Drug Design, Development and Therapy

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CLINICAL TRIAL REPORT

Comparing Liposomal Bupivacaine and Ropivacaine in Serratus Anterior Plane Block for Thoracoscopic Lobectomy: A Randomized Controlled Trial

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Background: The optimal analgesic regimen after video-assisted thoracoscopic surgery (VATS) is unclear. We aimed to examine whether ultrasound-guided serratus anterior plane block (SAPB) with liposomal bupivacaine could provide continuous and effective analgesic effects for lung cancer patients undergoing VATS.

Methods: A total of 64 patients were randomly allocated to receive either the liposomal bupivacaine (LB group) or the ropivacaine (RO group). The primary outcome was pain score at rest and on movement in the first three days after surgery. The secondary outcomes included intraoperative remifentanil consumption, perioperative consumption of sufentanil and flurbiprofen axetil, time to extubation, time to first bowel movement, time to first flatus, incidence of postoperative nausea and vomiting (PONV), length of intensive care unit (ICU) stay, length of hospital stay, hospitalization costs, and early recovery quality as assessed by QoR-15 score.

Results: The LB group had significantly lower pain scores at rest and on movement at 12h, 24h, 36h, 48h, and 72h after surgery, and lower pain scores on movement at 8h after surgery, when compared with the RO group. Perioperative sufentanil consumption and postoperative flurbiprofen axetil consumption were significantly reduced in the LB group than in the RO group. In addition, compared with the RO group, the LB group had earlier first flatus, mobilization, and urinary catheter removal, shorter ICU stay, lower incidence of PONV, and lower hospitalization costs. The QoR-15 scores in the first three days after surgery were significantly higher in the LB group than in the RO group. There were no statistically significant differences between the two groups regarding time to extubation, intraoperative remifentanil consumption, and length of hospital stay.

Conclusion: Ultrasound-guided SAPB with liposomal bupivacaine was effective in relieving postoperative pain for three days after surgery in patients undergoing VATS.

Keywords: serratus anterior plane block, video-assisted thoracoscopic surgery, liposomal bupivacaine, ropivacaine, postoperative pain

Introduction

Video-assisted thoracoscopic surgery (VATS) has become a mainstay in the surgical management of lung cancer[1,2] preferred for its less operative bleeding, smaller incisions, reduced stress response, better cosmetic outcomes and shorter hospital stay than traditional thoracotomy.[3,4] Despite the less invasive nature of VATS,[5] analgesic requirements remain a critical clinical issue, with patients often experiencing moderate to severe acute postoperative pain.[6] This underscores the need for effective perioperative analgesia for patients undergoing VATS.

Previously, thoracic epidural block (TEB) was widely used for effective analgesia in thoracic surgery. However, TEB has a high failure rate of up to 30%, with difficult catheter detachment or catheterization,[7] hemodynamic instability, intrathecal injection, epidural hematoma, peripheral nerve injury and urinary retention. Thoracic paravertebral block

Received: 16 January 2025
Accepted: 23 May 2025
Published: 4 June 2025

(TPVB) has been suggested as an alternative approach that could provide similar analgesia for patients undergoing VATS.[8] Nonetheless, TPVB has some disadvantages, including the risk of pneumothorax, spinal cord and nerve injury, a high incidence of incomplete block, and multi-site injection.[9] Currently, ultrasound-guided interfascial plane block including erector spinae plane block (ESPB)[10] and serratus anterior plane block (SAPB)[11] are available for VATS. Ultrasound-guided SAPB, a new analgesic technique, is considered superficial and safe, with minimal complications and stable hemodynamics compared with ultrasound-guided TPVB.[12] It can provide analgesia for the entire hemithorax and cover the incisions for VATS.[13] However, the duration of analgesia with a single SAPB analgesia with ropivacaine[14] or bupivacaine could not exceed eight hours,[15] and acute postoperative pain often last for three days in patients undergoing VATS.[16] Thus, there is a need to explore strategies to prolong the effective analgesic effects of SAPB.

Ultrasound-guided continuous SAPB has shown efficacy for prolonged analgesia in patients undergoing VATS.[17,18] However, the use of continuous SAPB with a catheter presents some disadvantages, such as the possibility of hematoma, catheters displacement or detachment, infection and the requirement for nurses with specialized training.[19] Liposomal bupivacaine is an extended-release formulation of the local anesthetic bupivacaine, encapsulated in multivesicular liposomes. This technology allows for prolonged drug release, providing sustained analgesia for up to 72 hours post-administration.[20] This study aimed to assess whether SAPB with liposomal bupivacaine could provide continuous and effective analgesic effects in patients undergoing VATS compared with ropivacaine.

Methods

Ethics Statement

This randomized, controlled, double-blind trial was approved by the Ethics Committee of the First Affiliated Hospital of Nanchang University (approval number 2023–265) on 14 September 2023 and was registered at the Chinese clinical trial registry (ChiCTR2300076281). Written informed consent was obtained from all patients, and this study was conducted in accordance with the principles of the Declaration of Helsinki. We included patients from November 2023 to April 2024. The work has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.[21]

Patients

Lung cancer patients who were scheduled for VATS lobectomy were enrolled at our hospital. Patients were eligible if they were aged 18–65 years, had body mass index (BMI) between 19.0 and 26 kg/m^2 and were classified as American Society of Anesthesiologists (ASA) physical status II to III. Exclusion criteria included chronic opioid use, allergies to the study drugs, refusal of SAPB, severe chronic renal or hepatic failure, previous thoracic surgery, a history of neuropathic pain, infection at the puncture site, participation in another study, patients with coagulopathy and those unable to communicate sufficiently for postoperative pain assessment using the NRS score.

Study Design

Our research was conducted at the First Affiliated Hospital of Nanchang University, a large tertiary teaching hospital located in Nanchang/China, with 300 thousand patients per year, four thousand VATS surgeries per year.

Randomization and Blinding

We randomly allocated 76 patients scheduled for VATS lobectomy to two groups: the LB group receiving SAPB with liposomal bupivacaine and the RO group receiving the same block with ropivacaine. A computer-generated number table method was used for randomization, conducted by a designated nurse who managed patient allocation. The allocation sequence was concealed within sealed, opaque envelopes containing each patient's grouping information. Subsequent to randomization, another nurse opened the envelope and prepared the local anesthetics based on the grouping information. The anesthesiologist performed SAPB and was blinded to the allocation. Data collection was recorded by an independent investigator. Blinding was maintained for the patients and all investigators.

Surgical and Anesthetic Procedure

All patients underwent SAPB in the specialized anaesthetic preparation room and received routine monitoring, including five-lead electrocardiogram, heart rate, noninvasive blood pressure and oxygen saturation. The anesthesiologist tested the cutaneous sensory blocked area using an ice cube at 30 minutes after SAPB (Figure 1). Subsequently, patients were transferred to the operating room. For anesthesia induction, 0.05 mg/kg of midazolam, 0.5 μg/kg of sufentanil, 0.3 mg/kg of etomidate and 0.3 mg/kg of cisatracurium were administered. After ensuring adequate oxygenation, visualized double-lumen bronchial intubation was performed and its position was confirmed via a visual screen. During surgery, general anesthesia was maintained with remifentanil and propofol (6mg/kg/h). The BIS was maintained between 45 and 55 in all patients. If the BIS fell below 45 and we would reduce the remifentanil dosage, if it exceeds 55 and we would increase the dosage.Patients who underwent VATS lobectomy at our hospital had three small incisions: anterior axillary line between the 3rd and 4th intercostal space, mid axillary line between the 7th and 8th intercostal space and shoulder blade line between the 8th and 9th intercostal space (Figure 1). All surgical procedure was performed by the same surgeon. After surgery, all patients were transferred to the intensive care unit (ICU) as scheduled. Postoperative analgesia was provided by patient-controlled intravenous analgesia using sufentanil (bolus: 0.05μg/kg; lockout: 20 minutes; maximum 4-hourly dose: 0.6 μg/kg). If patients complained of additional pain (Numerical Rating Scale [NRS] score≥ 4), 50 mg flurbiprofen axetil was injected intravenously at 6 h intervals.

Ultrasound-Guided SAPB Procedure

The SAPB was performed in the lateral position using a high-frequency linear ultrasound probe with 7.5 MHz (Huasheng, Shenzhen, China). After skin preparation, a skilled anesthesiologist positioned the linear probe along the patient's midaxillary line to identify the serratus anterior and latissimus dorsi muscles overlying the second to eighth ribs. The needle (Tuoren, Henan, China) was inserted into the interfascial plane between the serratus anterior and latissimus dorsi muscles at the level of the 5th rib (All patients were used the superficial SAPB in our study). Correct needle placement was confirmed by injecting 3 mL of saline (Figure 2). Then, 40 mL of 0.665% liposomal bupivacaine or 0.375% ropivacaine was administered to the serratus anterior plane.

Outcome Assessment

The primary outcome was postoperative pain intensity, measured using the Numerical Rating Scale (NRS) score ranging from 0 (no pain) to 10 (worst severe pain). Pain assessments were performed at 3h, 6h, 8h, 12h, 24h, 36h, 48h, and 72h after surgery, both at rest and on movement (during coughing). The secondary outcomes included intraoperative remifentanil consumption, perioperative consumption of sufentanil and flurbiprofen axetil, time to extubation, time to first bowel movement, time to first flatus, incidence of postoperative nausea and vomiting (PONV), length of ICU stay, length of hospital stay, hospitalization costs, and early quality of recovery as measured by the QoR-15 score.[22]

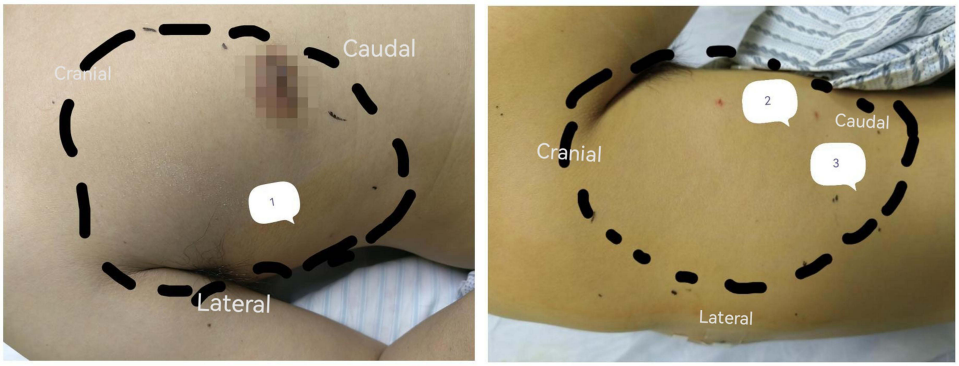

Figure 1 Block area of serratus anterior plane block. The 1,2,and 3 represent the three smaller incisions of video-assisted thoracoscopic surgery in our study. 1: Third and fourth intercostal spaces on the axillary front line; 2: Between the 7th and 8th ribs of the axillary midline; 3: Between the 8th and 9th ribs of the scapula line.

https://doi.org/10.2147/DDDT.S513287

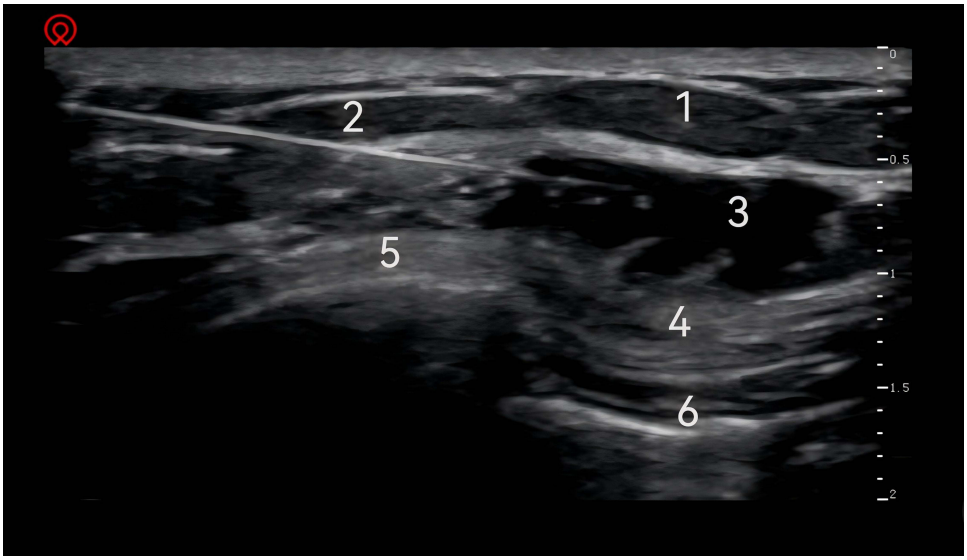

Figure 2 Ultrasound image of serratus anterior plane blocks. 1: Latissimus dorsi muscle; 2: Needle; 3: Local anesthetic; 4: Serratus anterior muscle; 5: Rib; 6: pleura.

Sample Size and Statistical Analysis

Sample size was determined based on our preliminary study, which included 10 patients with 5 patients in each group. The primary outcome of postoperative pain intensity during coughing at 24h after surgery was 2.1 ± 1.1 in the LB group versus 3.9 ± 1.7 in the RO group. To achieve a 90% statistical power with a 5% alpha level, each group required 32 patients. Considering potential missing data, the sample size was increased by 20%, resulting in a total of 38 patients in each group.

Data analysis was conducted using SAS software (version 9.1.3). Quantitative variables were analyzed using the Student's *t*-test or the Mann–Whitney *U*-test, depending on the normality of data distribution. Qualitative variables were analyzed using Chi-squared (χ^2) test or Fisher's exact test. Pain intensity at rest and on movement was analyzed with a two-way repeated-measures analysis of variance. A p-value of < 0.05 was considered statistically significant.

Results

A total of 76 patients were assessed for eligibility. Of those, 12 patients were excluded due to conversion to traditional thoracotomy for lung resection (five patients), refusal of follow-up (four patients) and missing data (three patients). Overall, 64 patients were randomized to the LB and RO groups (32 patients in each group). Patient flow diagram was shown in Figure 3. Demographic characteristics and surgical variables were comparable between the groups (Table 1).

Pain scores at rest were significantly lower in the LB group than in the RO group at 12h, 24h, 36h, 48h, and 72h after surgery, and the differences were not statistically significant at 3h, 6h, and 8h (Figure 4). Pain scores on movement showed no significant differences between the two groups at 3h and 6h after surgery (Figure 5). However, the LB group had lower pain scores on movement at 8h, 12h, 24h, 36h, 48h, and 72h after surgery compared with the RO group (Figure 5).

Perioperative sufentanil consumption, postoperative sufentanil consumption on the first, second and third postoperative days, and postoperative flurbiprofen axetil consumption were significantly reduced in the LB group compared with the RO group (Table 2). The LB group also had earlier first flatus, mobilization, urinary catheter removal compared with the RO group (Table 2). The length of ICU stay was significantly shorter in the LB group than in the RO group (Table 2). The QoR-15 scores on the first, second and third postoperative days were significantly higher in the LB group than in the RO group (Table 2). Additionally, the LB group reported a significantly lower incidence of PONV and reduced hospitalization costs (Table 2). No statistically significant differences were observed between the two groups regarding the time to extubation, intraoperative remifentanil consumption and the length of hospital stay (Table 2).

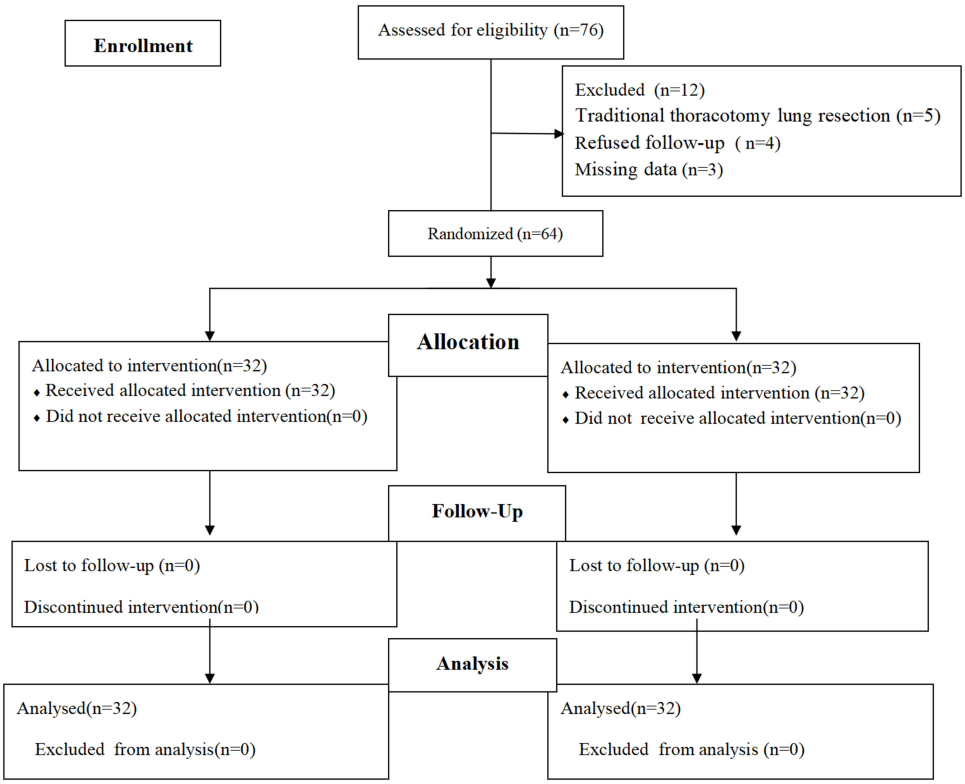

Figure 3 Patient flow diagram.

Discussion

Our results demonstrated that ultrasound-guided SAPB with liposomal bupivacaine provided effective analgesia in the first three days post-VATS. This technique reduced the postoperative consumption of sufentanil and flurbiprofen axetil, and shortened the time to first flatus, mobilization, and urinary catheter removal. It also decreased the incidence of PONV, shortened ICU stay, lowered hospitalization costs, and improved postoperative QoR-15 scores.

The SAPB has been widely used to provide effective analgesia in various surgical procedures, including breast surgery,[23] rib fractures,[24] thoracoscopic surgery,[25] and minimally invasive heart surgery.[26] In the realm of VATS, SAPB offers numerous advantages when compared to TEB and TPVB. Primarily, SAPB is safer than other analgesic modalities, which have the risk of hemodynamic instability, intrathecal injection, epidural hematoma, peripheral nerve injury, urine retention, pneumothorax, and spinal cord injury.[27] Moreover, the more superficial application of SAPB compared to TEB and TPVB, results in a higher success rate and a more precise block range.[5] Therefore, SAPB can provide enhanced safety and reproducibility in thoracoscopic surgery.

Table 1 Patient Demographics and Surgical Characteristics

	LB group(n=32)	RO group(n=32)	P-value
Age (yr)	51.7±8.3	51.6±8.2	0.952
Height(cm)	161.7±6.8	162.1±7.3	0.325
Weight (Kg)	62.3±8.2	60.7±8.4	0.552
Body Mass Index(BMI)(kg/m^2)	22.5±1.7	22.3±1.7	0.644
Sex ratio (M / F)	15/18	13/20	0.354
ASA classification (II/III)	22/11	19/14	0.429
Duration of surgery (min)	104.3±35.4	109.2±29.4	0.666
Intraoperative urine output (mL)	430±110	440±120	0.592
Intraoperative bleeding volume (mL)	90±50	100±40	0.679

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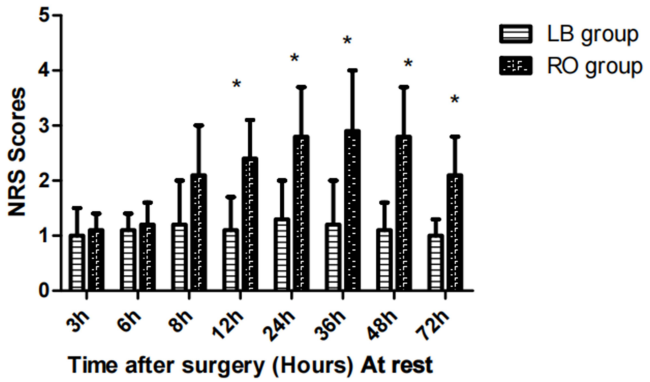

Figure 4 Pain intensity at rest after surgery which was measured using the Numerical Rating Scale (NRS) score. * P <0.05 considered statistically significant.
Abbreviation: LB, liposomal bupivacaine; RO, ropivacaine.

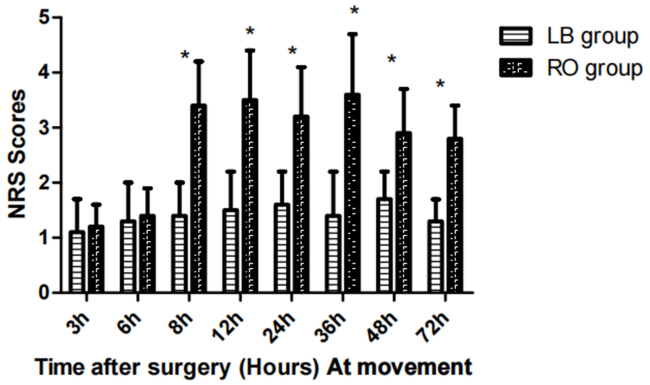

Figure 5 Pain intensity at movement after extubation which was measured using the Numerical Rating Scale (NRS) score. * P <0.05 considered statistically significant.
Abbreviation: LB, liposomal bupivacaine; RO, ropivacaine.

In this trial, the NRS scores for patients in the RO group were comparable to those in the LB group at rest at 8h and during coughing at 6h postoperatively. These results suggest that the anesthetic effect of ropivacaine does not exceed 8 hours, aligning with its known pharmacological profile.[28] Thoracoscopic surgery is commonly associated with severe

Table 2 Intra- and Postoperative Clinical Outcomes

	LB group(n=32)	RO group(n=32)	P-value
Intraoperative remifentanil consumption (mg)	1.12±0.48	1.05±0.34	0.17
Perioperative sufentanil consumption (μg)	85.22±24.75	139.53±23.27	<0.01
Sufentanil dosage on the first day after surgery (μg)	18.12±11.25	35.23±13.25	<0.01
Sufentanil dosage on the second day after surgery (μg)	24.37±13.34	45.47±11.56	<0.01
Sufentanil dosage on the third day after surgery (μg)	22.5±10.25	38.87±10.37	<0.01
Flurbiprofen axetil consumption(mg)	100±100	400±100	<0.01
QoR-15 score on the first day after surgery	118±12	107±7	<0.01
QoR-15 score on the second day after surgery	127±7	118±8	<0.01
QoR-15 score on the third day after surgery	130±6	122±8	<0.01
Time to extubation (h)	1.40±0.39	1.35±0.45	0.665
Time to mobilization (h)	27.4±13.1	37.8±11.7	<0.01
Length of stay in the ICU (h)	17.3±2.5	25.8±4.6	<0.01
Time until passage of flatus (h)	19.3±6.7	28.9±11.9	<0.01
Time until urinary catheter removal (h)	29±9	45±5	<0.05
Incidence of PONV (%)	5(15.6)	15(40.6)	<0.05
Length of hospital stay (days)	5±1.4	5±1.8	0.087
Hospital costs (RMB)	44,645±4735	48,373±8181	<0.05

and persistent postoperative pain at the VATS incision sites in the first 72 hours. The SAPB can provide analgesia to the entire hemithorax, with a cutaneous sensory block ranging from T2 to T9, which can cover the incisions of VATS.[16,29] However, the analgesic duration of a single-shot SAPB with ropivacaine is short. To overcome this limitation, ultrasound-guided continuous SAPB has been effectively used to prolong analgesia for patients undergoing VATS.[30,31] Nonetheless, continuous SAPB with a catheter has disadvantages of possible bleeding, cumbersome insertion, catheter displacement or detachment, infection, and difficulties in management and maintenance.[20] Therefore, it is critical to investigate easier methods to prolong the effective analgesic duration of SAPB.

Liposomal bupivacaine has been shown to be an effective postoperative analgesic as a stand-alone agent in numerous clinical studies.[32–34] Utilizing multivesicular liposome technology, it provides sustained release of bupivacaine hydrochloride for 72 to 96 hours.[35] In this trial, patients in the LB group had lower NRS scores at rest and on movement between 8 hours and 72 hours after surgery, as compared to those in the RO group. Our results indicate that ultrasound-guided SAPB with a single-shot liposomal bupivacaine can provide effective analgesia for three days after surgery without any observed side effects in patients undergoing VATS. To the best of our knowledge, this is the first randomized, controlled, double-blind trial comparing the effects of liposomal bupivacaine and ropivacaine in SAPB for managing pain after thoracoscopic surgery. Alexander and others[36] found that patients undergoing open total abdominal hysterectomy who received liposomal bupivacaine transversus abdominis plane (TAP) blocks required fewer postoperative opioids to achieve similar pain scores when compared to patients who received ropivacaine TAP blocks.Other studies[37] have reported that ultrasound-guided interfascial plane block with liposomal bupivacaine was not shown to provide effective analgesia for three days. Such difference may be attributed to the concentration and volume of liposomal bupivacaine, the type of nerve block approach and anesthesiologists' experience in interfascial plane block.[38] Therefore, our results indicate that ultrasound-guided SAPB with liposomal bupivacaine represents a novel, effective, safe, and promising technique for patients undergoing thoracoscopic surgery.

In this trial, we used patient-controlled intravenous analgesia with sufentanil, and observed that the RO group required more postoperative sufentanil consumption compared with the LB group. High-dose sufentanil could increase the incidence of PONV, pruritus, respiratory depression, and ileus, and prolong ICU stay.[39] Postoperatively, the LB group had a shorter time to first flatus and a lower incidence of PONV, potentially associated with less sufentanil consumption. Moreover, possibly due to the effective analgesic effect in the first three days after surgery, patients in the LB group had earlier mobilization and urinary catheter removal. These improvements resulted in higher QoR-15 scores in the first three days after surgery in the LB group.

Our study has the following limitations. Firstly, the volume and concentration of liposomal bupivacaine for SAPB in patients undergoing VATS were determined based on our clinical experience. Future studies are warranted to determine the optimal volume and concentration of liposomal bupivacaine for SAPB. Secondly, patients undergoing thoracic surgery are at increased risk for chronic post-surgical pain syndrome,[40] which may be reduced by effective pain management in the first three postoperative days.[41] However, our study did not extend patient follow-up to one year postoperatively to assess this potential benefit. Thirdly, as this study was conducted in a single center with specific sample population of VATS oncology patients, it is necessary to increase the sample size and other thoracic surgery in further studies to generalize our findings.

In conclusion, our study demonstrated that ultrasound-guided SAPB with liposomal bupivacaine was effective in relieving postoperative pain for three days in patients undergoing VATS. This technique reduced postoperative consumption of sufentanil and flurbiprofen axetil, shortened the length of ICU stay, shortened the time to first flatus, mobilization, and urinary catheter removal, and reduced the incidence of PONV. It also reduced hospitalization costs and improved postoperative QoR-15 scores.

Data Sharing Statement

For reasonable data requests, contact the corresponding author (Xiuhong Wang) by Email (wangxh19871227@163.com).

Ethics Approval and Consent to Participate

This study was approved by the First Affiliated Hospital of Nanchang University registered in the Chinese Clinical Trial Registry. Written informed consent was obtained from each patient.

Acknowledgments

This study received funding from department of science and technology of Jiangxi Province 20212BAG70034.Ethical approval was obtained from the First Affiliated Hospital of Nanchang University and was registered in the Chinese Clinical Trial Registry (ChiCTR2300076281).The trial was conducted in accordance with the Declaration of Helsinki.

Author Contributions

Yang Zhang, Wei Li and Aiping Wei were responsible for conceived, designed this study and collected the data. Shibiao Chen and Xiuhong Wang were responsible for study execution and manuscript writing. All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Funding

No funding or sponsorship was received for this study or publication of this article. The Rapid Service Fee was funded by the authors. The project was funded by the Jiangxi Provincial Health Commission (202410180), Jiangxi Provincial Administration of Traditional Chinese Medicine (2022B084), National Natural Science Foundation of China, Grant/Award Number: 82360385, and the Red Cross Society of China (CRCF-YXFN-202302065).

Disclosure

The authors report no conflicts of interest in this work.

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