Randomized Trial

Changes of Opioid Consumption After Lumbar Fusion Using Ultrasound-Guided Lumbar Erector Spinae Plane Block: A Randomized Controlled Trial

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Background: The erector spinae plane block (ESPB) is gaining popularity in lumbar fusion for postoperative pain management.

Objectives: The aim of this study was to investigate the changes of opioid consumption after surgery, the range of cold temperature sensory blockade, pain, and safety.

Study Design: Randomized controlled study.

Setting: Single center.

Methods: Patients who were randomized to ESPB with 0.375% ropivacaine (ropivacaine group) and mock ESPB with saline (saline group) and underwent posterior lumbar fusion surgery. The primary endpoint was the total dosage of oxycodone. Secondary endpoints included remifentanil consumption, postoperative pain scores, postoperative adverse events, safety, and range of cold hypoesthesia.

Results: Oxycodone consumption in the first 48 hours after surgery was significantly lower in the ropivacaine group than in the saline group ($P < 0.05$). Remifentanil consumption was significantly lower in the ropivacaine group compared with the saline group during the surgery (0.69 ± 0.03 mg vs. 0.85 ± 0.04 mg, $P < 0.05$). The areas of cold hypoesthesia were identified in the ropivacaine group after the block, but not in the saline group. Rest and exercise pain scores after surgery were significantly lower in the ropivacaine group than in the saline group ($P < 0.05$). The overall safety of the ropivacaine group were generally comparable to that of the saline group.

Limitations: The areas of cold hypoesthesia were tested at different time points after ESPB, but the area of sensory loss was not tested, and the recovery of postoperative sensation was not recorded. In addition, we tested only temperature sensation, but not acupuncture pain.

Conclusions: Ultrasound-guided lumbar ESPB reduces the amount of analgesics required during and after lumbar fusion and reduces the postoperative Visual Analog Scale pain score.

Key words: Erector spinae plane block, lumbar fusion, analgesia, opioid dose, randomized controlled study, ropivacaine, Visual Analog Scale pain score, postoperative

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Lumbar fusion is a common surgical procedure for spinal disorders, and it may be associated with severe acute postoperative pain (1-3). If the acute pain is not effectively controlled, it may develop into chronic pain, which will seriously affect the patient's recovery and postoperative quality of life (1-3). Although opioids are the main analgesic drugs used after lumbar fusion, high dose opioids tend to cause nausea and vomiting,

respiratory depression, cognitive dysfunction, and other side effects (4,5). Therefore multimode analgesia (MMA) has become the mainstream treatment of choice for perioperative pain management (6).

The ultrasound-guided erector spinae plane block (ESPB), an important component of MMA, was first reported by Forero et al (7) in 2016 as an effective treatment for neuropathic pain in the chest. It now plays an important role in perioperative analgesia. Pain after a lumbar fusion can be caused by tissue damage in the vertebral body, ligaments, muscle, and fascia (1). All of these tissues are supplied by the dorsal branch of the spinal nerve. During ESPB, the drug is injected between the deep surface of the erector spinae and the transverse process and then spreads between the planes of the fascia, blocking the dorsal and ventral branches of the spinal nerve, leading to extensive skin sensation loss and an analgesic effect (7-9). Therefore it is widely used in the fields of chest surgery, abdominal surgery, spinal surgery, and pain management (10-13). There are many studies reporting that thoracic ESPB provides analgesia for lumbar surgery (14-16), but there are few reports that lumbar ESPB provides analgesia for lumbar surgery.

Therefore the aim of this randomized controlled study was to investigate the changes of opioid consumption after surgery. The differences in the effective range of the lumbar ESPB block by the dynamic measurement of the range of cold temperature sensory blockade, postoperative Visual Analog Scale (VAS) pain score, and postoperative adverse reactions between the ESPB group and the mock group were compared.

Methods

Study Design and Patients

In the randomized controlled trial study, the patients were recruited in our hospital from September 15 to December 31, 2019. All patients provided written informed consent. This study was approved by the ethics committee of Taizhou Hospital of Zhejiang Province (approval number K20190801) and was registered in the Chinese Clinical Trial Registry (http://www.chictr.org.cn, #ChiCTR1900025888) on September 12, 2019.

The inclusion criteria were (1) age 45 to 70 years; (2) American Society of Anesthesiologists (ASA) physical status I or II; and (3) scheduled for lumbar fusion (17,18). The exclusion criteria were (1) body mass index (BMI) ≥30 kg/m2; (2) known allergies to local anesthetic drug; (3) infection near the puncture site; (4) abnormal coagulation function; (5) use of painkillers; or (6) communication difficulties with the medical staff.

Randomization and Blinding

The patients were randomly divided into 2 groups: the ropivacaine group (ESPB with 0.375% ropivacaine) and the saline group (mock ESPB with saline). A nurse who was not involved in the study handled the randomization, blinding procedures, and drug preparations. Anesthesiologists, postanesthesia care unit (PACU) personnel, and data collectors were not informed of the group assignments.

Intervention

Ultrasound-guided lumbar ESPB was performed in the preoperative preparation room. The patients were placed in a prone position after accessing a peripheral vein. A low-frequency convex array probe (1–5 MHz) of an ultrasonic instrument (Edge, FujiFilm Sonosite, Tokyo, Japan) was placed longitudinally 3 to 4 cm away from the posterior median line and positioned at the level of the L2 transverse process. In the ropivacaine group, the patients were injected with 0.375% ropivacaine (20 mL) when the tip of the needle (80 mm, 22-gauge) reached the interfacial plane between the L2 transverse process and the erector spine muscle using an in-plane technique. This was repeated on the opposite side. In the saline group, normal saline (20 mL) was injected in the same way. At 10, 20, and 30 minutes after block, the cold hypoesthesia range of each patient was measured with an ice cube and delineated with a marker pen. At the same time, body surface landmarks such as the bilateral subscapular angle, the bilateral iliac crest, the bilateral ischial tuberosity, and the sacral horn were marked. The marked area was covered with a sticky colorless transparent film to which the markings were transferred.

Anesthetic Procedure

The patients fasted for 8 hours prior to the procedure. After entering the operating room, they were routinely monitored, and a unified general anesthesia regimen was administered. The induction drugs were sufentanil 0.4 μg/kg, rocuronium 0.6 mg/kg, and propofol 1.5 to 2 mg/kg. After induction, a strengthened tracheal catheter (male inner diameter of endotracheal tube [ID] 7.5 mm, female ID 7.0 mm) was inserted. Propofol injection (3–10 mg/kg/h) and remifentanil

(0.2–0.5 μg/kg/min) were used for anesthesia maintenance. The bispectral index values of all patients were maintained between 40 and 60. Rocuronium was maintained by intermittent injection according to the surgical conditions. All patients were given sufentanil 5 μg, flurbiprofen 50 mg, and tropisetron hydrochloride 2 mg by intravenous injection 15 minutes before the end of surgery. Patients were transferred to the PACU and provided with patient-controlled intravenous analgesia with oxycodone for postoperative analgesia. The analgesia devices were set to a concentration of 0.2 mg/mL, with a lockout interval of 15 minutes, and a 7 mL bolus without an infusion dose. If the VAS pain score was 4 or more after extubation, 5 μg of sufentanil was given by intravenous injection as rescue analgesia.

Endpoint

In this study, the primary endpoint was the total oxycodone consumption. The secondary endpoints included remifentanil consumption in surgery; the number of pain-relieving doses of sufentanil in the PACU; the resting and exercise VAS pain scores (0 = no pain and 10 = the worst imaginable pain) at 30 minutes after extubation, and 6, 12, 24, 36, and 48 hours after surgery; the consumption of oxycodone at various time periods (0–6, 6–12, 12–18, 18–24, 24–36, and 36–48 hours after surgery); and the range of cold hypoesthesia after the block at 10, 20, and 30 minutes. The ranges of cold hypoesthesia were marked and transferred to transparent films. The patients' transfer membranes were scanned, converted into digital images, and saved in JPG format. The height and weight parameters of these patients were used in MATLAB (MathWorks, Natick, MA) programming to create a standard model. Three curves representing the 3 time points in each sample image were separated through image processing to obtain 3 sets of curves corresponding to the 3 time points. Multiple images at the same time point were synthesized into renderings based on the standard model. The area of cold temperature sensory blockade in all patients at the same time point was calculated. The occurrence of postoperative adverse events, such as postoperative nausea and vomiting, numbness, abdominal distension, respiratory depression, dizziness, drowsiness, perineal numbness, and lower limb sensorimotor disturbance, were monitored.

Statistical Analyses

The sample size of this study was calculated using the MedCalc 17.6 statistical software (MedCalc Software Bvba, Ostend, Belgium). Preliminary observations showed that the mean oxycodone consumption was 35 ± 5.6 mg at 48 hours after lumbar fusion. To reduce oxycodone consumption by 10%, with $\alpha = 0.05$ and $\beta = 0.20$, each group needed 18 patients. To allow for a 10% dropout rate this study sample size was 40 patients.

All statistical analyses were performed with IBM SPSS 20.0 (IBM Corp., Armonk, NY). Continuous data that were normally distributed were expressed as mean ± standard deviation, and that which was not normally distributed were expressed as median (interquartile) and analyzed using the independent sample t-test (normal distribution based on the Kolmogorov–Smirnov test) or the Mann–Whitney U test (skewed distribution). The categorical data were presented as numbers and percentages for each value of a variable and analyzed using the χ^2 test. *P* values < 0.05 were considered statistically significant.

Results

Characteristics of the Patients

From September to December 2019, 42 patients underwent lumbar fusion, of whom 40 consented to participate in the study. The patients were allocated to the saline group (n = 20) or the ropivacaine group (n = 20), all of whom completed the study (Fig. 1). The demographic characteristics and intraoperative data of the patients are shown in Table 1. There were no significant differences between the 2 groups in terms of age, gender, height, weight, BMI, ASA class, level of the surgical segment, and duration of surgery (all *P* > 0.05) (Table 1).

Opioid Consumption During and After Surgery

Remifentanil consumption was significantly lower in the ropivacaine group compared with the saline group during the surgery (0.69 ± 0.03 mg vs. 0.85 ± 0.04 mg, *P* < 0.05). The number of pain-relieving doses of sufentanil administered in the PACU in the ropivacaine group was significantly lower than that in the saline group (2 vs. 10, *P* < 0.05) (Table 2).

The median consumption of oxycodone at 0 to 6, 6 to 12, 12 to 18, and 18 to 24 hours after surgery and the total consumption of oxycodone were 1.40 (0.35–1.40) mg, 2.80 (2.80–4.20) mg, 4.20 (2.80–7.00) mg, 4.20 (4.20–6.65) mg, and 23.10 (18.20–30.46) mg, respectively, in the ropivacaine group, which was significantly less than in the saline group (4.20 [2.80–5.60] mg, 8.40 [5.60–8.40] mg, 7.00 [7.00–8.40] mg, 7.00 [5.60–8.05]

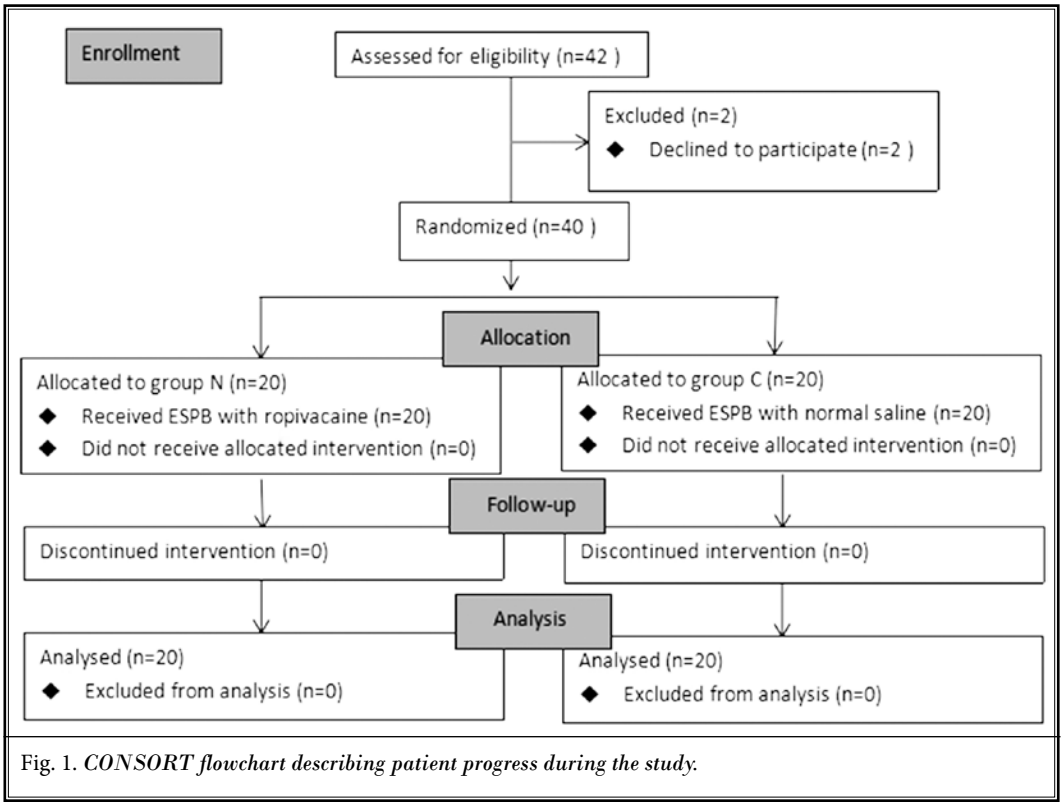

Fig. 1. *CONSORT flowchart describing patient progress during the study.*

Table 1. *Demographic and operative characteristics of the patients.*

	Saline Group (n = 20)	Ropivacaine Group (n = 20)	*P* Value
Age (years)	60 ± 2	59 ± 2	0.852*
Gender (M/F)	8/12	7/13	0.744†
Height (cm)	163 ± 2	160 ± 2	0.337*
Weight (kg)	64 ± 2	65 ± 2	0.906*
ASA status (I/II)	3/17	4/16	0.677†
Level of surgical segments (I/II)	14/6	15/5	0.723†
Duration of surgery (min)	123 ± 5	128 ± 6	0.540*
BMI (kg/m^2)	24.4 ± 0.5	25.3 0.7	0.310*

Values are presented as number or mean ± standard deviation. Abbreviations: F, female; M, male. *Independent sample *t*-test. †The χ^2 test.

mg, and 36.40 [22.56–39.20] mg, respectively) (all $P < 0.05$). However, there were no statistically significant differences in oxycodone consumption at 24 to 36 and 36 to 48 hours between the 2 groups (5.60 [2.80–7.00 mg] vs. 5.60 [4.55–7.00] mg and 4.20 [2.80–6.65 mg] vs. 4.20 [2.80–4.20] mg, respectively) (all $P > 0.05$) (Table 3).

Table 2. *Remifentanil consumption and the number of relieving doses of sufentanil in PACU.*

	Remifentanil Consumption (mg)	Number of Sufentanil Analgesic Remedies in PACU, n (%)
Saline group (n = 20)	0.85 ± 0.04	10 (50)
Ropivacaine group (n = 20)	0.69 ± 0.03	2 (10)
P value	0.011*	0.005†

Values are presented as number or mean ± standard deviation. *Independent sample *t*-test. †The χ^2 test.

Secondary Endpoints

At 10, 20, and 30 minutes after the ESPB block, there was no cold hypoesthesia range in the saline group, but there was a definite cold hypoesthesia range in the ropivacaine group. In the ropivacaine group, the range at 10 minutes after the block was from the T9 level to the S1 level (block area of 219.4 ± 15.6 cm^2). The range at 20 minutes after the block was from the T8 level to the S1 level (block area of 362.8 ± 20.6 cm^2). The range at 30 minutes after the block was from the T8 level to the S2 level (block area of 462.3 ± 22.4 cm^2) (Figs. 2 and 3, and Table 4).

The resting and exercise pain scores at 30 minutes after extubation, and at 6, 12, and 24 hours after surgery in the ropivacaine group were significantly lower than those in the saline group (all $P < 0.05$), but there were no significant differences in the rest and exercise pain scores at 36 and 48 hours after surgery between the 2 groups (both $P > 0.05$) (Table 5).

Safety

The incidence of postoperative bloating was 6/20 (30%) in the saline group and 5/20 (25%) in the ropivacaine group ($P > 0.05$). The incidence of dizziness was 3/20 (15%) in the saline group and 2/20 (10%) in the ropivacaine group ($P > 0.05$). In the study, we did not observe adverse events such as postoperative nausea and vomiting, lower limb sensorimotor dysfunction, respiratory depression, or perineal numbness (Table 6).

Discussion

The ESPB is gaining popularity in lumbar fusion for postoperative pain management. The aim of this study was to investigate the changes of opioid consumption after surgery, the range of cold temperature sensory blockade, pain, and safety. This trial suggests that ultrasound-guided lumbar ESPB reduces the amount of analgesics required during and after lumbar fusion and reduces the postoperative VAS pain score.

ESPB is a fascia plane block that greatly reduces the occurrence of adverse events such as pneumothorax, hematoma, and nerve injury (19). At present, most research on ESPB blocks is focused on the thoracic segment (14-16), with little research being undertaken on the lumbar segment. Tulgar et al (20) observed sensory loss in the range of L2 to L5 by ESPB at the level of the L4 transverse process. However, there has been no relevant study on the sensory loss by ESPB at the level of the L2 transverse process. Therefore ESPB was applied to the level of the L2 transverse process in this study. The results showed that the consumption of remifentanil during surgery and the number of pain-relieving doses of sufentanil in the PACU were lower in the ropivacaine group compared with the saline group, indicating that lumbar ESPB had a significant analgesic effect during lumbar fusion. This is consistent with findings in the literature that ESPB can provide good analgesia for lumbar surgery (21,22). In addition, the consumption of oxycodone was also reduced, which further indicated the high quality and long duration of the analgesia provided by lumbar ESPB.

Table 3. *Oxycodone consumption in the first 48 hours after surgery.*

	Saline Group (n = 20)	Ropivacaine Group (n = 20)	*P* Value*
0–6 h (mg)	4.20 (2.80–5.60)	1.40 (0.35–1.40)	< 0.001
6–12 h (mg)	8.40 (5.60–8.40)	2.80 (2.80–4.20)	< 0.001
12–18 h (mg)	7.00 (7.00–8.40)	4.20 (2.80–7.00)	0.002
18–24 h (mg)	7.00 (5.60–8.05)	4.20 (4.20–6.65)	0.009
24–36 h (mg)	5.60 (4.55–7.00)	5.60 (2.80–7.00)	0.931
36–48 h (mg)	4.20 (2.80–4.20)	4.20 (2.80–6.65)	0.906
Total 48 for h (mg)	36.40 (22.56–39.20)	23.10 (18.20–30.46)	< 0.001

Values are presented as median (interquartile).
*The Mann–Whitney *U* test.

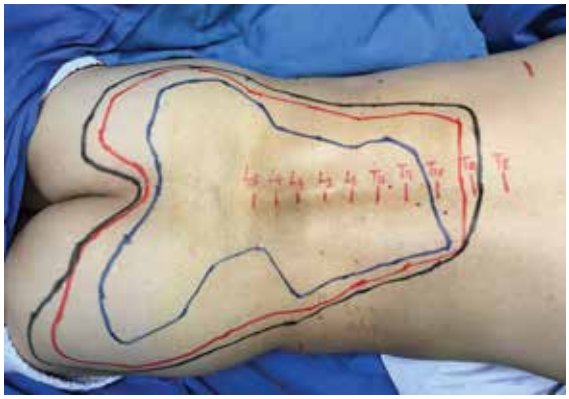

Fig. 2. *Range of anesthesia after ESPB. The blue line represents the range of cold hypoesthesia at 10 minutes after ESPB. The red line represents the range of cold hypoesthesia at 20 minutes after ESPB. The black line represents the range of cold hypoesthesia at 30 minutes after ESPB.*

The results also showed that there was no cold hypoesthesia range after ESPB in the saline group, whereas there was a definite range of cold temperature sensory blockade after ESPB in the ropivacaine group. The range of cold hypoesthesia extended up to T8 and down to S2 and was expanded to some extent with the passage of time after the block, which provides a clinical basis for the area covered by analgesia for lumbar fusion. These results indicate that ESPB leads to a definite cold temperature sensory block in the lumbar area, which could explain the lower doses of opioids.

In addition, the results of the present study showed

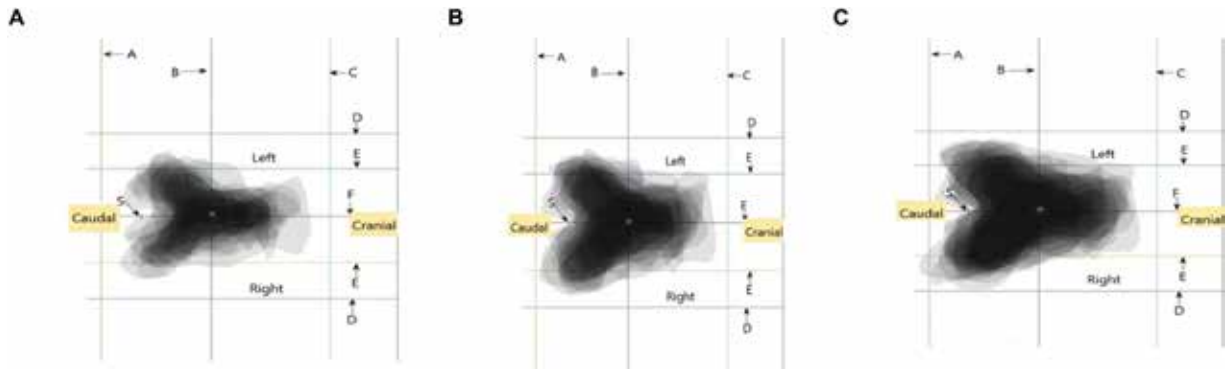

Fig. 3. *Range of anesthesia after ESPB in all patients. (A) Range of cold hypoesthesia at 10 minutes after ESPB. (B) Range of cold hypoesthesia at 20 minutes after ESPB. (C) Range of cold hypoesthesia at 30 minutes after ESPB. Line A: between the ischial tubercles; line B: between the iliac crests; line C, between the subscapular angles; line D, the axillary midline; line E, the subscapular angle; line F, the posterior midline; point S, the sacrum.*

Table 4. *Range of temperature hypoesthesia at different time points after ESPB block (n = 20).*

Range of Temperature Hypoesthesia, n (%)	Each Time Point After the Block		
	10 min	20 min	30 min
T8	0	1 (5)	1 (5)
T9	2 (10)	4 (20)	4 (20)
T10	3 (15)	8 (40)	9 (45)
T12	15 (75)	18 (90)	18 (90)
L1	18 (90)	20 (100)	20 (100)
L2	20 (100)	20 (100)	20 (100)
L3	19 (95)	20 (100)	20 (100)
L4	19 (95)	20 (100)	20 (100)
L5	15 (75)	19 (95)	20 (100)
S1	4 (20)	12 (60)	19 (95)
S2	0	0	2 (10)

Table 5. *Comparison of VAS scores at postoperative time points.*

	Saline Group (n = 20)	Ropivacaine Group (n = 20)	*P* Value*
Resting VAS scores			
30 min after extubation	1.0 (1.0–2.0)	0.0 (0.0–1.0)	< 0.001
6 h	2.0 (2.0–2.0)	0.5 (0.0–1.0)	< 0.001
12 h	2.0 (2.0–2.0)	0.0 (0.0–1.0)	< 0.001
24 h	2.0 (1.0–2.0)	1.0 (0.0–1.0)	0.008
36 h	1.0 (1.0–1.0)	1.0 (0.0–1.0)	0.056
48 h	0.0 (0.0–1.0)	0.0 (0.0–0.0)	0.300
Exercise VAS scores			
30 min after extubation	2.0 (2.0–3.0)	1.0 (0.3–2.0)	< 0.001
6 h	3.0 (3.0–3.0)	1.5 (1.0–2.0)	< 0.001
12 h	3.0 (3.0–3.0)	1.0 (1.0–2.0)	< 0.001
24 h	3.0 (2.0–3.0)	2.0 (1.0–3.0)	0.032
36 h	2.0 (2.0–2.0)	2.0 (2.0–2.0)	0.123
48 h	1.0 (1.0–2.0)	1.0 (1.0–1.0)	0.064

Values are presented as median (interquartile).
*The Mann-Whitney *U* test.

that lumbar ESPB reduced resting and exercise VAS pain scores at each time point observed within 24 hours after surgery, which further indicated the high quality and long duration of the analgesia provided by lumbar ESPB. The use of catheters placed in thoracic ESPB to provide long-term analgesia has been reported (23). Although the specific structure is different, the lumbar and thoracic erector spinae are continuous anatomically, allowing catheters to be placed in the lumbar plane of the erector spinae.

Postoperative bloating occurred in some patients in both groups, but there was no statistically significant difference between the 2 groups. The cause of postoperative bloating may be related to the anal exhaust time or the lumbar surgery itself (24). A low dose of dexmedetomidine can promote the recovery of gastrointestinal function after lumbar surgery (25). No adverse reactions such as nausea and vomiting, respiratory depression, or drowsiness occurred in either group. Adverse events associated with the nerve block, such as pudendal numbness and lower limb sensorimotor dysfunction, were not observed in this study. Although ultrasound-guided ESPB is simple and complications are rarely reported, a case of suspected pneumothorax caused by thoracic ESPB has been reported (26). Complications may be gradually discovered and reported as the use of ESPB becomes more

widespread in clinical practice. Additional studies will have to examine the safety of ESPB.

A strength of the present study was the comparison of the doses of opioids as the primary endpoint. Nevertheless, there were several limitations to this study. First, the sample size was relatively small, and the patients were highly selected, limiting the generalizability of the results. The areas of cold hypoesthesia were tested using ice, which relies mainly on the patient's own judgment of cold rather than an objective judgment criterion. Indeed, changes in skin blood flow can be monitored by photoplethysmography or laser Doppler during a nerve block, which is a more reliable and sensitive technique than a subjective assessment of skin temperature changes (27). Second, the areas of cold hypoesthesia were tested at different time points after ESPB, but the area of sensory loss was not tested, and the recovery of postoperative sensation was not recorded. Finally, we tested only temperature sensation, but not acupuncture pain. Although there is a good correlation between temperature sensation testing and acupuncture pain testing (28), there is some difference.

Conclusions

The results suggest that ultrasound-guided lumbar ESPB reduces the amount of analgesics required during and after lumbar fusion and reduces the postoperative VAS pain score. To our knowledge, this is the first report of ESPB at L2 that suggests that ESPB can be of use for lumbar surgery. Nevertheless, additional studies are necessary to confirm the results.

Table 6. *Postoperative bloating and dizziness.*

	Saline Group (n = 20)	Ropivacaine Group (n = 20)	*P* Value*
Incidence of bloating, n (%)	6 (30)	5 (25)	0.723
Incidence of dizziness, n (%)	3 (15)	2 (10)	0.632

Values are presented as number.
*The χ^2 test.

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Author Contributions

LZ contributed to conceptualization, design, supervision, validation, formal analysis, and writing of the original draft. LC participated in design, project administration, data curation, and writing of the original draft. XW contributed to data curation and formal analysis. YW contributed to project administration and data curation. MW contributed to project administration, data curation, writing of the review, and editing. JL contributed to conceptualization, design, resources, review, and editing. All authors read and gave final approval of the version to be published.

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