

Randomized Trial

Ultrasound-guided Retrolaminar Block Versus Thoracic Epidural Analgesia for Pain Control Following Laparoscopic Cholecystectomy

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Background: Anesthesiologists are always looking for a regional analgesic technique which is easy, safe, has a low complication rate, and provides satisfactory analgesia. A retrolaminar block is a recent modified paravertebral technique for analgesia in thoracoabdominal procedures with a local anesthetic injected at the retrolaminar site. It has the advantage of being safe and easy compared with traditional thoracic epidural analgesia but is still under investigation.

Objective: This study aimed to compare ultrasound-guided bilateral retrolaminar block with ultrasound-guided thoracic epidural analgesia for pain relief after laparoscopic cholecystectomy.

Study Design: A prospective randomized double-blinded clinical study.

Setting: Academic University Hospitals.

Methods: Fifty-two adult patients were randomly allocated into 2 equal groups at the end of the surgery: Group R (n = 26) received a bilateral ultrasound-guided retrolaminar block with 20 mL of 0.25% bupivacaine and 5 µg/mL adrenaline (1:200000) in each side. Group T (n = 26) received ultrasound-guided thoracic epidural analgesia with 20 mL of 0.25% bupivacaine and 5 µg/mL adrenaline (1:200000).

Results: The Numeric Rating Scale scores both at rest and during cough were statistically significantly lower in Group R compared with Group T at 30 minutes and one hour postoperatively. The pain scores were statistically significantly lower for about 4 hours in Group R group compared with 6 hours in Group T. The time for the first call of nalbuphine was highly statistically significantly shorter in Group R group (233.04 ± 5.27 minutes) compared with Group T (353.77 ± 5.16 minutes) (mean difference -120.37, (95% CI, -123.6 to -117.8) $P < 0.001$). The total amount of nalbuphine consumption in the first 12 hours was statistically significantly decreased in Group T (17.31 ± 5.52 mg) compared with Group R (27.69 ± 5.52 mg) (Mean difference 10.4, 95% CI 7.3-13.5), $P < 0.001$. The total number of patients who developed nausea and vomiting were statistically significantly greater in Group T (9 patients) compared with Group R group (3 patients), $P = 0.04$. Moreover, hypotension was statistically significantly more common among patients in Group T group (10 patients) compared with Group R (3 patients), $P = 0.025$. Both groups were comparable regarding patient satisfaction.

Limitations: There is limited literature in the field of the present study and sensory dermatome assessment, but this does not affect the results as we used an ultrasound-guided technique.

Conclusions: A single injection retrolaminar block provides adequate postoperative pain relief for about 4 hours compared with a single shot thoracic epidural that lasts about 6 hours. Patient satisfaction with both techniques was the same; about two-thirds of the patients were satisfied or very satisfied with either block.

Key words: Retrolaminar block, thoracic epidural, pain relief, laparoscopic cholecystectomy

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Acute pain after laparoscopic cholecystectomy does not match pain after other laparoscopic surgeries because of its complexity, so proper management of pain should be procedure-specific and multimodal. Many analgesic interventions with different mechanisms have been studied for their effects on pain relief after laparoscopic cholecystectomy (1).

Although acute pain after laparoscopic cholecystectomy is lower than open cholecystectomy, it still represents a clinical challenge. Postoperative pain is reported in 17%-41% of patients after laparoscopic cholecystectomy and is the main cause of prolonged recovery and hospital stay. Moreover, it may become chronic if intense and not well managed (2).

Thoracic epidural analgesia (TEA) is a key element for treating acute pain after abdominal, rib fracture, and thoracic surgeries by attenuating surgical stress response, helping early mobilization, and improving outcomes in comparison with systemic opioids. Few studies have investigated the role of TEA in minimally invasive procedures like laparoscopic abdominal procedures. In laparoscopic cholecystectomy, TEA is controversial as it is associated with many adverse effects such as hypotension, nausea, vomiting, bradycardia, and numbness, especially in the elderly (3-5).

Ultrasound-guided retrolaminar block is considered a new, easy, and simple analgesic technique for thoracoabdominal procedures. It targets the lamina and has a decreased incidence of complications such as hypotension, pleural disorder, and nerve injury. Its efficacy has been investigated in trauma patients (6-8). However, there is limited literature about the analgesic effects of retrolaminar blocks and uncertainty if it can replace traditional analgesic methods. This study was undertaken to investigate the analgesic effects of an ultrasound-guided retrolaminar block in comparison with ultrasound-guided thoracic epidural analgesia after laparoscopic cholecystectomy.

Our primary aim was to compare postoperative pain intensity using the Numeric Rating Scale (NRS-11). Our secondary aims were to compare the time for the first call of nalbuphine, the total amount of nalbuphine consumption in the first 12 hours postoperatively, patient satisfaction, and side effects.

METHODS

Study Design

From April through November 2021, this prospective double-blind randomized clinical study was con-

ducted after approval of our University's Institutional Review Board (IRB #6777-31-3-2021) and was registered at clinicaltrials.gov (NCT04835415, Date of registration: April 8, 2021) and followed the regulations of the Declaration of Helsinki on Medical Research. The first patient was enrolled on April 10, 2021.

Population

Fifty-two patients aged between 21-45 years, with a BMI of 25-35 (kg/m²), who had an American Society of Anesthesiologists (ASA) physical status of I or II, who were scheduled for elective laparoscopic cholecystectomy under general anesthesia, were enlisted in this study.

Patients with altered mental status, local infection at the site of puncture, a history of allergy to the study drugs (bupivacaine or nalbuphine), severe hepatic or kidney impairment, chronic pain, and hematological disorders (coagulation abnormality or anticoagulant therapy) were excluded from this study. The patient had the right to withdraw from the study at any time.

One day before the surgery, all patients were informed about the NRS-11 (9). The NRS-11 is a 10-cm line labeled from 0 = no pain to 10 = worst pain. The patients were instructed to represent their intensity of pain.

All patients were hospitalized and visited a day before the surgery. A full history taking and physical examination, including local examination of the back, and routine investigations were done. The goal and endpoints of the study were discussed with the patients and informed written consent was obtained from all of them.

General Anesthesia

In the preparation room an intravenous (IV) line was inserted, 10 mL/kg crystalloid fluid was started and midazolam 0.05 mg/kg was administered. After transferring the patient to the operating room, ASA monitors were applied, including 5-lead electrocardiography, noninvasive blood pressure, pulse oximeter, temperature and end-tidal CO₂ (ETCO₂). Pre-oxygenation with 100% oxygen for 3 minutes was followed by induction of anesthesia with 1.5 µg/kg fentanyl and propofol 2 mg/kg. Tracheal intubation was facilitated by atracurium (0.5 mg/kg). Anesthesia was maintained with 1.5% isoflurane in 100% O₂ and atracurium 0.1mg/kg/h. Mechanical ventilation was adjusted to keep the ETCO₂ from 30 to 35 mm Hg.

Randomization

At the end of the surgical procedure, and before

reversal of the muscle relaxant, 52 patients were randomly allocated into 2 equal groups using a computer-generated randomization table.

Group R (n = 26) received bilateral ultrasound-guided retrolaminar plane block with 20 mL of bupivacaine 0.25% plus 5 µg/mL adrenaline (1:200000).

Ultrasound-guided Retrolaminar Plane Block (Fig. 1)

Group R patients were turned to the lateral position then skin sterilization was done. Their spines were palpated from the vertebra prominens caudally to T7 and point marked to identify the spinous processes, which were confirmed by ultrasound (Sonosite Edge II, FUJIFILM Sonosite, Inc.) through counting from T12 with the characteristic last rib attached to its transverse process upward to the T7 lamina. The linear high frequency transducer (6-13 MHz) was placed in the parasagittal plane one cm lateral to the midline. A Tuohy needle (18G, B. Braun SE) was inserted in the in-plane view of the ultrasound probe and advanced from downward to upward to target the T7 posterior lamina surface at an angle of 90° to the skin until the needle tip contacted the posterior surface of targeted lamina (10). After negative aspiration, 20 mL of bupivacaine 0.25% plus 5 µg/mL (1:200000) adrenaline was injected. The procedure was repeated following the same steps on the other side.

Group T (n = 26): received ultrasound-guided thoracic epidural analgesia with 20 mL of bupivacaine 0.25% plus 5 µg/mL adrenaline (1:200000).

Ultrasound-guided Thoracic Epidural Analgesia (Fig. 2)

After turning the patient to the lateral position and sterilizing the skin, ultrasound scanning was done in the parasagittal oblique plane using a 2-5 MHz probe starting from the vertebra prominens then caudally to T7 at the level of the inferior border of the scapula to identify the thoracic intervertebral space (T7-8). Then the probe was directed medially to identify the dura matter at the T7-8 intervertebral space (11).

Needle Insertion

An 18G Tuohy needle was inserted in the in-plane view of the ultrasound probe to target the T7-8 intervertebral space from caudal to cephalad. After the needle tip reached the targeted interlaminar space, the loss of resistance technique was used to identify the epidural space. Twenty mL of bupivacaine 0.25% plus 5 µg/mL adrenaline (1:200000) was injected after negative aspiration.

After the block the inhalational anesthetic was turned off, and the muscle relaxant was reversed using neostigmine 0.05 mg/kg plus atropine 0.01 mg/kg. The patient was extubated and shifted to the recovery room.

In the recovery room, the outcome assessors (the physician anesthesiologists not sharing in the study) assessed outcomes.

Data Collected

- The primary outcomes measured were pain intensity measured by NRS-11 at rest and during cough at 30 minutes then one, 2, 4, 6, 8, 10, and 12 hours postoperatively. Fifteen mg IV nalbuphine (rescue

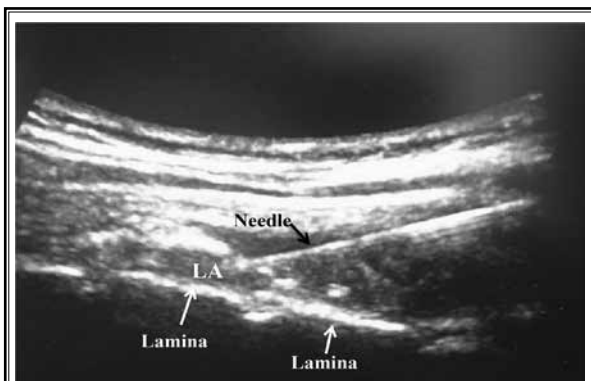


Fig. 1. Ultrasound-guided retrolaminar block illustrates the needle entry during injection of LA (local anesthetic).



Fig. 2. Parasagittal interlaminar oblique view of ultrasound-guided epidural analgesia. A = posterior complex (the ligamentum flavum, epidural space, and posterior dura mater). B = anterior complex (anterior dura mater, posterior longitudinal ligament, and the posterior surface of vertebral body or intervertebral disc). C = interlaminar gap.

analgesic) was given if the NRS-11 ≥ 4 . A postoperative analgesic regimen was initiated of IV ketorolac 30 mg every 6 hours with a maximum dose of 120 mg/d.

Secondary outcomes measured were the time for the first call of nalbuphine measured in minutes.

The total amount of nalbuphine consumption per mg during the first 12 postoperative hours.

At 24 hours postoperatively, patient satisfaction was recorded using a 5-point Likert-like verbal rating scale (12) by requesting that the patient evaluate his/her experience with postoperative analgesic administration. The scale was 1 = very dissatisfied, 2 = dissatisfied, 3 = neutral, 4 = satisfied, and 5 = very satisfied.

The number of patients who complained of nausea and vomiting was recorded; they were treated with 4 mg ondansetron.

Hypotension (mean arterial blood pressure decreased more than 20% from basal reading) and bradycardia (heart rate less than 50 beats/min) were recorded and treated with 12 mg ephedrine and 0.5 mg atropine, respectively.

Any bupivacaine-related side effects such as light-headedness, circumoral numbness, tongue paresthesia, irritability, muscle twitches, convulsions, bradycardia, hypotension, hypoventilation, and cardiac arrest were recorded and treated accordingly.

Other complications included dural puncture, nerve injury, spinal injection, epidural hematoma, and inadvertent pleural puncture.

Sample Size

Calculation of the sample size was based on the hypothesis that a retrolaminar block could achieve noninferior pain control compared to thoracic epidural analgesia. A sample size of at least 44 patients (22 patients per group) was required to be 95% sure that the lower limit of a one-sided 95% CI (or equivalently a 90% 2-sided CI) with an α error rate of 0.05 was above the noninferiority limit of -1, if there was no truly significant difference between retrolaminar and thoracic epidural analgesia (13). Allowing for drop outs, 26 patients in each group were enrolled in the study.

Statistical Analysis

Descriptive statistics were calculated; numerical variables are presented as mean (standard deviation) while categorical variables are presented as frequency

(percentages). Comparison of the numerical variables between the 2 independent groups was performed by using the independent samples Student's *t* test in case of normal distribution. If the numerical variables were not normally distributed, the Mann-Whitney U test was used. For the comparison of the categorical data, the χ^2 or Fisher's exact test was used. STATA 15.1 (StataCorp LLC) was used for the analysis. *P* values of < 0.05 were considered significant.

RESULTS

Fifty-five patients were enrolled in the study; 3 patients were excluded. One patient in Group T refused to complete the study and in 2 other patients the surgical procedure was converted to open cholecystectomy as presented in our CONSORT (Consolidated Standards of Reporting Trials) Statement (Fig. 3). As a result, 52 patients were randomly divided between the 2 groups (26 patients for each group).

- The 2 groups were comparable regarding age, gender, body mass index, and ASA physical status I and II (Table 1).
- Comparison of NRS-11 scores are shown in Fig. 4. NRS-11 scores both at rest and during cough were statistically significantly lower in Group R compared to Group T at 30 minutes and one hour postoperatively. The NRS-11 scores both at rest and during cough were statistically significantly lower for about 4 hours in Group R group compared to 6 hours in T group. At 10 hours the NRS-11 was statistically significantly higher in Group R compared to Group T. Otherwise, both groups were comparable.

The time for the first call of nalbuphine was highly statistically significantly shorter in Group R (233.04 ± 5.27 minutes) compared to Group T (353.77 ± 5.16 minutes) (mean difference -120.37, 95% CI, -123.6 to -117.8), $P < 0.001$. Regarding the total amount of nalbuphine consumption in the first 12 hours, the results showed that there was a statistically significant greater consumption in Group R (27.69 ± 5.52 mg) compared to in Group T (17.31 ± 5.52 mg) (mean difference 10.4, 95% CI, 7.3-13.5), $P < 0.001$ (Table 2).

- The total number of patients who developed nausea and vomiting was statistically significantly greater in Group T group (9 patients) compared to Group R (3 patients), $P = 0.04$. Moreover, hypotension was statistically significantly more common among patients in Group T group (10 patients) compared

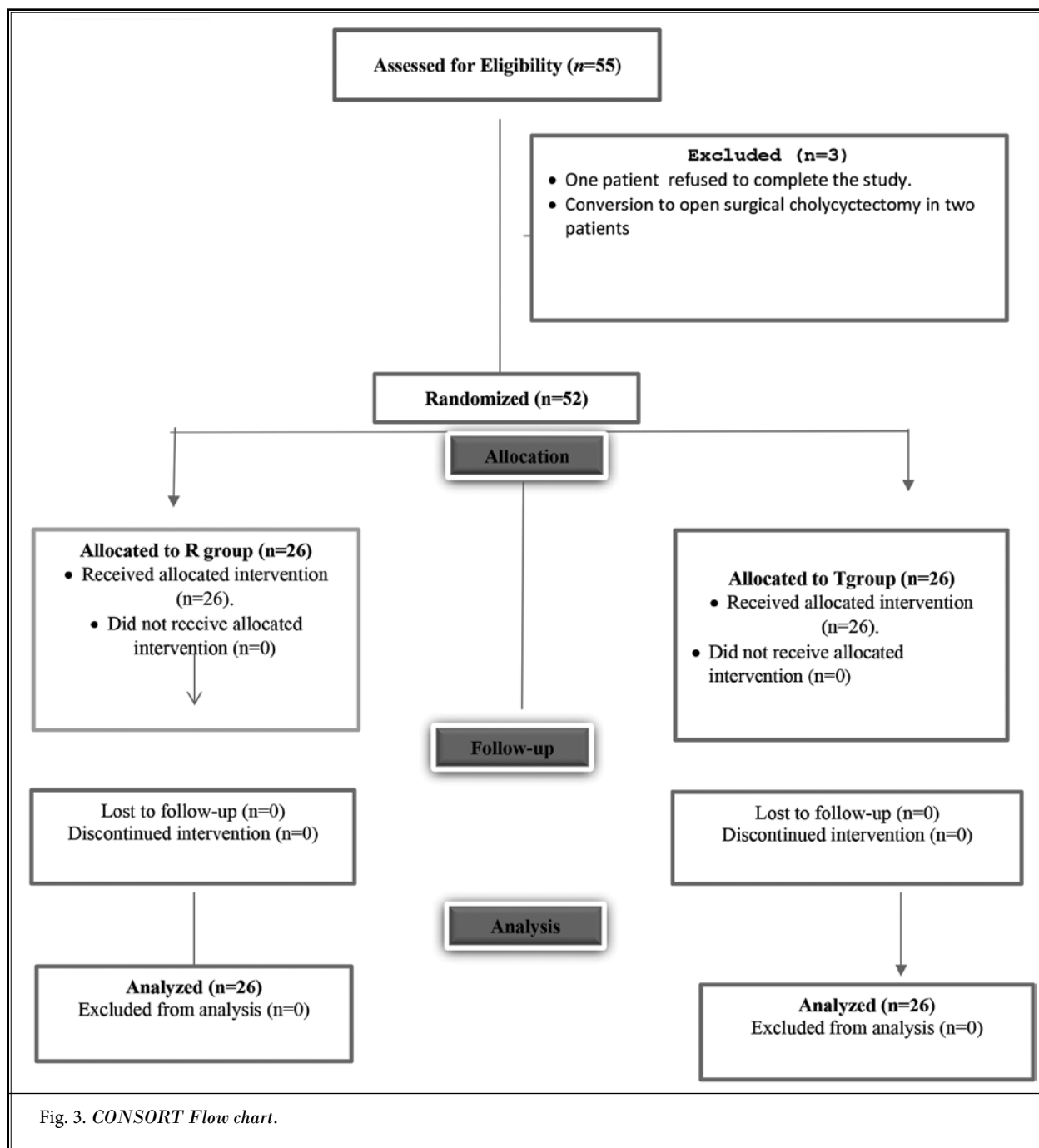


Fig. 3. CONSORT Flow chart.

to Group R (3 patients), $P = 0.025$. Otherwise, there were no other bupivacaine-related side effects or any complication related to either block technique (Table 2).

- Both groups were comparable regarding satisfaction $P > 0.05$ (Table 2).

DISCUSSION

The results of this randomized clinical study reveal that a bilateral ultrasound-guided retrolaminar block decreased the pain intensity in patients after laparoscopic cholecystectomy in the early postoperative period at 30 minutes and one hour. There were fewer postop-

Table 1. Demographic characteristics of patients in the 2 groups.

Variables	Group R n = 26	Group T n = 26	P value
Age (years)	35 ± 6.27	33.96 ± 7.28	0.6
BMI (kg/m ²)	30.48 ± 3.62	31.9 ± 2.22	0.1
Gender			0.80
Women	18 (69.2%)	17 (65.4%)	
Men	8 (30.8%)	9 (34.6%)	
ASA			0.56
I	15(57.7%)	17(65.4%)	
II	11(42.3%)	9 (34.6%)	

Data were expressed as mean ± sd or number (%), P > 0.05 = non-significant

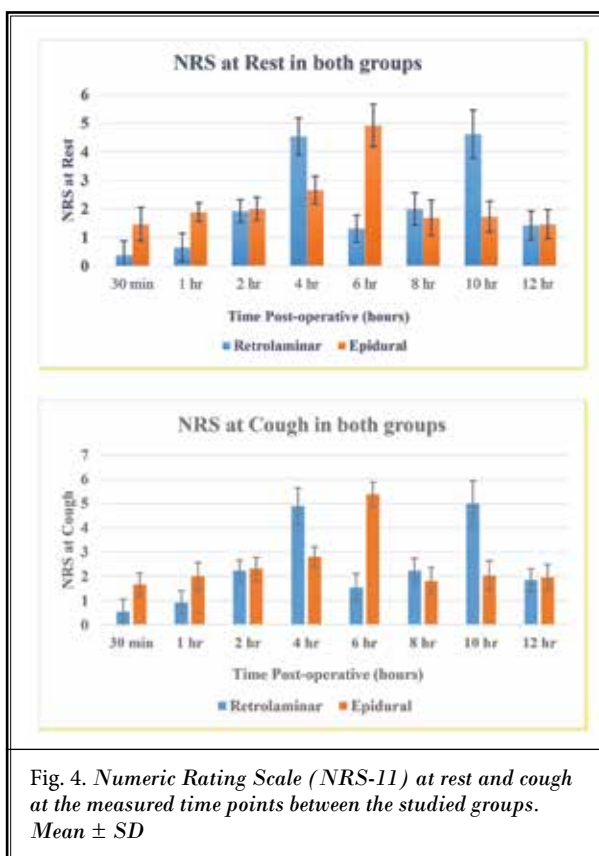


Fig. 4. Numeric Rating Scale (NRS-11) at rest and cough at the measured time points between the studied groups. Mean ± SD

erative complications but a shorter duration of analgesia, lasting for about 4 hours compared to 6 hours for ultrasound-guided thoracic epidural analgesia.

The present study provides an alternative analgesic technique for laparoscopic cholecystectomy, especially for patients with coagulopathy or who are more prone to TEA-induced hypotension. Furthermore, routinely used blocks for laparoscopic cholecystectomy, such as quadra-

tus lumborum and transverse abdominis plane blocks (14,15) lack the advantages of a retrolaminar block. Quadratus lumborum block is a difficult, deep technique that includes manipulation of the fascia near to blood vessels at the paravertebral space, and has a high incidence of vascular injury (16). However, transverse abdominis plane blocks are easier than quadratus lumborum blocks; they provide excellent somatic analgesia for abdominal wall procedures but fail in providing visceral pain relief (17).

To date, there is only one study we could find that compares the 2 techniques (13) but they have a different research design from our current study.

A recent study by Hwang, et al (18) revealed that postoperative pain scores at rest and during cough were lower in a group receiving a retrolaminar block one hour postoperatively compared to a control group. The duration of analgesia was 3 hours when investigating the analgesic effect of a single ultrasound-guided retrolaminar block in patients undergoing breast surgery. This correlates with our study's results.

Onishi et al (19) reported that pain scores were significantly decreased immediately after breast cancer surgery compared to a control group and the duration of analgesia was 2-3 hours postoperatively. The time to the first call for analgesia in the present study was prolonged (233.04 ± 5.27 minutes) in Group R due to injection of a local anesthetic at the end of the surgery and the use of epinephrine.

The analgesic effect of a retrolaminar block is due to the anterior spread of the local anesthetic through the ligaments of the costotransverse joint to the intervertebral foramen, epidural space, and paravertebral space (20).

In accordance with our study results, a recent meta-analysis done by Liang et al (21) found that resting pain scores were significantly higher at 4-6 hours in TEA compared to 1-2 hours in thoracic paravertebral block after thoracoscopic surgery.

Rabie et al (22) found that the analgesic duration of a single thoracic epidural block lasts for 8 hours postoperatively after thoracotomy in neonates. In our study the analgesic duration of a single bolus thoracic epidural block lasted for only 6 hours postoperatively since we injected a local anesthetic at the end of the surgery as opposed to Rabie et al (22) who injected a local anesthetic after induction of anesthesia and before skin incision.

In our study, we injected a local anesthetic in a single block in order to avoid biases since a continuous retrolaminar block is not a conventional method and because

Table 2. Analgesic parameters, side effects, and patient satisfaction between the studied groups.

	Group R n = 26	Group T n = 26	Mean difference 95% CI	P value
Time for the first call of nalbuphine (min)	233.04 ± 5.27	353.77 ± 5.16	-120.37 (-123.6, to 117.8)	< 0.001
Total nalbuphine consumption (mg)	27.69 ± 5.52	17.31 ± 5.52	10.4 (7.3-13.5)	< 0.001
Side effects				
Nausea & Vomiting	3 (11.5%)	9 (34.6%)		0.04
Bradycardia	2 (7.7%)	3 (11.5%)	---	0.63
Hypotension	3 (11.5%)	10 (38.5%)		0.025
Patient satisfaction				
Dissatisfied	3 (11.5%)	8 (30.8%)		
Neutral	4 (15.4%)	3 (11.5%)		
Satisfied	7 (26.9%)	6 (23.1%)	---	0.44
Very satisfied	12 (46.2%)	9 (34.6%)		

Data were expressed as mean ± sd, or number (%). P values < 0.05 = significant.

the study population was undergoing laparoscopic cholecystectomy, which is considered as a one-day, minimally invasive surgery. Besides, we injected a local anesthetic at the end of the surgical procedure in order to avoid the effect of intraoperative general anesthesia on the results.

Mowat et al (23) noticed that a bolus injection of dye in the epidural space of a porcine model, which is anatomically closely correlated to the human spine, produced a greater spread in the epidural space than infusion. This supports the longer duration of analgesia and lower nalbuphine consumption in our study after the bolus injection in Group T group compared to Group R. Another possible explanation for the shorter duration of analgesia in Group R is the posterior distribution of most of the local anesthetic injected to the back muscles (24-26) plus the limited spread to the paravertebral space as it is volume dependent (6). Hwang, et al (18) concluded that a retrolaminar block was insufficient to decrease morphine requirements.

The total number of patients who developed nausea and vomiting and hypotension was significantly higher in Group T compared to Group R. Otherwise, there were no other bupivacaine-related side effects or any other complications related to either block techniques. Liu, et al (27) concluded that a retrolaminar block is associated with lower a incidence of nausea and vomiting after laparoscopic nephrectomy compared to local infiltration of analgesia.

Hong et al (28) reported that anatomically low thoracic epidural anesthesia from T5-L4 produced hypotension by blocking the splanchnic fibers and peripheral sympathetic nervous system. Also, laparoscopic surgery usually increases the occurrence of hypotension.

The guidelines of the American Society of Regional Anesthesia and Pain Medicine 4th edition (29) recom-

mends that any procedure's management must be dependent on the injected site's vascularity, occurrence of bleeding, and compressibility, with the exception of deep plexus, perineural, or deep blocks. The local anesthetic in a retrolaminar block is injected between the deep paraspinous muscles and thoracic laminae, which is devoid of large blood vessels, and is compressible due to the superficiality of the bony floor and the site of injection. Using ultrasonography makes both block techniques easy and lessens the chance for severe complications. This explains the absence of any complication related to either technique, such as pneumothorax, nerve injury, and hematoma.

In our study, a retrolaminar block significantly lowered pain scores in the early postoperative period compared to thoracic epidural analgesia that lasted up to 6 hours postoperatively, making the patients in both groups satisfied with analgesia. The studies by Hwang, et al (18) and Murouchi, et al (30) concluded that both retrolaminar block and paravertebral block produced satisfactory analgesia after mastectomy.

Limitations

Limited literature in the field related to our study is the first limitation. Sensory dermatome assessment is a second limitation, but it does not affect the results as we used an ultrasound-guided technique.

CONCLUSION

A single-injection retrolaminar block provides adequate postoperative pain relief for about 4 hours compared to a single-injection thoracic epidural that provides relief for about 6 hours. Satisfaction with both techniques was the same; about two-thirds of patients were satisfied or very satisfied with either block.

Recommendation

Ultrasound-guided retrolaminar block is an easy, safe technique and provides early effective pain relief compared to ultrasound-guided thoracic epidural analgesia, but according to our results it has a shorter pain relief duration. Therefore, we recommend the addition

of an adjuvant to local anesthetics injected in the block in order to get the benefit of both early pain relief and a prolonged duration of analgesia without increasing the volume of bupivacaine since a retrolaminar block is volume dependent (6).

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