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Research article

Comparison of three concentrations of ropivacaine in posterior quadratus lumborum block: A randomized clinical trial

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ABSTRACT

Background: A conclusive evidence regarding the optimal concentration and volume of local anesthetic for quadratus lumborum block is lacking.
Methods: In this single-center, prospective, randomized, controlled study, 60 patients scheduled for laparoscopic colorectal surgery were randomly assigned to 3 different combinations of volume and concentration of ropivacaine (3 mg/kg) - Group 0.25%, Group 0.375% and Group 0.5%. All subjects received ultrasound-guided posterior quadratus lumborum block prior to the induction. The primary outcome was the complete sensory block rate of surgical site measured at 30 min after quadratus lumborum block, after extubation, at 12, 24, and 48 h after operation. Secondary outcomes were the changes in hemodynamic parameters before and after incision (ΔSBP, ΔDBP and ΔHR), postoperative pain score, the sufentanil consumption after surgery, length of stay and adverse reactions.
Results: The sensory block rate of surgical site at 5 time points differed significantly among the three groups ($P < 0.001$). Both Group 0.375% ($P < 0.001$) and Group 0.5% ($P < 0.001$) had a higher sensory block rate than Group 0.25%, but no significant difference was observed between the former two. Group 0.375% and Group 0.5% had lower postoperative pain scores, lower sufentanil consumption after surgery and shorter length of stay. No statistical difference was observed in ΔSBP, ΔDBP, ΔHR and the incidence of adverse reactions.
Conclusions: 0.375% and 0.5% ropivacaine in posterior quadratus lumborum block provide better sensory block of surgical site when compared to 0.25% in laparoscopic colorectal surgery.
Trial registration number: Chinese Clinical Trials Registry (ChiCTR2100043949).

1. Introduction

Laparoscopic radical resection is currently the mainstay of treatment for colorectal cancer. Although the procedure is minimally invasive, postoperative pain is still a major problem that cannot be neglected, which is associated with a variety of poor outcomes, including increased risks of adverse cardiovascular events and pulmonary complications, increased length of stay (LOS) and decreased quality of life [1]. As the most common analgesic for pain management, opioids may result in adverse reactions, such as nausea,

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vomiting, ileus and urinary retention. While the gold standard for pain management in patients undergoing colorectal surgery, thoracic epidural analgesia presents several potential risks, such as spinal cord injury, epidural hematoma, and total spinal anesthesia [2]. Transversus abdominis plane blocks (TAPB) may be more suitable for lower abdominal surgery due to their dermatomal limitation (T10 to L1) [3]. Thus, easier and lower-risk analgesic techniques are required for improving perioperative pain management in abdominal surgery.

The quadratus lumborum block (QLB) is a fascial plane block of the posterior abdominal wall, which may generate an analgesic effect through local anesthetic that covers the thoracolumbar fascia and spreads to the paravertebral space [4,5]. Published studies have found that QLB has the potential to provide the extensive sensory blockade (T6 to L2) with analgesic effect lasting up to 48 h and, therefore, it is highly suitable for analgesia following upper and lower abdominal surgery [4,6–8]. However, seemingly conflicting conclusions on the benefits from QLB in perioperative pain management have been reported, which may result from different concentrations and volumes of local anesthetic [9–11]. A conclusive evidence regarding the optimal concentrations and volumes of local anesthetic for QLB is currently lacking. The objective of this trial was to compare the efficacy of three different combinations of concentration and volume of a fixed dose of ropivacaine in ultrasound-guided QLB in laparoscopic colorectal surgery, and thereby identify the appropriate administration regimen to satisfy postoperative analgesia requirements.

2. Methods

2.1. Ethics

Our study protocol was approved by Medical Ethics Committee of Houjie Hospital of Dongguan, Dongguan, China (Approval number: [2019] Houyilunshen (No.053), Approval date: August 1, 2019). This trial was registered prior to subject recruitment with the Chinese Clinical Trials Registry (www.chictr.org.cn, Registration number: ChiCTR2100043949, Principal investigator: Wei-Feng Liu, Date of registration: March 6, 2021), and was performed in accordance with the principles of Declaration of Helsinki. All subjects were required to sign a written informed consent before enrollment. This manuscript adheres to the applicable CONSORT guidelines.

2.2. Subjects

Patients scheduled for elective laparoscopic colorectal surgery in Houjie Hospital of Dongguan, China, were screened in our trial. The inclusion criteria were as follows: (1) ASA physical status I to III, (2) Aged between 18 and 75 years old, (3) Body mass index (BMI) of 18–24 kg m^{-2}, (4) Scheduled for laparoscopic colorectal surgery with an expected operative duration of 2–4 h. Exclusion criteria included: (1) No consent to participate in our trial, (2) Incomplete medical histories, (3) Failure to comprehend or use the Visual Analogue Scale (VAS) scoring system or patient-controlled intravenous analgesia (PCIA) pump, (4) Anatomical abnormalities at the puncture sites, (5) Long-term use of analgesics, (6) History of allergy to ropivacaine or opioids, (7) Coagulation disorders, (8) Severe cardiac, pulmonary, hepatic or renal disease prior to surgery.

2.3. Randomization and masking

According to a computer-generated randomization sequence, patients were randomly allocated in a 1:1:1 ratio to three groups—Group 0.25% (3 mg kg^{-1} of ropivacaine diluted in saline to a concentration of 0.25%), Group 0.375% (3 mg kg^{-1} of ropivacaine diluted to a concentration of 0.375%) and Group 0.5% (3 mg kg^{-1} of ropivacaine diluted to a concentration of 0.5%). The allocation codes were concealed in opaque, sealed envelopes, and disclosed just prior to QLB. Preparation and injection of ropivacaine was performed by a specific researcher who was aware of the grouping. The QLB operator was not blinded and not involved in anesthetic management and outcome assessment. Both subjects and study personnel responsible for outcome assessment were blinded to the grouping.

2.4. Procedures

All patients fasted according to the ASA guidelines [12]. Upon arrival in the operating room, continuous electrocardiogram (ECG), heart rate (HR), noninvasive blood pressure (NIBP) and pulse oxygen saturation (SpO_2) were monitored. The subjects received dexmedetomidine (0.4 μg kg^{-1}) for sedation before the QLB and was placed in the lateral position. All subjects were then treated with bilateral posterior QLB. A 3–5 MHz convex array probe was placed transversely in the midaxillary line between the iliac crest and costal margin to display the external oblique, internal oblique, and transversus abdominis muscles, and then moved dorsally until the shamrock sign (quadratus lumborum muscle, erector spinae muscle and psoas major muscle) became visible. The nerve block needle was inserted in-plane from the lateral abdomen to reach the posterior surface of the quadratus lumborum muscle. After negative aspiration, 1.5 mg kg^{-1} ropivacaine at the corresponding concentrations and volume was injected unilaterally according to grouping information. Subsequently, the same procedure was repeated on the contralateral side. All the ultrasound-guided nerve blocks were performed by the same experienced anesthesiologist.

After completion of the QLB procedure and the determination of the block level, all patients received standardized general anesthesia. Anesthesia was induced with midazolam (0.10–0.20 mg kg^{-1}), propofol (1.5–3.5 mg kg^{-1}), sufentanil (0.5 μg kg^{-1}) and cisatracurium (0.15–0.20 mg kg^{-1}). After endotracheal intubation, anesthesia was maintained with propofol (5–8 mg kg^{-1} h^{-1}) titrated to maintain bispectral index of 40–60, remifentanil (0.2–0.4 μg kg^{-1} min^{-1}) and cisatracurium (0.1–0.15 mg kg^{-1} h^{-1}).

Intraoperative blood pressure and HR were maintained at ± 20% baseline. All surgeries were performed by a same surgical team with a standardized laparoscopic technique. PCIA pump was provided using sufentanil (3 μg kg^{-1}) and 10 mg of tropisetron mixed with 0.9% saline to a volume of 150 ml, with bolus of 3.0 ml, lockout interval of 15 min and no background infusion. The subjects were encouraged to push the analgesic-demand button when VAS scores ≥4.

2.5. Measurements and outcomes

A specific anesthesiologist blinded to the intervention was responsible for intraoperative data recording and outcome assessment of all included subjects. Basal blood pressure and HR were calculated as the average values of two separate measurements taken at 5-min intervals prior to any manipulations began. Infusion doses of propofol and remifentanil, as well as duration of surgery, were recorded.

The primary outcome was the complete sensory block rate of surgical site (T6 to L1 dermatomes). The sensory block plane was measured by using ice (2 = normal sensation; 1 = partial loss of cold sensation; 0 = complete loss of cold sensation) at 30 min after QLB, after extubation, at 12, 24, and 48 h after operation. The score = 0 was considered as a complete sensory block. The complete sensory block rate was defined as the proportion of dermatome segments with complete loss of cold sensation in total 16 segments (bilateral T6 to L1 dermatomes). Secondary outcomes included: (1) the changes in hemodynamic parameters immediately before and 5 min after incision (recorded as ΔSBP, ΔDBP and ΔHR), (2) the VAS score at rest and on movement at 2, 6, 12, 24, and 48 h after surgery, (3) postoperative sufentanil consumption, including the time to the first PCIA bolus and the cumulative sufentanil consumption by the PCIA device within 48 h after surgery, (4) LOS, (5) adverse reactions, including postoperative nausea and vomiting (PONV), urinary retention, hypoesthesia or motor block in the lower limbs and pruritus. The muscle strength of the lower limb was assessed using the active straight leg raise test at 30 min after QLB, after extubation, at 12, 24, and 48 h after operation. The muscle strength grade ≤3 was considered as motor block (0 = none; 1 = muscle flicker without movement; 2 = movement, but not against gravity; 3 = movement against gravity; 4 = movement against some resistance; 5 = normal strength). The above perioperative data and follow-up results were all recorded in a case report form.

2.6. Sample size calculation

Sample size was calculated by PASS 15.0 software (NCSS, LLC) on the basis of results from our unpublished pilot work. The details of the sample size calculation are described in S1. Considering a 20% dropout rate, at least 60 subjects (20 in each group) were required, with a power of 0.95 and type I error of 0.05.

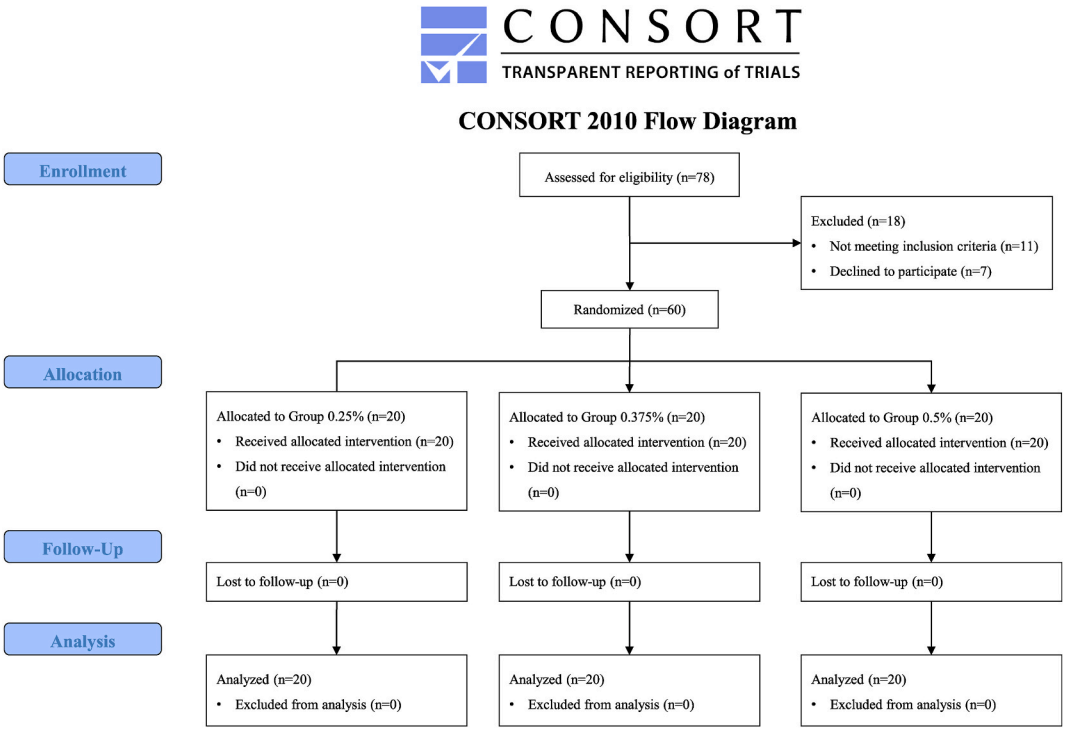

Fig. 1. CONSORT flow diagram.

2.7. Statistical analysis

SPSS 26.0 software (IBM Corp., Armonk, NY, USA) was used for data analysis in this trial. Patients' characteristics and intraoperative data were summarized as mean ± SD for continuous variables and frequencies (percentages) for categorical variables. We assessed balance between the pairwise groups on baseline variables using absolute standardized difference (ASD), defined as the absolute difference in means or proportions divided by the pooled SD. Any variables with ASD >0.62 (ie, $1.96 \times \sqrt{\frac{1}{20}+\frac{1}{20}} \approx 0.62$) were considered as imbalanced. Normally distributed data (passed the Shapiro-Wilk test), nonnormally distributed data and categorical data were compared using one-way ANOVA, the Kruskal-Wallis H test and Pearson's χ^2 tests (or Fisher exact test if appropriate), respectively. Generalized estimating equations were used to analyze the effects of different concentrations and volumes of ropivacaine on the complete sensory block rate of surgical site and postoperative VAS score. The pairwise log-rank test was applied in comparisons of Kaplan–Meier plots for an elapsed time until the first PCIA bolus. A two-sided P-value <0.05 was considered to be statistically significant.

3. Results

A total of 78 patients were screened from March 22, 2021 to August 24, 2021. Sixty were finally enrolled and randomly assigned to three groups (n = 20 in each): Group 0.25%, Group 0.375% and Group 0.5%. All randomized patients completed the full study protocol. (Fig. 1).

3.1. Patients' characteristics and intraoperative data

Patients' baseline data were well balanced among three groups. Intraoperative data, including propofol and remifentanil consumption as well as durations of surgery, did not differ statistically (Table 1).

3.2. Primary outcome

In the overall view, the complete sensory block rate of surgical site at 5 time points differed significantly among the three groups ($P < 0.001$). Pairwise comparison revealed that both Group 0.375% ($P < 0.001$) and Group 0.5% ($P < 0.001$) had a higher complete sensory block rate than Group 0.25%. However, no significant difference ($P = 0.58$) was observed between Group 0.375% and Group 0.5% (Fig. 2). Dermatomal sensory block levels at 5 time points are shown in Fig. 3. All three concentrations of ropivacaine could provide sensory blockade with coverage from T6 to L1 at 30 min after QLB. During the following 48 h, sensory blockade in Group 0.25% resolved faster than those in Group 0.375% and Group 0.5%. At 48 h after surgery, 0.375% and 0.5% ropivacaine could provide sensory blockade with coverage from T8 to T11, while 0.25% ropivacaine had little or no effect.

3.3. Secondary outcomes

Table 2 summarized the secondary outcomes. No significant difference in the changes in hemodynamic parameters before and after incision among the three groups. Both at rest and during movement, VAS score after surgery in both Group 0.375% ($P < 0.001$) and Group 0.5% ($P < 0.001$) was lower than that in Group 0.25% at 5 time points, and meanwhile, VAS score in Group 0.375% was lower than that in Group 0.5% at 5 time points ($P < 0.001$). Kaplan-Meier survival curves showed that the elapsed time was significantly longer in Group 0.375% ($P < 0.001$) and Group 0.5% ($P < 0.001$) than in Group 0.25%, while no difference ($P = 0.97$) was observed between Group 0.375% and Group 0.5% (Fig. 4). Compared to Group 0.25%, the cumulative sufentanil consumption by the PCIA device within 48 h after surgery was significantly lower in Group 0.375% ($P < 0.001$) and Group 0.5% ($P < 0.001$), and no marked

Table 1
Baseline characteristics and intraoperative data.

	Group 0.25% (n=20)	Group 0.375% (n=20)	Group 0.5% (n=20)	ASD		
				0.25% versus 0.375%	0.25% versus 0.5%	0.375% versus 0.5%
Age (years)	56.9 ± 12.7	55.3 ± 13.3	55.3 ± 11.7	0.12	0.14	0.00
Gender				0.10	0.31	0.20
Male	13 (65)	12 (60)	10 (50)			
Female	7 (35)	8 (40)	10 (50)			
Weight (kg)	57.0 ± 7.4	58.7 ± 7.3	58.1 ± 8.3	0.23	0.13	0.08
BMI (kg m^{-2})	21.2 ± 1.3	22.0 ± 1.7	21.7 ± 1.9	0.52	0.29	0.17
Propofol (mg)	1063 ± 146	1091 ± 137	1124 ± 175	0.20	0.38	0.21
Remifentanil (μg)	2942 ± 156	2985 ± 273	2983 ± 324	0.19	0.16	0.01
Duration of surgery (min)	147 ± 14.7	149 ± 14.9	149 ± 13.7	0.18	0.19	0.00

Data are mean ± SD or n (%). ASD is a measure of the average difference between pairwise groups. ASD, absolute standardised difference; BMI, body mass index.

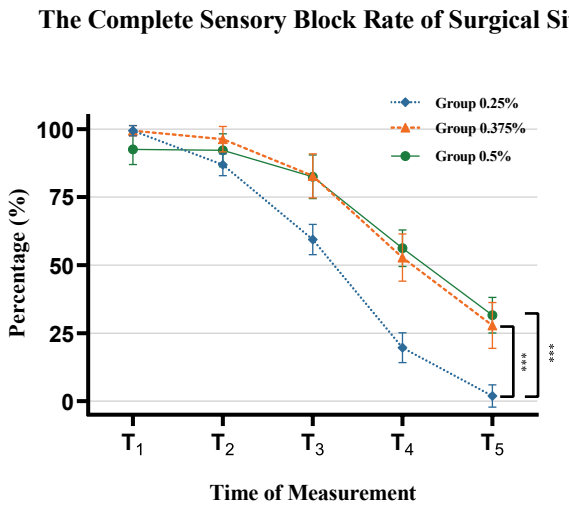

Fig. 2. The complete sensory block rate of surgical site (T6-L1) at 5 time points. T_1, 30 min after QLB; T_2, after extubation; T_3, at 12 h after operation; T_4, at 24 h after operation; T_5, at 48 h after operation. *** indicates that $P < 0.001$.

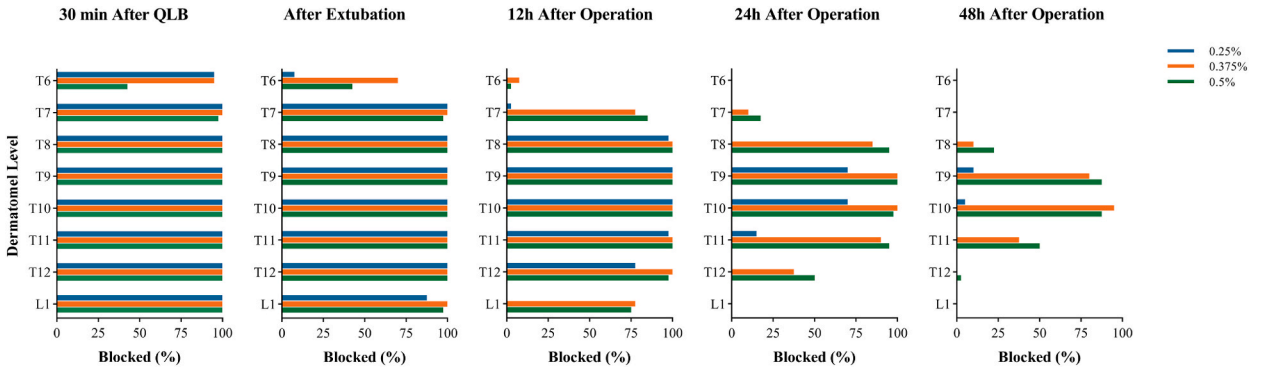

Fig. 3. Dermatome coverage at 5 time points. QLB, quadratus lumborum block.

difference ($P = 0.81$) between the latter two was found. LOS was significantly shorter in Group 0.375% ($P < 0.001$) and Group 0.5% ($P < 0.001$) than in Group 0.25%, while no difference ($P = 0.22$) was observed between Group 0.375% and Group 0.5%. No statistical difference was seen in the incidence of PONV, urinary retention, hypoesthesia or motor block in the lower limbs and pruritus.

4. Discussion

This trial compared efficacy of ultrasound-guided posterior QLB with different combinations of concentration and volume of a fixed dose of ropivacaine in laparoscopic colorectal surgery. Our results showed that Group 0.375% and Group 0.5% had a significantly higher complete sensory block rate of surgical site than Group 0.25% within 48 h after surgery, but no significant difference between Group 0.375% and Group 0.5% was observed. Postoperative pain scores and sufentanil consumption differed statistically among the three groups.

Due to the extensive sensory blockade and the satisfactory duration of analgesic effect, QLB is theoretically well-suited for perioperative analgesia in abdominal surgery [6,7,13]. Nevertheless, some previous studies have not demonstrated the benefits of QLB for postoperative analgesia [10,14]. This discrepancy may be attributed to the use of inappropriate concentrations and volumes of local anesthetics. In theory, a low concentration with a large volume of local anesthetic may provide a broader blockade, albeit with a slower onset and shorter duration, whereas a high concentration with a small volume may result in a limited blockade range. Therefore, given the limitation of the maximum safe dose of local anesthetic, the design of the concentration and volume becomes crucial. Our results demonstrate that 0.375% and 0.5% ropivacaine have a longer duration of sensory blockade and offer a more satisfactory sensory block range compared with 0.25% ropivacaine when applied to posterior QLB in laparoscopic colorectal surgery. At 48 h after surgery, 0.375% and 0.5% ropivacaine could provide sensory blockade with coverage from T8 to T11, while 0.25% ropivacaine had little or no effect. This phenomenon supported the aforementioned theoretical hypothesis. In terms of postoperative pain, patients in Group 0.375% and Group 0.5% have lower VAS scores. Even the results show that the difference between Group 0.375% and Group 0.5% was

Table 2
Secondary outcomes.

	Group 0.25% (n = 20)	Group 0.375% (n = 20)	Group 0.5% (n = 20)	*P*-value
ΔSBP (mmHg)	15 [12 to 16]	14 [13 to 15]	15 [12 to 17]	0.41
ΔDBP (mmHg)	12 ± 3	13 ± 2	13 ± 3	0.75
ΔHR (bpm)	12 [11 to 15]	14 [11 to 16]	16 [13 to 16]	0.10
VAS score at rest				<0.001
2 h	1 [0 to 1]	0 [0 to 0]	1 [0 to 1]	
6 h	1 [1 to 2]	1 [1 to 1]	1 [1 to 1]	
12 h	3 [3 to 3]	1 [1 to 1]	1 [1 to 1]	
24 h	4 [4 to 4]	2 [1 to 2]	2 [2 to 2]	
48 h	4 [3 to 4]	2 [2 to 3]†††	3 [2 to 3]†††‡‡‡	
VAS score during movement				<0.001
2 h	1 [1 to 1]	1 [1 to 1]	1 [1 to 1]	
6 h	2 [2 to 2]	1 [1 to 1]	1 [1 to 1]	
12 h	4 [4 to 4]	2 [2 to 2]	3 [2 to 3]	
24 h	5 [4 to 5]	3 [3 to 3]	3 [3 to 3]	
48 h	4 [4 to 4]	3 [3 to 3]†††	3 [3 to 3]†††‡‡‡	
Sufentanil consumption within 48 h after surgery (μg)	11 [9 to 13]	4 [3 to 4]†††	4 [3 to 7]†††	<0.001
LOS (h)	122 ± 3	111 ± 5†††	113 ± 4†††	<0.001
Adverse reactions				
PONV	1 (5.0)	0 (0)	1 (5.0)	1.00
Urinary retention	1 (5.0)	0 (0)	1 (5.0)	1.00
Hypoesthesia	1 (5.0)	0 (0)	1 (5.0)	1.00
Motor block	4 (20.0)	0 (0)	5 (25.0)	0.06
Pruritus	1 (5.0)	1 (5.0)	1 (5.0)	1.00

Data are mean ± SD, n (%), or median [IQR]. DBP, diastolic blood pressure; HR, heart rate; LOS, length of stay; PONV, postoperative nausea and vomiting; QLB, quadratus lumborum block; SBP, systolic blood pressure; VAS, Visual Analogue Scale. †††$P < 0.001$ versus Group 0.25%, ‡‡‡$P < 0.001$ versus Group 0.375%.

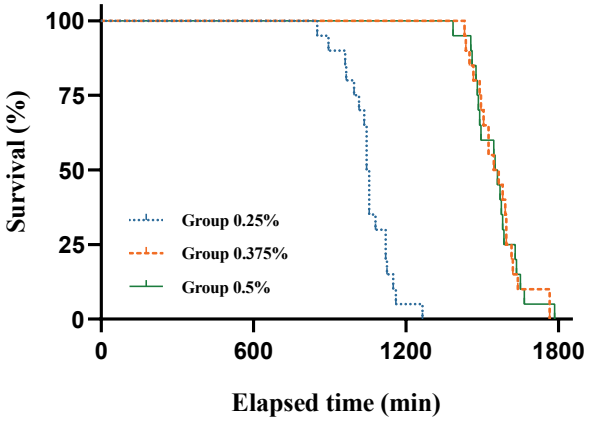

Fig. 4. Kaplan–Meier survival curves of elapsed time from the end of surgery to the first PCIA bolus.

statistically significant, the magnitude of the difference was too small to be considered clinically meaningful. In addition, QLB with 0.375% and 0.5% ropivacaine reduced the demand for opioids after surgery. The results of the present study provide a reference for the optimal administration regimen of ropivacaine in QLB.

Based on the anatomical relationship between needle tip and quadratus lumborum, the approaches of QLB could be divided into anterior, lateral, posterior and intramuscular. Different approaches may have different mechanisms of action. Anterior QLB may be associated with local anesthetic spread to the lumbar nerve roots and branches as well as the thoracic paravertebral space [15,16]. Lateral QLB may be related to local anesthetic spread to the transversus abdominis muscle plane and subcutaneous tissue, thereby limiting its dermatomal block range to some extent. Intramuscular approach may act through intramuscular local anesthetic penetration to the surrounding thoracolumbar fascia. Posterior QLB may exert its clinical effect by local anesthetic spread along the middle thoracolumbar fascia intertransverse area, which has extensive sensory innervation by both A- and C-fiber nociceptors and mechanoreceptors [17,18]. Further, posterior QLB is performed in the most superficial plane of four approaches with a lower risk of visceral damage. Based on above considerations, posterior QLB may be the best option for abdominal surgeries and was chosen in our study. Our results showed that regardless of the concentrations of ropivacaine, posterior approach could provide a satisfactory sensory block level and the block effect could last for 48 h, confirming its superiority.

The study has several limitations. First, we applied strict criteria for inclusion, therefore, whether the conclusions are also applicable for patients who aged <18 or >75 years old, with BMI <18 or >24 kg m^{-2}, or undergoing other types of surgeries remains to be elucidated. Second, due to the difference in the anatomical location of needle tip placement, there are discrepancies in the spread of local anesthetic among the four QLB approaches [19]. Accordingly, the applicability of our findings for other types of QLB needs to be further researched. Third, the QLB operator was not blinded to the grouping. Although the QLB operator was not involved in anesthetic management and outcome assessment, the potential risk of bias could not be completely avoided. Fourth, the numbers of groups based on the concentrations of ropivacaine in present study were limited. Other concentrations were not included in our studies because of the lower frequency of clinical application. Fifth, blood concentrations of ropivacaine were not monitored. Doses close to the upper safety limit of ropivacaine were used in our study. Even at the recommended dose, some patients with poor tolerance (e.g., receiving chemotherapy, with ileus) may have a high risk of local anesthetic systemic toxicity (LAST). The systemic toxicity of ropivacaine should be considered, and blood concentration monitoring is advised to reduce the risk. Furthermore, a previous animal experiment demonstrated the possible presence of a systemic analgesic effect of ropivacaine, which could potentially be attributed to its anti-inflammatory properties [20]. However, it should be noted that this effect has not yet been confirmed in any clinical studies. Monitoring blood concentrations could prove beneficial in investigating this potential systemic effect. Sixth, regarding the adverse effects, the small sample size may be not sufficiently powered to detect the possible discrepancies among the groups.

In conclusion, 0.375% and 0.5% ropivacaine in posterior QLB provide better sensory block of surgical site in laparoscopic colorectal surgery in comparison with 0.25% ropivacaine. Posterior QLB with 0.375% and 0.5% ropivacaine may be more appropriate for perioperative analgesia in laparoscopic colorectal surgery.

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Ethics statement

This study was reviewed and approved by Medical Ethics Committee of Houjie Hospital of Dongguan, with the approval number: [2019] Houyilunshen (No.053). All participants/patients (or their proxies/legal guardians) provided informed consent to participate in the study.

Data availability statement

Data will be made available on request.

CRediT authorship contribution statement

Wen-Kao Huang: Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Formal analysis, Conceptualization. **Zhao-Kai Lu:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Fan Deng:** Writing – review & editing, Writing – original draft, Formal analysis, Conceptualization. **Xing-Xia Chen:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **Xiao-Yu Zhuo:** Writing – review & editing, Writing – original draft, Software, Formal analysis. **Ke-Xuan Liu:** Writing – review & editing, Writing – original draft, Methodology, Formal analysis. **Wei-Feng Liu:** Writing – review & editing, Writing – original draft, Project administration, Funding acquisition, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.heliyon.2024.e28434.

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