protocol. In the PACU and ward, the hemodynamic parameters were noted at intervals of 0, 30 min, 1, 2, 4, 6, 12, and 24 hours. When the patients met the requirements for standard discharge, they were moved to the ward.

#### **Outcomes assessment**

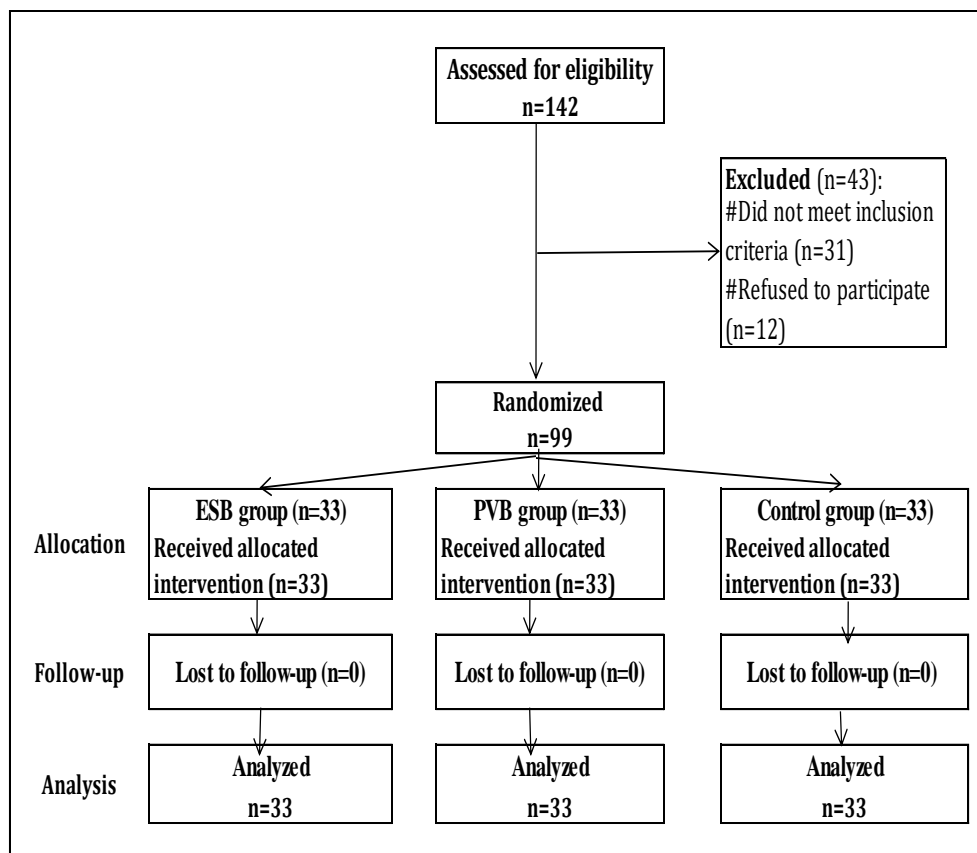
The primary outcome was the first analgesic requirement (the time to first analgesic request from the time of complete postoperative recovery). The secondary outcomes were to assess the total amount of rescue analgesics needed during the 1<sup>st</sup> 24 hours, as well as postoperative complications such as PONV, pneumothorax, pruritus, shivering, hypotension, bradycardia, and respiratory depression (respiratory rate <10/min) and patient satisfaction (using an NRS score). Using a numerical rating scale (NRS) (ranging from 0-10 cm: where 0 = no pain, 10 = worst pain), pain scores were assessed at the time of arrival in the PACU as well as at 30 minutes, 1, 2, 6, 12, and 24 hours.

#### **Sample size calculation**

Using G Power 3.1.9.2.12, the sample size was calculated. The smallest sample size was determined based on a prior study that compared the analgesic effects of ESPB and the well-known paravertebral block in patients scheduled for elective breast surgery (13, 14). The sample size was calculated to identify differences in the time to initial analgesia requirement. According to the findings of Elewa et al., the minimum necessary sample size was determined to be 30 patients per group (number of groups=3) (total sample size=90 patients), using a power of 80% (=0.20) to detect a standardized effect size time to first required analgesia (primary outcome) of 0.5309 and level of significance 5% ( $\alpha$  error accepted =0.05) (15). After adjustment for a dropout rate of 10%, the sample size was increased to 33 patients per group (number of groups=3) (Total sample size =99 patients) (16).

#### **Statistical methodology**

Statistical Package for Social Sciences (SPSS) software, version 28.0, IBM Corp., Chicago, USA, 2021, was used to code, tabulate, and statistically analyze the collected data. The Shapiro-Wilk test was used to determine the quantitative data's normality,



**Figure 2.** Flow chart of the studied cases.

followed by mean and SD (standard deviation) descriptions and an ANOVA test to compare them. We compared qualitative data presented as numbers and percentages with Fisher's Exact and Chi-Square tests for variables with low expected numbers. For pairwise comparison, the post hoc Bonferroni test was used. If the  $p$ -value was  $< 0.050$ , the significance level was considered significant.

## Results

A total of 142 patients were assessed for eligibility in the study; 31 patients were excluded because they did not meet the inclusion criteria, and 12 patients refused to share in the study. Finally, 99 patients scheduled for open splenectomy were enrolled in this study. Patients were randomly allocated into three groups (33 in each group). The Consolidated Standards of Reporting Trials (CONSORT) flow chart is presented in Fig 2.

Demographic data were comparable, including age, sex, and BMI. Similarly, ASA status, duration, indication of surgery, and duration of anesthesia did

not differ significantly across the studied groups (Table 1).

Regarding HR and MAP, there were no significant differences at baseline, after induction, and after intubation. In contrast, HR and MAP at 30 minutes after induction (20 min after the block), during the operation, at PACU, and within 2, 6, 12, and 24 hours after surgery, respectively, were significantly higher in the control group than ESPB and PVB groups ( $P < 0.001$ ). However, there were no significant differences between the ESPB and PVB groups.

Intraoperative total fentanyl consumption was higher in the control group ( $214 \pm 21.9 \mu\text{g}$ ) than in both the ESPB group ( $142.4 \pm 7.4 \mu\text{g}$ ;  $P < 0.001$ ) and the PVB group ( $144.8 \pm 8.8 \mu\text{g}$ ;  $P < 0.001$ ), while there was no statistically significant difference between both ESPB and PVB groups (Table 2). Also, intraoperative isoflurane consumption was significantly higher in the control group compared to ESPB and PVB groups  $P < 0.001$ .

Time to first requested analgesia was significantly shorter in the control group ( $0.1 \pm 0.1$  hour) with no significant difference between ESPB and

PVB groups (12.5±1.6 hour), (and 12.4±1.5 hour) respectively. Postoperative total morphine consumption was significantly lower in both ESPB (5.4±1.4 mg) and PVB (5.5±1.5mg) groups than the

control group (19.1±2.2 mg; p < 0.001).

Through the first 24 hours following the procedure, the ESPB and PVB groups' NRS scores for postoperative pain were lower than those of the control

**Table 1:** Demographic data and operative characteristics of patients.

Variables		ESP (N=33)	PVB (N=33)	Control (N=33)	p-value
Age (years)		36.5±6.4	35.8±7.0	38.3±7.3	^0.317
Sex (n, %)	Male	21 (63.6%)	24 (72.7%)	23 (69.7%)	#0.720
	Female	12 (36.4%)	9 (27.3%)	10 (30.3%)	
BMI (kg/m <sup>2</sup> )		26.8±1.4	26.4±1.4	26.3±1.3	^0.346
ASA (n, %)	II	28 (84.8%)	31 (93.9%)	27 (81.8%)	§0.418
	III	5 (15.2%)	2 (6.1%)	6 (18.2%)	
Indication of Splenectomy (n, %)	Trauma	12 (36.4%)	14 (42.4%)	16 (48.5%)	§0.899
	Thalassemia major	10 (30.3%)	6 (18.2%)	5 (15.2%)	
	Splenomegaly with hypersplenism	6 (18.2%)	5 (15.2%)	6 (18.2%)	
	Splenic cyst	4 (12.1%)	6 (18.2%)	4 (12.1%)	
	Lymphoma	1 (3.0%)	2 (6.1%)	2 (6.1%)	
Duration of surgery (minutes)		122.5±4.4	121.1±4.7	122.8±5.5	^0.324
Duration of anesthesia (minutes)		154.9±4.7	154.2±5.6	156.2±6.4	^0.355

Data presented as Mean±SD unless mentioned otherwise. ^ANOVA test. #Chi square test. §Fisher's Exact test. BMI, body mass index; ASA, American Society of Anesthesiology Classification.

**Table 2:** The comparison regarding postoperative pain perception intraoperative analgesia and postoperative analgesia.

Time	ESP (N=33)	PVB (N=33)	Control (N=33)	p-value
<b>Postoperative pain perception (NRS score)</b>				
Minute-0	0.9±0.6a	1.0±0.6a	7.9±1.0b	^<0.001*
Minute-30	2.0±0.6a	2.1±0.7a	5.0±0.8b	^<0.001*
Hour-1	1.8±0.6a	2.0±0.7a	5.1±0.8b	^<0.001*
Hour-2	1.3±0.9a	1.5±0.8a	5.2±0.8b	^<0.001*
Hour-6	1.6±0.9a	1.7±0.8a	5.6±0.9b	^<0.001*
Hour-12	3.9±0.7a	4.0±0.7a	6.4±1.0b	^<0.001*
Hour-24	4.1±0.7a	4.2±0.6a	5.4±1.3b	^<0.001*
<b>Intraoperative analgesia</b>				
Consumed Isoflurane dose (MAC)	0.8±0.1a	0.8±0.1a	1.5±0.1b	^<0.001*
Total Fentanyl dose (µg)	142.4±7.4a	144.8±8.8a	213.8±21.9b	^<0.001*
<b>Postoperative analgesia</b>				
Time to first request analgesia (hours)	12.5±1.6a	12.4±1.5a	0.1±0.1b	^<0.001*
Total morphine consumption /24 hours (mg)	5.4±1.4a	5.5±1.5a	19.1±2.2b	^<0.001*

Data presented as Mean±SD. PO: Postoperative. ^ANOVA test. \*Significant. Homogenous groups had the same symbol, "a, b" based on the post hoc Bonferroni test. NRS, Numeric Rating Scale; MAC minimum alveolar concentration.

**Table 3:** The comparison regarding postoperative adverse effects.

Adverse effect	ESP (N=33)	PVB (N=33)	Control (N=33)	p-value
Bradycardia	7 (21.2%)a	6 (18.2%)a	0 (0.0%)b	§0.012*
Hypotension	7 (21.2%)a	7 (21.2%)a	0 (0.0%)b	§0.009*
Pruritus	2 (6.1%)a	3 (9.1%)a	12 (36.4%)b	#0.002*
Shivering	7 (21.2%)a	6 (18.2%)a	17 (51.5%)	#0.005*
Nausea and vomiting	3 (9.1%)a	4 (12.1%)a	14 (42.4%)b	#0.001*
Urine retention	3 (9.1%)a	3 (9.1%)a	13 (39.4%)b	#0.001*
Respiratory depression	0 (0.0%)a	0 (0.0%)a	4 (12.1%)b	§0.033*
Pneumothorax	0 (0.0%)	0 (0.0%)	0 (0.0%)	NA

NA: Not applicable. #Chi square test. \*Significant. Homogenous groups had the same symbol, "a, b" based on the post hoc Bonferroni test.

group ( $p < 0.001$ ), as shown in (Table 2).

Regarding postoperative adverse effects, the incidence of PONV was statistically lower in the ESPB and PVB groups [3 patients (9.1%)], [4 patients (12.1%)] than in the control group (14 patients (42.4%)). However, bradycardia and hypotension were significantly less frequent in the control group, with no significant difference between the ESPB and PVB groups. Pruritus, shivering, urine retention, and respiratory depression were significantly most frequent in the control group, with no significant difference between ESPB and PVB groups (Table 3). There were no reported cases of pneumothorax in all groups.

## Discussion

This prospective, randomized study showed that US-guided ESPB and US-guided PVB were feasible and effective regional analgesic techniques in reducing postoperative pain experienced by patients who underwent open splenectomy surgery.

The paravertebral block provides postoperative analgesia for thoracic and upper abdominal surgeries. However, the Paravertebral block covers 1-2 dermatomes above and below the injection level. Therefore, multiple injections are usually required to induce analgesia in the surgical area. Unfortunately, the thoracic paravertebral block may be associated with complications such as pneumothorax, hypotension, and bradycardia secondary to sympathetic block. For ESPB, the US landmarks were

clear and characteristic, especially after the identification of the transverse processes of the thoracic vertebra. The erector spinae plane (ESP) block may be a suitable alternative to the paravertebral block for thoracoabdominal wall surgeries. An effective relief of postoperative pain should be done as a crucial role of enhanced recovery after surgery (ERAS).

Although GA with opioid-based intravenous analgesia is effective, it has several disadvantages: high opioid doses are occasionally required to maintain perioperative analgesia, which can have postoperative severe effects like shivering, pruritus, nausea, vomiting, and respiratory depression (17). Additionally, it might cause postoperative hyperalgesia (18). In this population, multimodal analgesia may be an effective strategy. The PVB can cause both somatic and visceral nerve blocks (19). the mechanism of action of ESPB is still not fully understood, but local anesthetic may diffuse to the thoracic paravertebral space and intercostal spaces, where it blocks sympathetic fibers as well as the ventral and dorsal rami of spinal nerves. As a result, when performed at a lower thoracic level, the ESPB is thought to provide visceral and somatic abdominal analgesia (20).

The present study proved that the regional analgesic techniques, ESPB and PVB, already prolonged the postoperative analgesia duration, reduced morphine consumption, and reduced pain scores during the first 24 hours after splenectomy. On the same side, a study by Gürkan Y and his colleagues (21), which included patients undergoing breast

surgery, has shown that US-guided ESPB and PVB provided adequate analgesia and have an opioid-sparing effect by reducing morphine consumption. Also, Stewart JW and his colleagues (22) proved no significant differences in the resting or movement-evoked pain scores between PVB and ESPB up to day seven after a radical mastectomy. A recent meta-analysis aligns with our study, which demonstrated that postoperative analgesic effects of PVB and ESPB are similar (23). On the contrary, Chen N et al. (24) concluded that PVBs are superior to ESPBs for postoperative analgesia after thoracoscopic surgery. As we did, the author conducted the PVB with multiple injections on different levels versus a single dose injection for the ESPB.

In our study, we experienced ESPB, which can serve as a safe and effective method for regional analgesia. It was practically easier to perform than paravertebral block, and it can avoid injury of the pleura, major vessels, or nerves, so it seemed to have no significant complication. Further, ESPB did not interfere with respiratory functioning (25). In the results of this trial, there was no significant difference between both groups in the development of pneumothorax, but it is also a major clinical issue that should be considered.

Similarly, Fang B et al. (10), who worked on pain relief for patients undergoing thoracotomy, found that preoperative single-injection ESPB provided similar effects to TPVB, and ESPB had the advantage of a lower adverse effect incidence. Other clinical trials (26, 27) considered that the technique has a specific complication rate and a risk/benefit ratio, which should be considered.

The fruitful gain in our research with the nerve block for pain management was the reduction of opioid requirements and their resulting risky side effects (e.g., PONV, pruritus, and respiratory depression), as there was no significant difference between both ESPB and PVB groups when compared with the control group which recorded higher complication results. On the same side, other trials by Yao et al. (28) and El Hawary H et al. (29) recorded similar results with decreased postoperative opioids and their side effects. Furthermore, we found that in the ESPB group, patients complained of slight epigastric pain in the PACU that was relieved by acetaminophen and

antispasmodic. It was also notified by a previous trial (30).

Limitations of the study: First, the inability to extend the block by a catheter for infusion instead of a single injection and the precise pain assessment. Second, some patients could not be enrolled in the study due to massive coagulopathy or being explored urgently to control intra-abdominal bleeding. Third, we could not examine the dermatomal level following the ESPB or PVB group procedure because the study's methodology involved giving blocks to patients under general anesthesia.

## Conclusion

This study has concluded that US-guided ESPB and PVB provided adequate postoperative analgesia after open splenectomy and decreased total opioid consumption and their side effects. However, ESPB was technically easier and more effective with a single injection than PVB with a bi-level injection.

## Acknowledgment

None.

## Conflicts of Interest

The authors declare that they have no conflict of interest.

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