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Comparison of analgesic efficacy of ultrasound-guided erector spinae block with port site infiltration following laparoscopic cholecystectomy

Magdy Mohammed Mahdy, Essam Ezzat Abdelhakeem, Ayman Mohamed Fawzy and Mostafa Samy Abbas

Department of Anesthesia and Intensive Care, Faculty of Medicine, Assiut University, Assiut, Egypt

ABSTRACT

Background: One of the foremost common medical reasons for delayed discharge following ambulatory surgery is pain. Erector spinae plane block (ESPB) is a comparatively new technique utilized for intra- and post-operative analgesia. We aimed to compare the analgesic efficacy of ESPB with port site infiltration in laparoscopic cholecystectomy (LC) patients.
Methods: Forty-four patients 18–60 years old with body mass index (BMI) of 18–35 kg/m^2 who were scheduled for laparoscopic cholecystectomy were randomized into two groups (22 patients each) either to obtain an ultrasound-guided Bilateral ESPB (group A) or port-site infiltration of local anesthetic (group B) after anesthesia induction. The primary outcome was the total postoperative nalbuphine consumption in the first 24 h.
Results: The overall amount of rescue analgesia was significantly lower in group A (8.27 ± 1.12 mg for nalbuphine as first-line rescue analgesic and 10 patients needed ketorolac as second line rescue analgesic) than in group B (15.92 ± 2.11 mg for nalbuphine as first-line rescue analgesic and 22 patients needed ketorolac as second-line rescue analgesic) during the first 24 h postoperatively. The time to first analgesic request showed statistically significant difference between the two groups with longer time in group A (p value < 0.001). The numerical rate score at rest and when coughing was significantly lower in group A than group B.
Conclusion: Erector spinae plane block was superior to port site infiltration regarding decrease in analgesic consumption and prolongation in time of postoperative rescue analgesia in patients undergoing laparoscopic cholecystectomy.

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1. Introduction

One of the foremost common medical reasons for delayed discharge (17–40%) following ambulatory surgery is pain [1,2]. Laparoscopic cholecystectomy (LC) pain is different from open cholecystectomy pain in both type and mechanism [3]. Distention of the peritoneal cavity and irritation of the diaphragm brought on by increased intra-abdominal pressure and insufflation with CO2 also contribute to visceral pain in addition to somatic pain from the incisions for port entry [4,5].

Paracetamol, NSAIDs, opioids [2], incision site infiltration with local anesthesia, and different maneuvers of regional anesthesia [as transversus abdominis plane block (TAP), oblique subcostal transversus abdominis plane block (OSTAP or STAP), and paravertebral block] are the typical analgesic options for postoperative pain [6–8]. These methods, with the exception of paravertebral block, only treat somatic pain, making them insufficient in some cases [9].

Erector spinae plane (ESP) block is a comparatively new technique utilized for intra- and post-operative analgesia. Forero et al. [10] first described the technique in 2016, when it was applied to the management of thoracic neuropathic pain.

The erector spinae block is accomplished by injecting a local anesthetic in-between the transverse process and the erector spinae muscles (spinalis, longissimus, iliocostalis/from medial to lateral). The local anesthetic is spreading in a cephalic and caudal direction. According to earlier research, the solution is likely to block both dorsal and ventral rami of the spinal nerves and cause both visceral and somatic pain to be blocked as it crosses the internal intercostal membrane [11,12].

Erector spinae plane (ESP) block possesses some benefits over Transverse Abdominis Plane (TAP) block in abdominal surgery. The ESP block could be used to anesthetise any level, while the TAP block typically covers dermatomes below T7 [13].

With the assumption that both erector spinae plane block and port-site infiltration are efficient to provide good post-operative analgesia after laparoscopic cholecystectomy, our aim was to compare the effectiveness of bilateral USG-guided ESPB and port-site infiltration for this purpose.

CONTACT Magdy Mohammed Mahdy magdy.mahdy@aun.edu.eg Department of Anesthesia and Intensive care, Faculty of medicine, Assiut University, Assiut 71515, Egypt

2. Materials and methods

2.1. Enrollment and eligibility

This prospective randomized single-blinded clinical trial was conducted in Assiut University Hospitals, Egypt, after obtaining Hospital Ethical Committee approval under number: (17101091) and registered at "http://www.clinicaltrial.gov" under number: (NCT04167176). Forty-four ASA I-II patients at age of 18 to 60 with a body mass index (BMI) of 18 to 35 kg/m^2 who were listed for laparoscopic cholecystectomy provided written informed consent. Patients with known drug allergies, skin infections at the needle puncture site, chronic pain syndromes, coagulopathy, chronic opioid use, and patients who administered any analgesics within 24 h of surgery were all excluded from the trial. Patients were enrolled in the study from 15 September 2020, to 17 September 2022.

2.2. Randomization and blindness

Using a web-based randomizer (http://www.randomizer.org), the participating patients were randomized to one of two groups to receive either an erector spinae plane block ($n = 22$, Group A/study group) or local anesthetic infiltration at the sites of the laparoscopy ports ($n = 22$, Group B/control group). In this study, neither the Participant nor Outcomes Assessor know which treatment or intervention was received until the trial is over.

2.3. Preoperative protocol

Recruited patients were taught how to assess their acute postoperative pain before surgery using the numerical rating scale (NRS), which ranged from 0 to 10, with 0 representing no pain and 10 representing the most intense pain being imagined [14].

2.4. Anesthetic procedure

An IV line was inserted and secured in the holding area prior to surgery. According to the hospital's protocol, all patients received IV injection of pantoprazole 40 mg, ondansetron 8 mg, antimicrobial prophylaxis, and midazolam 1–2 mg.

Standard monitors were used, including noninvasive blood pressure, pulse oximetry, electrocardiography, temperature, and capnography. Fentanyl 1–2 µg/kg and Propofol 2 mg/kg were used to induce anesthesia. Rocuronium bromide 0.6 mg/kg was used to facilitate endotracheal intubation and maintain skeletal muscle relaxation during surgery with the aid of train of four. Oxygen-air mixture 40% and isoflurane were used to maintain anesthesia. To guarantee normocarbia, controlled ventilation with closed circuit is used. After induction of general anesthesia nasogastric or orogastric tube was used to deflate the stomach which was removed at end of surgery. Patients underwent the intervention in accordance with their group assignment after anesthesia induction and under strict aseptic conditions.

After inducing anesthesia, patients in the erector spinae plane block group were positioned on their left side. Betadine 2% was used for sterilization. About 2.5–3 cm lateral to the T9 spinous process, a linear high-frequency ultrasound probe (linear 6–13 MHz, SonoSite M-Turbo®, Bothell, DC, USA) was positioned longitudinally in a parasagittal orientation. Superficial to the tip of the T9 transverse process, the erector spinae muscles were recognized. An out-of-plane approach was used to introduce a 21 G 10 cm needle. Deep to the erector spinae muscle, the fascial plane was entered with the needle tip. The erector spinae muscle being lifted off the transverse process shadow on ultrasonographic imaging confirmed the needle's tip placement. Twenty milliliters of a mixture of 10 mL of bupivacaine 0.5%, five mL of lidocaine 2%, and 5 mL of normal saline were administered. On the opposing side, the same intervention was repeated.

For the local infiltration approach, the same surgeon conducted pre-incisional port-site infiltration using a 20 ml mixture of 10 ml bupivacaine 0.5%, 5 ml lidocaine 2%, and 5 ml saline after inducing anesthesia. The volume was equally divided between port sites. A total of four ports were created: one each in the supraumbilical, subxiphoid, and right subcostal regions at the mid-clavicular and anterior axillary lines. At the end of surgery, train of four (TOF) was used to guide reversal of neuromuscular blockade by neostigmine and atropine. After extubation, patients were moved to the post-anesthesia care unit (PACU).

2.5. Data measurements

Heart rate (HR) and mean arterial blood pressure (MAP) were measured intraoperatively every 5 min for the first 30 min and then every 15 min after that until the end of surgery. During surgery, any hemodynamic response was noticed. Supplemental analgesia with IV fentanyl 0.5 µg/kg was given for an intraoperative HR or MAP increase of more than 20% of baseline. There was no other intraoperative analgesic administered. Pneumoperitoneum was removed from all patients following surgery.

All patients received 1 g intravenous infusion of paracetamol every 8 h following surgery. A bolus of 0.05 mg/kg intravenous nalbuphine and an infusion of 30 mg intravenous ketorolac were given as first- and second-line rescue analgesics, respectively, for breakthrough pain.

After surgery, pain on the numeric rate scale (NRS) was serially measured at 1, 2, 4, 8, 16 and 24 h. The type of intervention received was unknown to both the outcome assessor and the patients. If the NRS was less than 2 at the recommended time of delivery, the regular paracetamol dose was skipped. When the patient complained of pain or when the NRS was higher than 4, rescue analgesics were given. The time of the first analgesic request and NRS at that moment were noted. The period from block administration to the point at which NRS was ≥4 when assessed at serial intervals or the patient complained of pain was considered the duration of analgesia. If the NRS score is greater than 4, a bolus of 0.05 mg/kg nalbuphine as a first-line rescue analgesic may only be administered 2 h later. The total amount of rescue analgesics required throughout the initial 24 h was recorded. We reported postoperative nausea and vomiting as well as shoulder pain for the first 24 h.

Ondansetron 0.1 mg/kg IV was administered to patients as a rescue antiemetic. If ondansetron had no effect, 10 mg (0.2–0.5 mg/kg) of IV metoclopramide was administered. Occurrence of any complications such as hematoma, bleeding, local anesthetic systemic toxicity, pneumothorax, and allergic reactions was also observed.

Total postoperative nalbuphine use in the first 24 h was our primary outcome. Time till the patient first requested rescue analgesia, NRS score, changes in hemodynamics, and side effects were the secondary outcomes.

2.6. *Statistical analysis*

To calculate sample size, the G*power software, version 3.1.9.2, was utilized [15]. The mean (standard deviation) total morphine requirement along the first 24 h after surgery in the local anesthetic infiltration group in a prior study [16] comparing TAP block to local anesthetic infiltration in participants having conventional four port laparoscopic cholecystectomy was 15.4 (9.2) mg. With an alpha error of 0.05, a sample size of 22 would be needed for each group to achieve a reduction in opioid requirement of 50%. Forty-four people were chosen as the final sample size for the study.

With the aid of the SPSS software package from IBM version 20.0, data were entered into the computer and evaluated. (Armonk, NY: IBM Corp) [17] Number and percentage were used to describe qualitative data. The Kolmogorov–Smirnov test was used to determine whether the distribution was normal. For normally distributed data, the mean and standard deviation were used, and for data with an abnormal distribution, the median and range (minimum and maximum) were used. The 5% level was used to determine whether the results were significant.

To compare the two groups under study, the tests used were the Chi-square test for categorical variables, the Student t-test for quantitative variables with a normal distribution, and the Mann Whitney test for quantitative variables with an abnormal distribution.

3. Results

We enrolled 44 patients for the study and randomly assigned them to one of two groups as illustrated in the CONSORT flow-chart (Figure 1). We found insignificant differences among both groups regarding patient characteristics (i.e., age, sex, BMI, and ASA classification) and operative time (p value > 0.05) as shown in Table 1.

Regarding analgesic consumption as shown in Table 2: The time to first analgesic request in hours showed a statistically significant difference between the two groups with longer time in group A (p value < 0.001), but NRS at first analgesic request showed no statistically significant difference between the two groups (p value > 0.05).

The total 24 h Nalbuphine consumption as first-line rescue analgesic (mean ± SD) was 8.27 ± 1.12 mg in group A and 15.92 ± 2.11 mg in group B (*p value < 0.001*). Number of patients who need Ketorolac as second-line rescue analgesic as well as Paracetamol consumption in gm were significantly higher in group B in comparison to group A (p value < 0.001).

However, Supplemental intraoperative Fentanyl consumption showed no statistically significant difference between the two groups (p value > 0.05).

Regarding Numerical rate score at rest, there was a statistically significant difference in the median (range) during the postoperative 24 h with a significant increase in group B when it is compared to group A, except at 4 and 24 h, there were no statistically significant differences in the two groups; however, the score was higher in group A at 8 h as shown in Figure 2.

Similarly, there was a statistically significant difference in the median (range) NRS when coughing during the postoperative 24 h with significant increase in group B when it is compared to group A, except at 16 and 24 h there were no statistically significant differences in the two groups; however, the score was higher in group A at 4 and 8 h as shown in Figure 3.

The hemodynamic parameters: heart rate and mean blood pressure were significantly higher in group B than in group A during the intraoperative and postoperative period except at baseline as shown in Figures 4,5.

Regarding Post-operative nausea and vomiting and shoulder pain, there were statistically significant differences between the two groups with lower incidence in group A (p value < 0.05) as shown in Table 3. None of the groups exhibited any other complications such as bleeding, hematoma, local anesthetic systemic toxicity, allergic reactions, paresis, or pneumothorax.

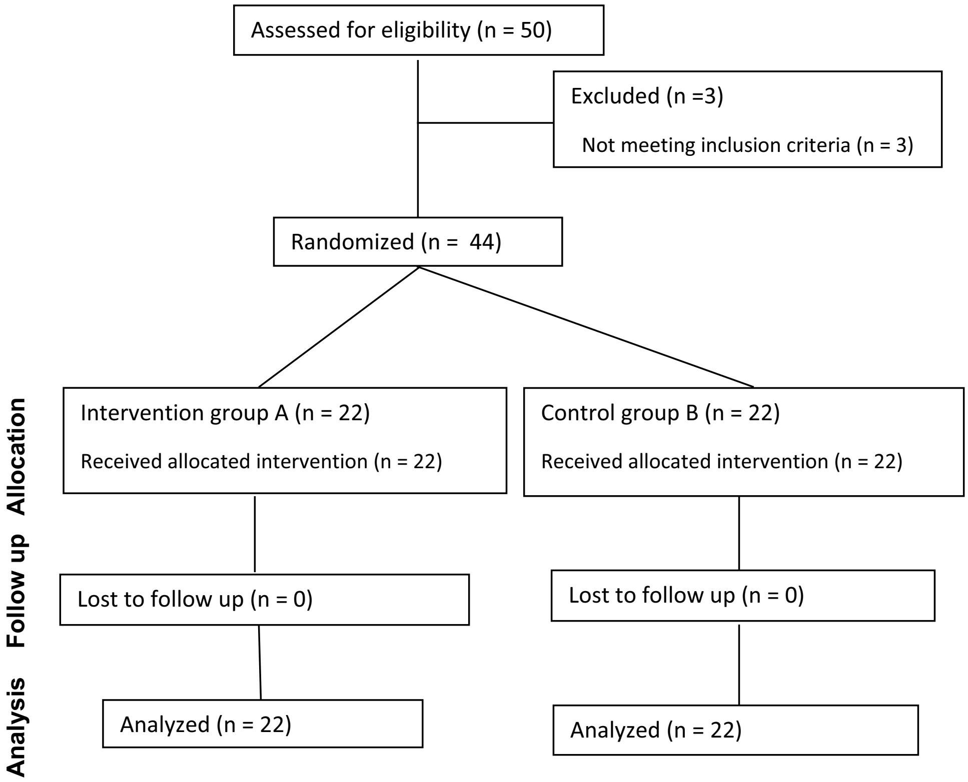

Figure 1. The CONSORT flow diagram. CONSORT indicates consolidated standards of reporting trials.

Table 1. Patient characteristics and operation time.

Patient characteristics	Group A ($n = 22$) Mean ± SD	Group B ($n = 22$) Mean ± SD	P-value
Age (years)	37.82 ± 12.95	40.05 ± 11.23	0.546
Sex: No. (%)			
Male	4 (18.2%)	3 (13.6%)	1.000
Female	18 (81.8%)	19 (86.4%)	
BMI	29.88 ± 3.27	29.91 ± 4.18	0.977
ASA: No. (%)			
I	18 (81.8%)	20 (90.9%)	0.664
II	4 (18.2%)	2 (9.1%)	
Operation time (min)	46.36 ± 7.90	47.05 ± 5.27	0.738

Data are presented as mean ± SD or number (%). BMI Body mass index, ASA American society of anesthesiologists. P-value <0.05 was considered statistically significant.

Table 2. Analgesic consumption.

	Group A ($n = 22$) Mean ± SD	Group B ($n = 22$) Mean ± SD	P-value
First analgesic request (h)	6.23 ± 1.51	1.00 ± 0.00	0.000*
NRS at first analgesic request	4.55 ± 0.67	5.05 ± 1.00	0.058
Nalbuphine consumption (mg)	8.27 ± 1.12	15.92 ± 2.11	0.000*
Ketorolac No. (%)	10 (45.5%)	22 (100.0%)	0.000*
Paracetamol consumption (gm)	1.59 ± 0.50	2.77 ± 0.43	0.000*
Fentanyl consumption (mic)	109.09 ± 19.74	106.82 ± 23.38	0.729

Data are presented as mean ± SD or number (%). NRS Numerical rate scale. P-value <0.05 was considered statistically significant. *Statistically significant.

4. Discussion

In the previous 5 years, the Ultrasound-Guided Erector Spinae Plane block (US-ESPB), which was first reported by Forero et al. in 2016, has become increasingly popular [10]. This innovative regional approach offers analgesia by acting on the dorsal and ventral rami of the spinal nerves, depending on the injection site at which level. The local anesthetic distributes over numerous levels as the erector spinae fascia extends cranially to the nuchal fascia and caudally to the sacrum [18].

According to earlier studies, US-ESPB effectively managed pain following various surgical procedures. Following abdominal surgery, various

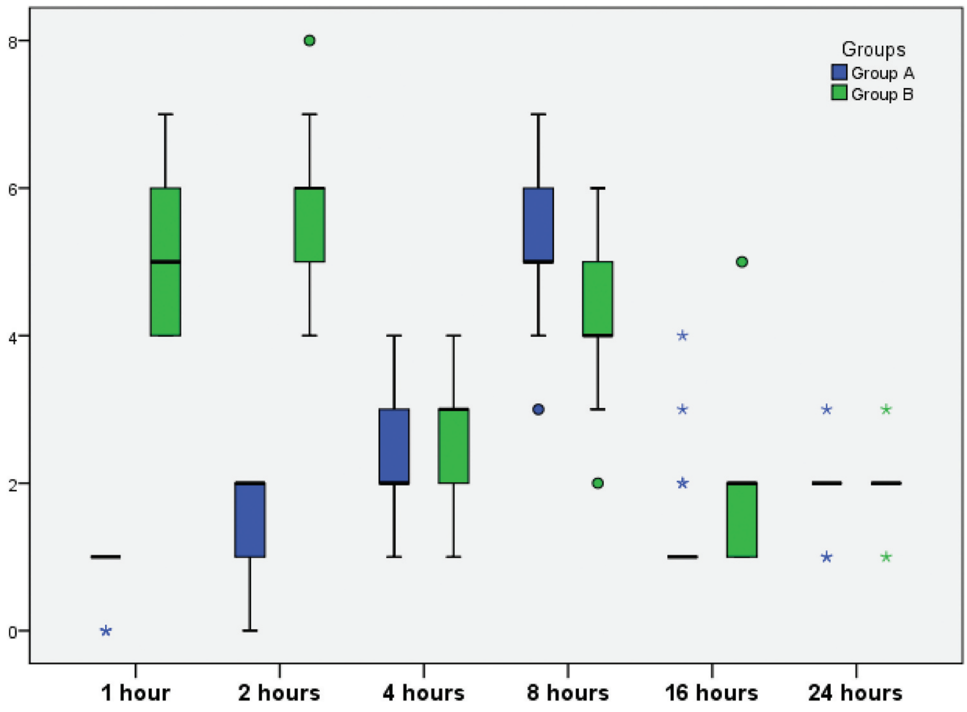

Figure 2. Numerical Rate Scale (NRS) at rest.

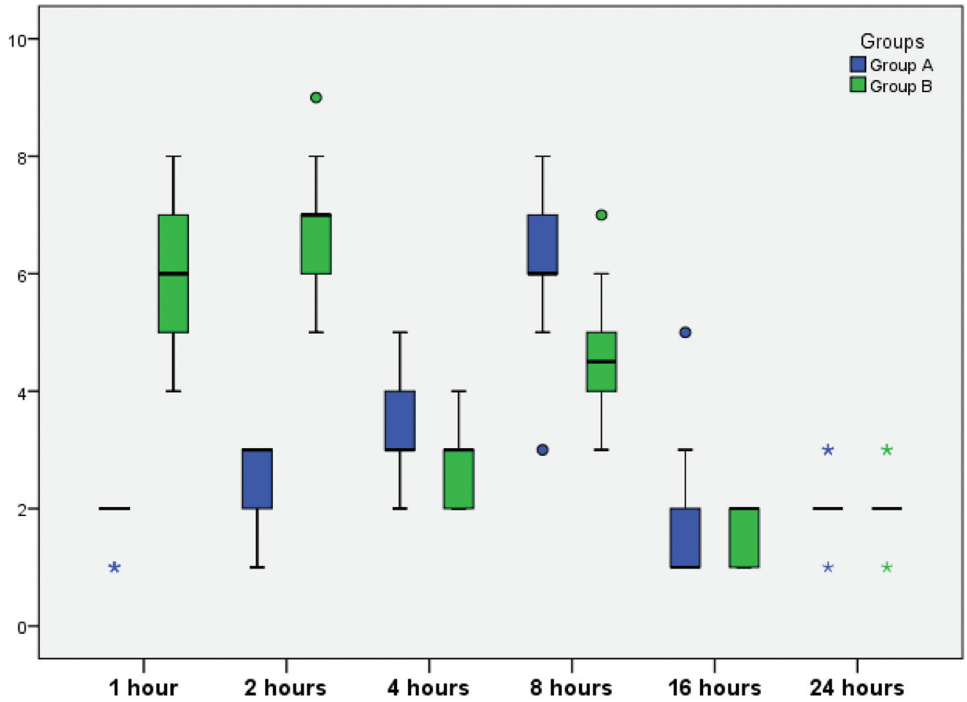

Figure 3. Numerical Rate Scale (NRS) when coughing.

randomized controlled trials indicated that US-ESPB appeared to be beneficial in reducing pain and improving function [19–21]. Yet, there are not enough studies in this field. Therefore, the main goal of this study was to compare the effects of port-site infiltration with bupivacaine to US-ESPB block on postoperative opioid consumption and analgesic impact after laparoscopic cholecystectomy.

We found that group A provided adequate pain relief with no major adverse effects. As shown by the statistically significant prolonged time of first analgesic request, statistically significant decrease in the total amount of nalbuphine consumption as first-line rescue analgesic (8.27 ± 1.12 mg compared to 15.92 ± 2.11 mg in group B). Ten participants in group A needed ketorolac as second-line rescue analgesic, while all participants in group B needed ketorolac. The total amount

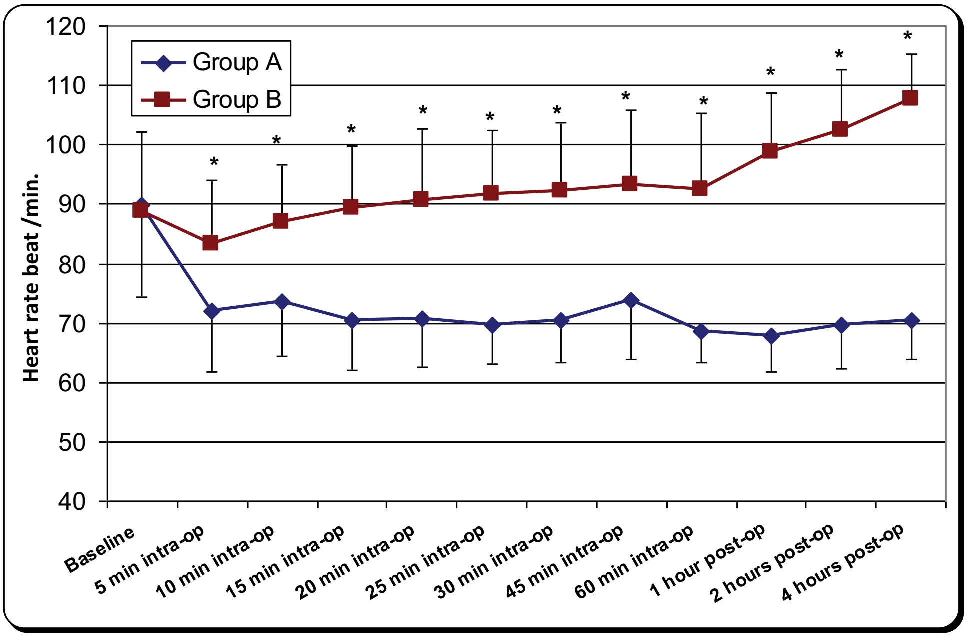

Figure 4. Heart rate (mean ± standard deviation) (y axis). Time in minutes (x axis). $P < 0.05$ was considered statistically significant. * Statistically significant.

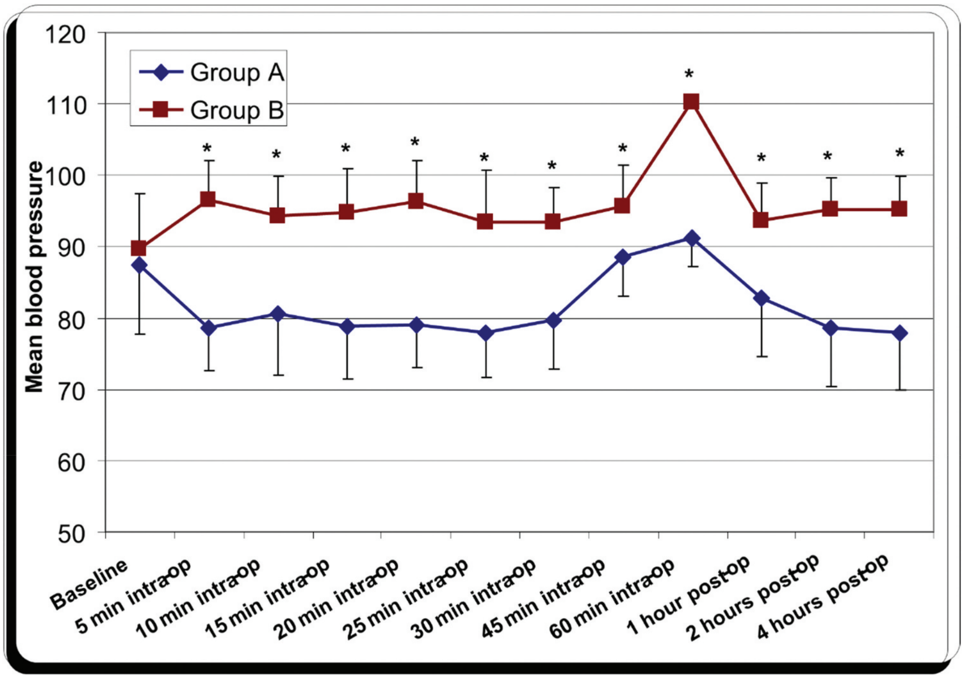

Figure 5. Mean blood pressure (mean ± standard deviation) (y axis). Time in minutes (x axis). $P < 0.05$ was considered statistically significant. *Statistically significant.

Table 3. Postoperative nausea and vomiting and shoulder pain.

	Group A (*n* = 22)		Group B (*n* = 22)		
Side effects	No.	(%)	No.	(%)	P-value
Nausea/vomiting	2	9.1	8	36.4	0.031*
Shoulder pain	0	0.0	14	63.6	0.000*

Data are presented as number (%). P-value <0.05 was considered statistically significant. * Statistically significant.

of paracetamol consumption was 1.59 ± 0.50 gm in group A while in group B, it was 2.77 ± 0.43 gm. Also, there was a significantly lower numerical rate score at rest and when coughing along 24 h postoperative in group A when compared to group B.

Acute pain after LC involves diverse components, including the trocar site induced incisional pain, parietal pain, local visceral pain, as well as referred shoulder pain. According to that, subsequent studies assessed the benefit of Ultrasound-guided fascial plane blocks for postoperative analgesia after LC [2,22].

Ibrahim et al. (2020) stated that OSTAP/TAP block successfully reduced postoperative pain and delivered good analgesia for somatic and parietal pain affecting most of the anterior abdomen [23]. Visceral pain caused by damage to tissues during gall bladder removal is generally thought to be the most important factor after LC and it is known that TAP/OSTAP blocks fail to affect visceral nerves. Hence, an another strategy to reduce visceral pain in the context of multimodal analgesia might be required after LC [24–27].

ESPB has developed to overcome the existing limitations to the available pain-relieving strategies. The target location for injection is the space between the transverse process of the vertebra and the erector spinae muscle sheath, which reduces the risk of pneumothorax. As the given volume seems to spread not only cranially and caudally but also into paravertebral area anteriorly, ESPB may block somatic and visceral pain and offer several dermatomal analgesia at the injection site [28].

Additionally, according to Altiparmak et al. (2020), the unilateral block generates sensory blockage over the dermatomes on the opposing side because the local anesthetic migrates into the epidural space due to the rise in intra-abdominal pressure after pneumoperitoneum [29]. Previous studies used VAS for assessment of post-operative pain, and they also found that ESPB had better analgesic effect with significant higher VAS at different times of post-operative period [11,18,30,31].

In agreement with this study, ***Tulgar et al. (2018)***, when they studied the effect of erector spinae block after ileostomy closure, they found similar prolongation of time for the first analgesic request in the study group when it was compared to the control group [20].

The prolonged analgesic effect of ESPB might be accounted for by the local anesthetic's extension to the paravertebral region and the dorsal and ventral rami of the spinal nerves. A sensory blockade across the dermatomes on the other side is reportedly caused by the local anesthetic spread to that side as well as its vast distribution region. Due to these factors, ESPB had been reported to effectively prolong analgesia in a variety of surgeries [19,20,29].

Our findings agree with ***Ibrahim et al. (2020)***, when they studied the effect of erector spinae block versus port site infiltration after LC on the total amount of morphine consumption as rescue analgesic postoperative. They found similar reduction in analgesic consumption when it was compared to the port site infiltration group [31].

Also, ***Kown et al. (2020)*** showed that ESPB analgesia decreased the total amount of analgesics consumed for up to 24 h. Additionally, the ESPB group consumed fewer intraoperative opioids than the non-ESPB group. Opioid usage was reduced by 14% during surgery and 37% after surgery in the ESPB group, compared to non-ESPB group [28].

In agreement with this study, ***Ozdemir et al. (2022)***, When they compared the effects of erector spinae block and oblique subcostal transversus abdominis block (OSTAB) for pain relief after a laparoscopic cholecystectomy. They found similar reduction in analgesic consumption in the study group (ESPB) when it was compared to the control group (OSTAB) [32].

Our study results were also consistent with ***Altiparmak et al. (2020****) as well as* ***Tulgar et al. (2018)***, when they studied the impact of erector spinae block on numerical rate score following laparoscopic cholecystectomy. They found similar reduction in numerical rate score in the study group when it was compared to the control group [29,33].

Regarding hemodynamics, group A showed significant better hemodynamic profile compared to group B which was consistent with the results of ***Mohammed et al. (2022)*** when they studied the effect of erector spinae block on hemodynamic profile after laparoscopic cholecystectomy. They found similar reduction in mean arterial blood pressure in the study group when it was compared to the control group [34].

In contrast, ***Altiparmak et al. (2020)*** did not find significant difference as regards mean atrial blood pressure at different times of assessment between the ESPB and the control group. This discrepancy with our result may be attributed to different sample size, selection bias, and different population [29].

In our study, only two patients experienced nausea and vomiting in group A while eight patients had nausea and vomiting in group B. Although, ***Kown et al. (2020)*** demonstrated that the prevalence of nausea and vomiting after surgery was the same in both the ESPB and the control groups. This discrepancy with our result may be attributed to different sample size and increased consumption of nalbuphine as first rescue analgesic [28].

Two ESPB problems that have been recorded include pneumothorax and motor weakness. Because it was done under US, pneumothorax was quite uncommon. When ESPB was applied at the lower thoracic and lumbar levels, the local anesthetic diffused to the lumbar plexus, causing motor paresis [35].

In general, the amount and concentration of the local anesthetic play a role in determining the effectiveness and safety of an interfacial plane block. According to reports, lumbar ESPB combined with a high-dose local anesthetic volume effectively relieves lumbar back pain [33]. ***Tulgar et al.*** used a concentration of 0.375% bupivacaine as a local anesthetic to avoid block failure and inadequate sensorial block [20]. ***Hanning et al. (2018)*** gave individuals who had underwent LC bilateral injections of 20 ml of 0.5% ropivacaine [26]. ***Karaca and Pınar et al. (2020)*** detected local anesthetic systemic toxicity (LAST) when applied 50 ml of 0.25% bupivacaine for lumbar ESPB [27].

As a result, it was unclear what the ideal volume and concentration of local anesthetic should be for ESPB. In this study, bilateral 20 cc 0.25% bupivacaine with 2% lidocaine injections were used to increase the efficiency of both blocks without reporting any complications. However, we believe that applying blocks before surgery may have concealed mild complications associated with LAST while under general anesthesia.

Our study acknowledges some limitations. First, no dermatomal mapping was conducted; thus, any potential patchy block or block failure in ESPB could not be detected. Second, we did the block while the patient is anaesthetized and did not wait to see if the block was effective before making the skin incision. Third, although ESPB seems to be superior to port site infiltration based on statistical significance, ESPB is considered as an invasive procedure for cholecystectomy. Fourth, not all side effects related to opioids (for example, respiratory depression, pruritus, and ileus) were observed and investigated. Moreover, there are no outcomes collected relevant to the patient experience or resource use. Finally, the small sample size and being conducted in single center.

And yet, our study had several strengths, including being a randomized controlled trial that assessed the effect of ESPB on hemodynamics. Furthermore, we evaluated not only visceral and somatic pain, but also the frequency of postoperative shoulder pain. More studies are needed to establish the appropriate drug concentration and volume to be delivered.

5. Conclusion

Erector spinae plane block (ESPB) was superior to port site infiltration regarding, decrease in analgesic consumption and prolongation in time of postoperative rescue analgesia in patients undergoing laparoscopic cholecystectomy.

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Disclosure statement

None of the authors have any personal, professional, or financial conflicts of interest to declare.

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ORCID

Magdy Mohammed Mahdy http://orcid.org/0000-0001-8076-4171

Abbreviations

ESPB	Erector spinae plane block
BMI	body mass index
LC	laparoscopic cholecystectomy
NSAIDs	non-steroidal anti-inflammatory drugs
TAP	transversus abdominis plane
OSTAP	oblique subcostal transversus abdominis plane
US-ESPB	ultrasound-guided Erector spinae plane block
ASA	American Society of Anesthesiologists
NRS	numerical rating scale
IV	intravenous
TOF	train of four
PACU	post-anesthesia care unit
HR	heart rate
MAP	mean arterial pressure
SPSS	Statistical Package for the Social Sciences
CONSORT	Consolidated Standards of Reporting Trials
VAS	Visual Analogue Scale
LAST	local anesthetic systemic toxicity.

Author contributions

Magdy Mohammed Mahdy: Conceptualization, Methodology, Software, Investigation, Writing – Review & Editing.

Essam Ezzat Abdelhakeem: Validation, Data Curation, Writing – Review & Editing, Supervision.

Ayman Mohamed Fawzy: Software, Formal analysis, Investigation, Writing – Original Draft.

Mostafa Samy Abbas: Validation, Writing – Review & Editing, Supervision.

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