International Journal of Medical Anesthesiology

E-ISSN: 2664-3774
P-ISSN: 2664-3766
www.anesthesiologypaper.com
IJMA 2023; 6(1): 118-125
Received: 22-01-2023
Accepted: 28-02-2023

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Ultrasound guided erector spinae plane block versus quadratus lumborum block for post-operation analgesia in laparoscopic cholecystectomy surgeries: A randomized controlled trial

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DOI: https://doi.org/10.33545/26643766.2023.v6.i1b.383

Abstract
Background: An effective interfascial plane block for laparoscopic (lap) cholecystectomy and other abdominal procedures is the Quadratus Lumborum Block type II (QLB-II). The erector spinae plane block (ESPB), which is guided by ultrasound (US), is a recently described interfascial plane block that is gaining popularity. This research aims to evaluate the relative effectiveness of ultrasound ESPB and US QLB in the treatment of immediate post-operation pain following lap cholecystectomy.
Methods: Sixty cases (21-65 years old, from both sexes) having elective lap cholecystectomy were enrolled in this prospective randomized double-blind research. The cases were randomly classified into three equal groups, C group: received general anesthesia (GA) only, ESPB: received GA and bilateral US ESPB and QLB: received GA and bilateral US QLB.
Results: Duration of performing block was significantly less in group ESPB versus group QLB. Intraoperative heart rate and mean arterial pressure were significantly less after incising the skin, at 30 min in ESPB and QLBs versus group C. Total fentanyl dosage and morphine dosage in 1st 1 day were significantly less in group ESPB and QLB versus group C. NRS at 6, 24 hour was significantly less in ESPB and QLBs versus group C. First time to call for analgesic requirement was significantly delayed in the ESPB and QLBs versus the C group.
Conclusions: The ESPB is as efficient as posterior QLB to provide effective analgesia as comparable results of lower NRS, intraoperative fentanyl and post-operation opioid dosage, delayed first time to call for analgesic requirement and is lower side effects versus control in cases undergoing elective laparoscopic cholecystectomy.

Keywords: Erector spinae plane block, quadratus lumborum block, ultrasound guided, laparoscopic cholecystectomy, analgesia

1. Introduction
Pain is a major contributor to post-operation mortality and the main cause of extended hospital stays following laparoscopic (Lap) cholecystectomy. Cases undergoing Lap cholecystectomy often experience pain and discomfort at the incision sites (the back and shoulders). Between 12 and 60 percent of people experience shoulder and sub-diaphragmatic discomfort. Post-operation discomfort is typically at its worst within the first few hours after surgery and gradually improves over the following two to three days [1].
Lap cholecystectomy is a less invasive alternative to open cholecystectomy that also results in less post-operation discomfort. Pain after lap cholecystectomy, on the other hand, has both somatic and visceral components, including pain from the port entrance wounds, the removal of the gallbladder, and the abdominal insufflation that causes peritoneal distention and peritoneal injury [2-4].
As of now, lap cholecystectomy discomfort has been managed with gas drainages, intraperitoneal saline, intraperitoneal injections of local anesthetics, and intraperitoneal injections of opioids. These techniques were effective in reducing discomfort following lap cholecystectomy, but they were not free of drawbacks. Because of these considerations, lap cholecystectomy has been the subject of numerous analyses of regional anesthetic (RA) [5].
Many novel interfascial blocks have been defined and put into practice as a result of the incorporation of ultrasonographic technology into RA practice [6].

In lap cholecystectomy and other abdominal surgeries, the Quadratus Lumborum Block type II (QLB-II) has been shown to be an efficient interfascial plane block [7].
Recently defined as an interfascial plane block, the ultrasound-guided erector spinae plane block (ESPB) was first reported by Forero *et al*. [8].
Studies show that ESPB alleviates the pain associated with lap cholecystectomy [2, 10], and it has been used to address both acute and chronic pain.
Determining which is better between ultrasound-guided ESPB and ultrasound-guided QLB in controlling post-operation pain following lap cholecystectomy is the focus of this study.

2. Materials and Methods

Sixty patients (21-65 years old, frombpth sexes having elective lap cholecystectomy at Tanta University Hospitals, Egypt between March 2021 and March 2022 were enrolled in this prospective randomized double-blind study.
The research was approved by institutional ethical committee (code: 34503/2/21) and registration on clinicaltrials.gov (ID: NCT04845711) and informed written consent was obtained from each case.
Case refusal, coagulopathy, allergic to local anesthetic, hepatic or kidney abnormalities impacting drug excretion, mental dysfunction or condition that affects cognition, use of medication like gabapentin that could affect pain perception, and BMI > 40 kg/m2 were all disqualifying factors.
Group allocation was utilizing by sealed, opaque envelopes and random numbers produced by a computer: The cases were divided into three categories at random. (20 cases each): group I: C group (n=20): cases received general anesthesia (GA) only, group II: ESPB (n=20): cases received GA and bilateral US ESPB and group III: QLB (n=20): cases received GA and bilateral US QLB. All participants and the medical staff involved in gathering data and providing follow-up were unaware of the case's assigned group. Only one anesthesiologist, who did not take part in data gathering or analysis, performed all blocks.

2.1 Preoperative preparation

Preoperative assessment included a complete blood count, coagulation profile, random blood sugar, and liver and renal function tests, along with a clinical examination.
During the preanesthetic assessment, all cases were familiarized with numerical rating scale (NRS), from 0 to 10 with 0 represent no pain while 10 represent maximum intolerable pain.

2.2 Intraoperative

An intravenous line was placed, blood pressure and heart rate were continuously monitored with electrocardiograms and monitoring devices such as pulse oximeters were used in the operating theater. Cases received midazolam 0.02 mg/kg. Propofol (2 mg/kg) and fentanyl (1 g/kg) were used for producing GA. Atracurium 0.1 mg/kg was given to ease tracheal insertion. To keep the case unconscious, 1 MAC of isoflurane was used. (In O2-Air mixture 50%-50%) and Atracurium 0.02mg/kg.
Regional anaesthetic technique was performed after induction of GA, ultrasound guided with a convex transducer, while lying on one's side. In all instances, 20 mL of a Bupivacaine 0.25% solution was used as the local anesthetic. The combination was used on both sides.

2.3 Technique of ultrasound guided erector spinae plane block (US ESPB)

ESPB was performed with the case in lateral position on both sides. A high-frequency ultrasound transducer (Philips CX50 Extreme edition) was placed in a longitudinal orientation 3 cm lateral to the midline. In order to identify counting of ribs using ultrasound three muscles were identified as superficial to the hyperechoic transverse process shadow as follows: trapezius, rhomboid major, and erector spinae. However, when the rhomboid major muscle disappears this indicates that we are at the level of the 7th dorsal vertebra then counting down to the level of the 9th dorsal vertebra (T9). Under aseptic precautions an 18-gauge the transverse process (TP) was reached by inserting the needle in a craniocaudal direction towards T9 TP in-plane to the US probe and stopping when it contacted the TP. After ensuring the needle was in the right spot, we performed a hydro-dissection using 2–3 cc of saline. 2o ml 0.25% bupivacaine was administered. The largest amount of LA solution would be 20 ml, and the total dose of bupivacaine would not exceed 2 mg/kg [11].

2.4 Technique of ultrasound guided quadratus lumborum block (Type II US-QLB)

QLB was carried out with the case lying on both sides. A high-frequency linear array US probe is used following local povidone iodine sterilization (5-13 MHz). Above the iliac crest, a clean sheath was positioned. After Petit's triangular localization, abdominal muscles identified: transversus abdominus, external and internal obliques. Both oblique muscles were tracked back until a hyperechoic line indicated the TLF layers. To the lower right of the Latissmus dorsi muscle is the QL. The "Shamrock sign" is recognized during the QLB the transverse process of L4 serves as the stalk, while the PM muscle, the QL, and the ES serve as the leaves. Using an in-plane method, a 22G (50 mm) needle was inserted anteromedially along the ultrasound probe's posterior edge. The QL and ES muscles were punctured with the needle's point. Hydrodissection imaging was used to verify the needle was properly positioned before administering 20 mL of bupivacaine 0.25%. The highest volume of local anesthetic solution would be 20 ml [11].
All groups received fentanyl 0.5 μg/kg was given if there was increase in HR or mean arterial blood pressure (MAP) more than 20% of the base line (after exclusion of other causes than pain). Extubation was performed, neostigmine 0.05 mg/kg and atropine 0.01 mg/kg were administered to reverse the effects of the muscle relaxant, and transferral to the post anesthesia care unit (PACU) once surgery was complete.
All cases were given IV multimodal analgesia consisting of paracetamol (1 g q 8 h), Diclofenac K (15 mg q 6 h), and morphia after release from operation room, when NRS ≥ 4 (Figure 23-Figure 24) [12].

2.5 Measurements

All measurements recorded by an investigator who wasn't aware about the research design or intervention. HR and MAP recorded before induction of anesthesia (base-line value), after incising the skin by 5, 15, 30 minutes, and post-operative. Intraoperative fentanyl dosage was recorded.

Numerical rating scale [13] (NRS; 0 = no pain, 10 = maximum pain) post-operation pain evaluated at PACU discharge, 6, 12, 18, and 1 day. Analgesia rescue time was noted. The total amount of morphine administered in the first post-operation day was noted. PONV, hematoma, hypotension (defined as any drop in the MAP of >20% of the prior baseline value), and bradycardia, as well as any other intraoperative or post-operation complication, were all noted.

2.6 Justification of sample size

The sample size was calculated based on the following: 95% confidence limit, 80% power of the research, group ratio 1:1, the range of expected primary outcome (efficacy) is 50-90% and 5 cases were added to overcome drop-out. Therefore, each group contained twenty cases.

2.7 Statistical analysis

The 25th edition of the statistical program SPSS (Statistical Package for the Social Sciences) was used for the study's statistical analysis. (IBM Inc., Chicago, IL, USA). Histograms and the Shapiro-Wilks normalcy test were used to determine whether parametric or nonparametric statistical testing was appropriate for the data. The F test was used to compare the three groups, and the post hoc (Tukey) test was used to compare the means and standard deviations of the pairs of groups. The paired T test was used to compare two independent variables among members of the same cohort. Kruskal-Wallis test was used to evaluate non-parametric variables expressed as median and IQR, and Mann-Whitney (U) test was used to compare each pair of groups. The Wilcoxon test was used to evaluate the means of two continuous variables for each group. The Chi-square test was used for statistical analysis of categorical variables presented as frequencies and percentages. The cutoff for statistical significance was set at a two-tailed P value of less than 0.05.

3. Results

Of the 97 patients evaluated for participation in this prospective, randomized, double-blind study, 26 did not qualify and 11 declined. The remaining 60 cases were divided into three categories using a random number generator. (20 cases in each). All sixty cases were followed and subjected to statistical analysis. (Figure 1).

There was an insignificance upon comparison of baseline data (age, gender, BMI, ASA and physical status) duration of surgery of both groups. Duration of performing block was significantly less in the ESPB versus the QLB (P value < 0.001). [Table 1].

Intraoperative HR and MAP in the C group were significantly higher after incising the skin, and at 30 min versus the baseline HR and MAP, but were significantly less at 5 min and 15min as versus baseline HR and MAP and were similar post-operative as versus baseline. Intraoperative HR in the ESPB and QLB was significantly decreased after incising the skin, at 5, 15, and at 30 min versus baseline and was similar post-operative as versus baseline. [Figure 2].

Intraoperative MAP and HR were similar at baseline, at 5, 15 min and post-operative in all groups. Intraoperative HR and MAP were significantly less after incising the skin, at 30 min in the ESPB and QLBs versus the C group and were similar between the ESPB and QLBs. [Figure 2]

Intraoperative MAP was significantly less at 5, 15, 30 min and at versus baseline MAP in the ESPB, while was similar after incising the skin and post-operative versus baseline MAP. Intraoperative MAP was significantly less after incising the skin, at 5,15 and 30 min as versus baseline in the QLB and was similar post-operative versus baseline MAP. [Figure 2].

Total Fentanyl dosage was significantly less in the ESPB and QLBs versus the C group and was similar between the ESPB and QLBs. First time to call for analgesic requirement was significantly delayed in the ESPB versus the C group(P value <0.001) and in the QLB versus the C group and was similar between the ESPB and QLBs. Total morphia dosage in 1st 1 day post-operation was significantly different in all groups. Total morphia dosage in 1st 1 day post-operation was significantly less in the ESPB and QLBs versus the C group and was similar between the ESPB and QLBs [Table 2].

NRS score in the ESPB was similar at all measurements (6, 12, 18 and 24 hr) versus NRS score on arrival to PACU while it was insignificant difference in ESPB and QLBs. [Figure 3] NRS score was similar on arrival to PACU, 12 and 18 hour in all groups and was significantly different at 6 and 24 hour (P value = 0.001 and 0.004 respectively). NRS score at 6, 24 hour was significantly less in the ESPB and QLBs versus the C group (P value< 0.05) and was similar between the ESPB and QLBs. [Figure 3].

PONV was significantly less in the ESPB and QLBs versus the C group (P value =0.009). Bradycardia and hypotension were similar in all groups. Hematoma didn't occur in any case in the three groups. [Table 3].

Table 1: Case's characteristics, duration of surgery and duration of performing block in all groups

		C group (n = 20)	ESPB (n = 20)	QLB (n = 20)	P value
Age (years)		43.2 ± 13.75	42.15 ± 14.04	45.75 ±14.59	0.710
Gender	Male	6 (30%)	8 (40%)	9 (45%)	0.610
	Female	14 (70%)	12 (60%)	11(55%)	
ASA physical status	I	12 (60%)	11(55%)	14 (70%)	0.987
	II	8 (40%)	9 (45%)	6 (30%)	
BMI (kg/m^2)		28.43±2.88	28.83±3.54	27.12±2.91	0.571
Duration of surgery (min)		67.80±17.77	65.05±18.31	71.75±16.3	0.183
Duration of performing block (min)		--	8.00±1.81	10.25±1.83	< 0.001*

Data are presented as mean ± SD or frequency (%). ASA: American Society of Anesthesiologists BMI: body mass index, *: significant as P value <0.05.

Table 2: Intraoperative fentanyl dosage, first time to call for analgesic and total post-operation fentanyl dosage

	C group (n = 20)	ESPB	QLB	P value	
Intraoperative fentanyl dosage	112.5±11.41	71±6.41	74.5±5.1	< 0.001*	P1<0.001*, P2= <0.001*, P3= 0.366
First time to call for analgesic requirement	4.7±1.17	18.4±3.69	17.4±4.08	0.571	P1<0.001*, P2 <0.001*, P3 = 0.591
Total post-operation morphine dosage	5.7±1.17	2.4±0.82	2.6±0.94	< 0.001*	P1<0.001*, P2= <0.001*, P3= 0.591

Data is expressed as mean ± sd *: significant as P value <0.05. P1: P value between the C and ESPBs, P2: P value between the C and QLBs, P3: P value between the ESPB and QLBs.

Table 3: Complications in all groups

	C group (n = 20)	ESPB (n = 20)	QLB (n = 20)	P value
PONV	7 (35%)	1 (5%)	1 (5%)	0.009*
Hematoma	0(0%)	0(0%)	0(0%)	---
Hypotension	5(25%)	4 (20%)	3 (15%)	0.625
Bradycardia	2 (10%)	1(5%)	1 (5%)	0.535

PONV: post-operation nausea and vomiting, *: significant as P value <0.05

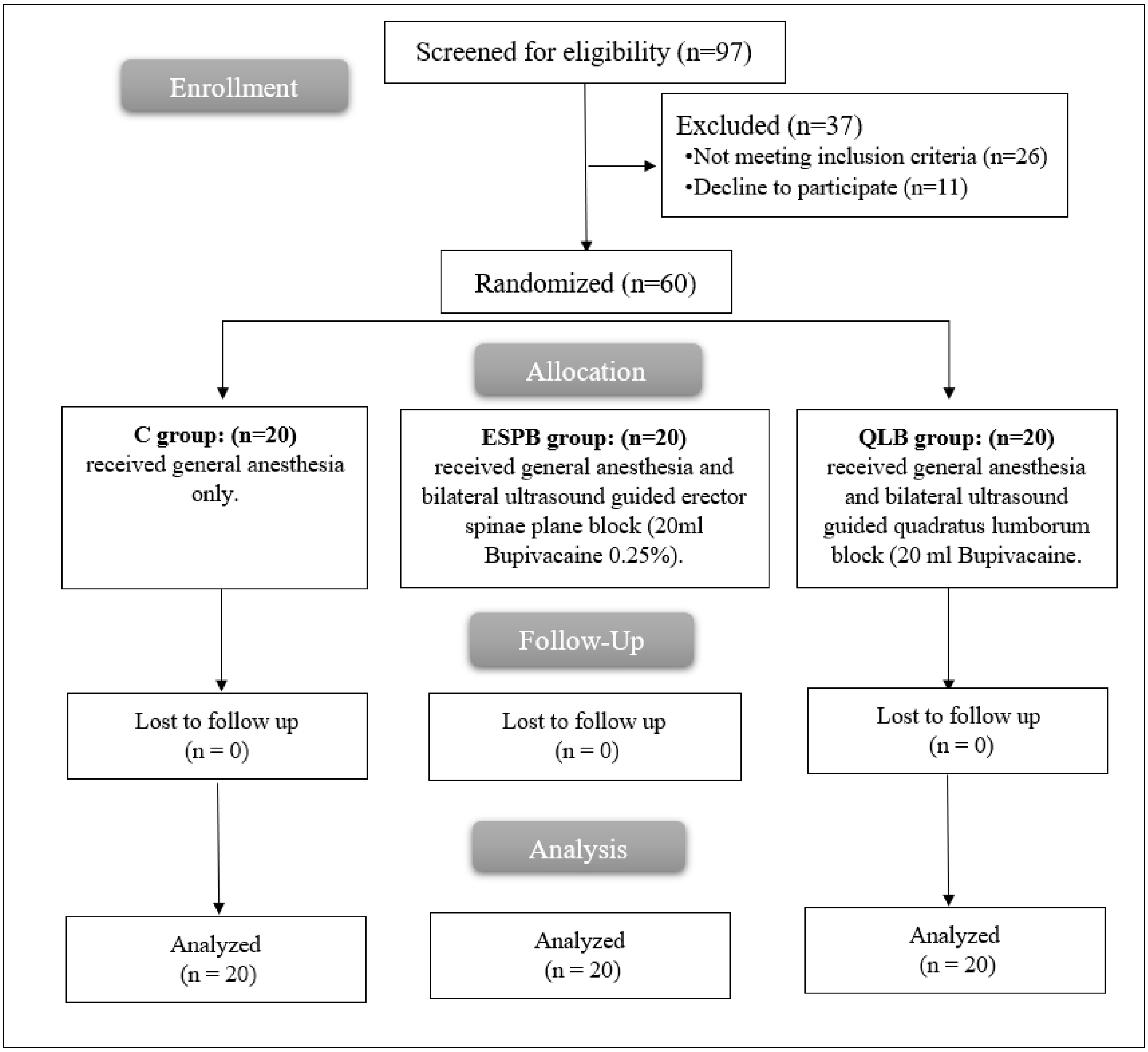
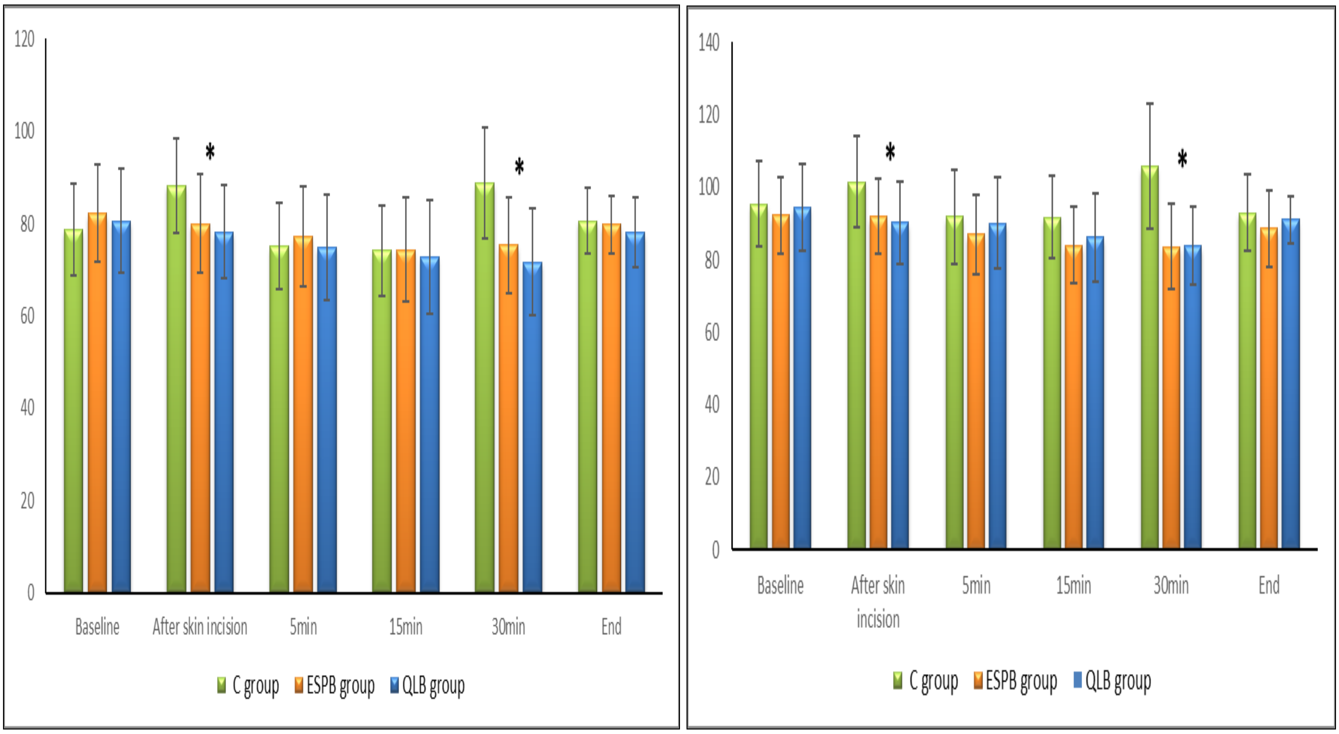


Fig 1: CONSORT flowchart of the enrolled cases



(a) **(b)**

Fig 2: Intraoperative heart rate (beats/min) changes (a) and mean arterial pressure (mmHg) chnages (b) in the controls, ESPB, and QLB.

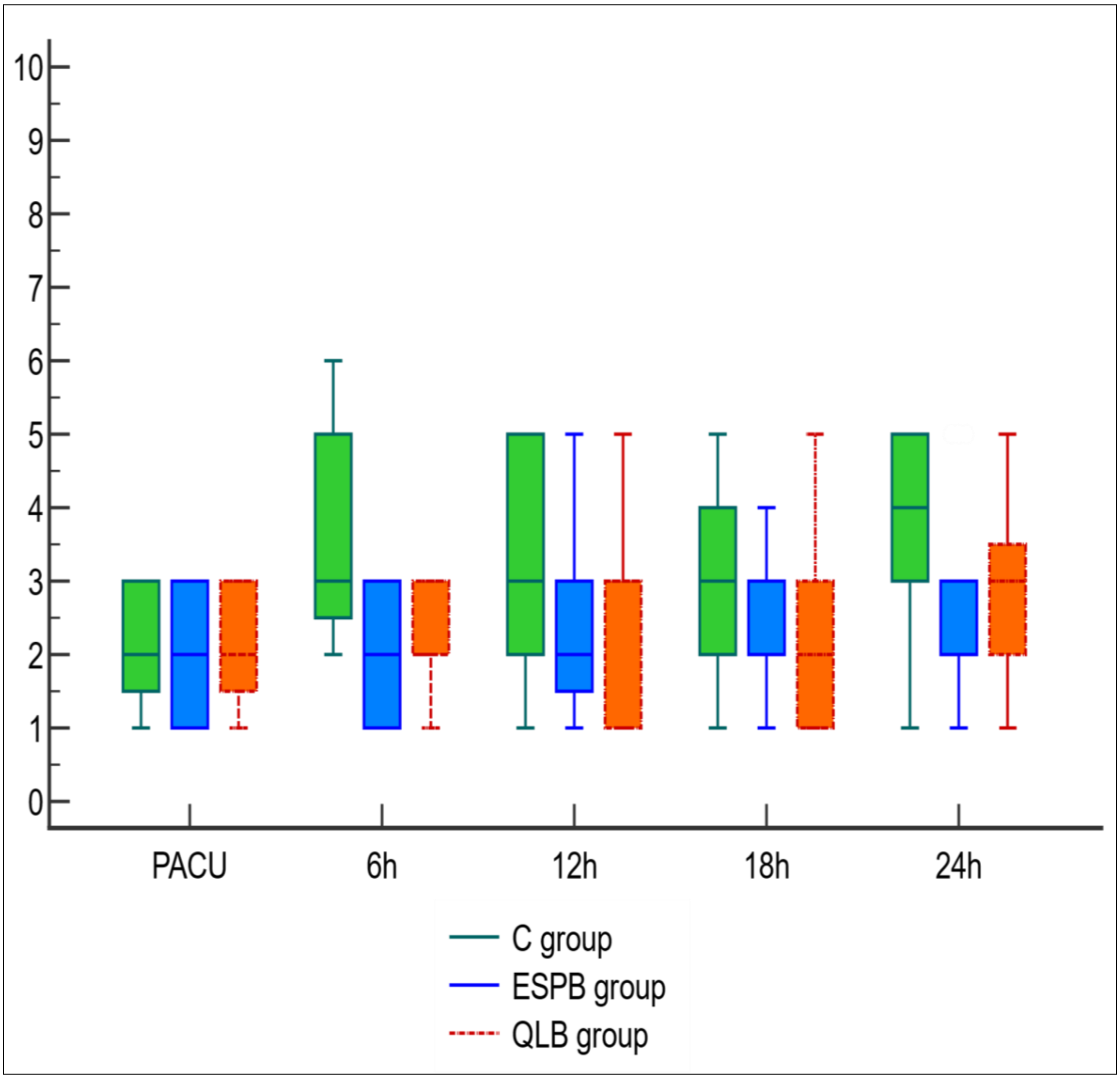


Fig 3: Comparison of NRS score changes in all groups

4. Discussion

It has been showed that the ultrasound (US)-guided field block was effective in reducing pain and analgesic requirement after laparoscopic cholecystectomy [14].

The quadrates lumborum block (QLB) was first characterized by Blanco *et al*. in 2007 [15]. The local anesthetic (LA) agent is expanded beyond the transverse abdominis plane to the thoracic paravertebral region, which is the primary benefit of QLB versus transverse abdominis plane block. The analgesic impact of a LA solution and the during along which it remains effective are both proportional to the extent to which the anesthetic agents in the solution are able to diffuse throughout the target area. Several investigations have shown that QLB may lessen the need for opioids after surgery [16, 17]. The quadratus lumborum block (QLB) has a LA effect in the paravertebral space (PVS) that is thought to be useful against both somatic and visceral pain after surgery [18].

In the current research, duration of performing block was significantly less in group ESPB versus group QLB (P value < 0.001). In the same line with our findings, Abd Ellatif and Abdelnaby [19] noticed that the time of performing the block was statistically significant shorter (5.64±0.66 vs. 9.36±1.0 *p*< 0.001) in ESPB versus QLB.

Regarding hemodynamics, our results are supported by Elkotory *et al*, [20] who observed that there was no noticeable variation in intraoperative MAP or HR between the two groups. Our results are in agreement with Abd Ellatif and Abdelnaby [19] who reported that the No noticeable variation was found between the groups in terms of MAP or HR at baseline, immediately following induction, or twenty minutes after induction; however, MAP was significantly less in the QLB and ESPBs versus the controls at forty minutes, one hour, and two hours, and post-operative.

In this research, total fentanyl dosage was significantly less in group ESPB and QLB versus groups C (P value<0.001) and was similar between groups ESPB and QLB. Our results are in agreement with Abd Ellatif and Abdelnaby [19] who reported that there was no statistically significant difference between the ESPB and QLB groups and the controls when it came to intra-operative fentanyl doses. Also, our results are supported by Kang *et al*. [21] documented that intraoperative fentanil dosage was comparable between ESPB and QLB.

In the current research, NRS was similar at PACU, 12 and 18 hours in all groups and was significantly different at 6 and 24 hour (P value = 0.001 and 0.004 respectively). NRS at 6, 24 hour was significantly less in ESPB and QLBs versus group C (P value< 0.05) and was similar between ESPB and QLBs. Similar to our findings, Elkotory *et al*, [20] reported insignificant difference regarding pain score between QLB and ESB. Our results are compatible with Kang *et al*., (2021) [21] who demonstrated insignificant differences in resting pain scores at 24, 48 and 72 h post-operationly between ESPB and QLBs. Moreover, Aksu *et al* [22] reported no significant difference was determined between the groups' face, Legs, Activity, Cry and Consolability (FLACC) scores at 0, 1, 3 or 6 h post-operationly (*p*> 0.05).

In contrast to our findings, Aygun *et al*, [17] reported that at resting and moving/coughing NRS scores, NRS scores were significantly less in the ESPB at 1st hour (*p*< 0.001) versus QLB. The deviation from our findings may be attributed to different mixture used for block as they used 30 mL bupivacaine 0.5%, 10 mL lidocaine 2% and 20 mL normal saline whereas we used 20 mL bupivacaine 0.25%.

In the current research, first time to call for analgesic requirement was significantly delayed in group ESPB and group QLB versus groups C (P value <0.001) and was similar between groups ESPB and QLB. Similarly, Abd Ellatif and Abdelnaby [19] reported that the first time to rescue analgesic was highly statistically significant shorter (*p*< 0.001) in controls versus the other 2 groups (ESPB and QLBs) with no significant difference between these 2 groups.

In the present research, total morphia dosage in 1st 1 day post-operation was significantly different in all groups (P value<0.001). Total morphia dosage in 1st 1 day post-operation was significantly less in ESPB and QLBs versus groups C (P value<0.001) and was similar between groups ESPB and QLB.

Similar to our findings, Fargaly *et al*, [23] documented that the median morphine dosage was significantly less in QLB versus TAPB group. In agreement with our findings, Huang and 1 day after surgery, cases underwent US ESPB required significantly less IV opioids (standardized mean difference [SMD] = -2.18; 95% CI -2.76 to -1.61, *p*< 0.00001). Weighted mean difference of 8.84 (95% CI: - 12.54 to - 5.14), (*p*< 0.001) IV mg morphine equivalents, was reported by Kendall *et al*, [25] for the accumulated impact of ESPB on post-operation opioid dosage. Aygun *et al*. [17] also reported that both groups had similar 24-hour median morphine doses of 3.40±1.42 mg for ESPB and 3.47±1.57 mg for the QLB-II group (p = 0.083). Initial, six-hour, twelve-hour, and eighteen-hour morphine doses were also comparable (*p*>0.05). In the present research, regarding the side effects, PONV was significantly less in ESPB and QLBs versus group C (P value =0.009). Bradycardia and hypotension were similar in all groups. Hematoma didn't occur in any case in the three groups. In the same context, Fargaly *et al*, [23] reported that Both techniques QLB showed non-significant Also, Abd Ellatif and Abdelnaby [19] reported that no block-related or local anesthetic-toxicity-related complications were observed among the intervention groups (QLB and ESPB).

Further clinical studies are needed with multicenter cooperation and on larger scale to validate our findings and studies comparing these blocks in different types of surgeries. Furthermore, studies regarding the most effective volume of used local anesthetic are required. A plethora of studies are required by application of different local anesthetic as levobupivacaine. Depending on the patient's condition and the clinician's preference, either ESPB or QLB methods may be used.

5. Conclusion

The ESPB is as efficient as posterior QLB to provide effective analgesia as comparable results of lower NRS, intraoperative fentanyl and post-operation opioid dosage, delayed first time to call for analgesic requirement and is lower side effects versus control in cases undergoing elective laparoscopic cholecystectomy. Considering the technical difficulties, the prolonged performance, the potential avoiding of thoracic dermatomes, and the unwanted complications of QLB, ESPB is a highly promising alternative to be improved as a method for post-operation lap cholecystectomy relief.

6. Duration of interest Sponsors, and funding sources: Nil

7. Conflict of interests: Nil

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How to Cite This Article
Hamada ME, Elahwal LA, Eid GM, Gendy HMEDE. Ultrasound guided erector spinae plane block versus quadratus lumborum block for post-operation analgesia in laparoscopic cholecystectomy surgeries: A randomized controlled trial. International Journal of Medical Anesthesiology. 2023;6(1):118-125.