Optimal strategies of paravertebral nerve block combined with general anesthesia for postoperative analgesia in patients undergoing lobectomy: a comparison of the effects of different approaches for serratus anterior plane block

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#Methods

This randomized controlled trial was designed according to the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement. We obtained ethical approval from the Institutional Review Boards of Tianjin Chest Hospital to conduct the trial. Written informed consent was obtained from each patient and their guardian. The trial was registered at chictr.org (ChiCTR2000041350). This study was a prospective, double-blind, randomized controlled study. A total of 120 patients, regardless of gender, with an American Society of Anesthesiologists (ASA) physical status classification of grade I–III, age 18–65 years old, and body mass index (BMI) 20–25, who planned to undergo thoracoscopic lobectomy in Tianjin Chest Hospital from December 2020 to June 2021, were selected. The exclusion criteria were as follows: allergy to local anesthetic drugs, severe abnormal coagulation function, systemic or puncture site infection, nerve injury, a history of long-term alcohol consumption, long-term use of psychotropic drugs and opioids, preoperative adjuvant chemotherapy or radiotherapy, not cooperative, involved in other clinical trials, and refusal to participate. Using the random number table method, the patients were divided into the patient-controlled intravenous analgesia group (PCIA group), the single serratus anterior plane block group (SPB group), and the continuous serratus anterior plane block group (CSPB group), with 40 cases in each group. Routine preoperative preparation including electrocardiogram (ECG), heart rate (HR), oxygen

saturation (SpO_2), and bispectral index (BIS) were monitored after entering the room, oxygen was inhaled by mask, and peripheral arterial and venous access was established. For the induction of anesthesia, midazolam 0.5–1.0 mg/kg, sufentanil 0.5–1.0 μg/kg, etomidate 0.2–0.3 mg/kg, and cisatracurium 0.3 mg/kg were used. After adequate oxygenation and denitrification, double-lumen bronchial intubation was performed. Fiberoptic bronchoscopy was used to determine the location of the tracheal tube, which was then fixed, and the anesthesia machine was connected. The tidal volume was 6–8 mL/kg, frequency was 12–14 bpm, positive end-expiratory pressure (PEEP) was 4 mmHg, and oxygen concentration was 60–80%. After intubation, the patient was changed to the lateral decubitus position on the operative side, and the T4 and T7 TPVB on the affected side was guided by ultrasound. The 22 G puncture needle was inserted into the plane, and the corresponding paravertebral space was reached under direct ultrasound. A 10 mL dose of 0.4% ropivacaine was given at each point. For anesthesia maintenance, an intravenous target-controlled infusion (TCI) of propofol was used, the plasma target concentration was 1–2 μg/mL, and cisatracurium 5–10 mg was administered intermittently. Intraoperative blood pressure was maintained at 20% above or below the baseline, with a BIS of 40–60 and $PETCO_2$ 35–45 mmHg.

Before awakening after surgery, the patients were maintained in the position during surgery. After aseptic preparation of the skin with iodophor,the SPB group patients the ultra-sound probe was placed over the midclavicular region of the thoracic cage in the sagittal plane, and then the subcutaneous tissue, latissimus dorsi, serratus anterior, intercostal muscle, and pleura superficial to the fourth and fifth ribs in the midaxillary line were identified. The superficial SAPB was targeted to the interfascial plane between the serratus anterior muscle and the latissimus dorsi muscle. Once again, there was no blood and no gas, and the remaining 0.375% ropivacaine was injected slowly, with 15 mL in total. In the CSPB group, the serratus anterior muscle was punctured by the same method, and 15 mL 0.375% ropivacaine was injected into the serratus anterior muscle, and then the epidural catheter was inserted. The depth of the catheter was 5 cm, and the position of the catheter was determined again by ultrasound after the skin was properly fixed. Patients in the 3 groups recovered after surgery, and the endotracheal tube was removed after reaching the indication of extubation. The analgesia pump was connected before returning to the postoperative care unit of thoracic surgery. Patients in the PCIA group and SPB group

were connected to an intravenous controlled analgesia pump, and the formula was: sufentanil 2–3 μg/kg + butoranol 12 mg + 0.9% sodium chloride injection to 150 mL, background dose was 2 mL/h, patient-controlled analgesia (PCA) dose was 2 mL, and the locking time was 15 min. The CSPB group was connected to a continuous serratus anterior block automatic analgesia pump, and the formula was: 0.5% ropivacaine normal saline 300 mL, background infusion dose 6 mL/h, PCA dose 6 mL, and locking time 45 min. The duration of self-controlled analgesia in the 3 groups was 48 h after surgery. For example, when Visual Analogue Scale (VAS) score >4, the self-controlled analgesia pump could be pressed once. If the analgesia was ineffective, an intramuscular morphine injection of 10 mg was administered for analgesia.

The general condition of the patients (gender, age, IBM), the duration of the operation, and the amount of intraoperative blood loss were recorded. VAS scores were obtained immediately after extubation (T2), 6 h (T3), 12 h (T4), 24 h (T5), and 48 h (T6) after the operation. The first postoperative analgesia time, the number of effective presses of the electronic analgesia pump 48h after the operation, the total amount of opioids used in the electronic analgesia pump, and the number of times of postoperative analgesia relief were also recorded. Before surgery (T1), 12 h (T4), 24 h (T5) after surgery (PaO_2), lactic acid (LAC), blood glucose (GLU). Postoperative adverse reactions, such as nausea, vomiting, and dizziness, were recorded. One day before surgery (T0) and 48 h after surgery (T6), patients' quality of recovery (QoR-40) scores were also recorded, along with the time of the first postoperative activity and the total length of hospitalization (days). The incidence of chronic pain was assessed and recorded by telephone follow-up 2 months after surgery.

The sample size was calculated based on our pilot study, in which the mean VAS at 24 h after surgery was 4.8 in the PCIA group, with an approximate standard deviation of 1.1. A 1.5-point decrease in the VAS score was considered clinically significant. For a study power of 80% and an α value of 0.05, the required sample size per group was calculated to be 34. Given an estimated dropout rate of 15%, we recruited 40 patients (after applying the preoperative exclusion criteria) for each group.

SPSS19.0 software was used for statistical analysis. Measurement data conforming to a normal distribution were expressed as mean ± standard deviation ($\bar{x}\pm s$), while measurement data with a skewed distribution were expressed as median

and interquartile range (IQR). One-way ANOVA was used for comparisons between groups, and the *t*-test was used for pair comparisons. Enumeration data were expressed as percentages, and the chi-square test was used. $P<0.05$ was considered statistically significant.

This study was a double-blind trial, and patients and postoperative follow-up personnel were unaware of the patient groups. If severe adverse events were observed in participants during the study, physicians were expected to execute an emergency break and perform relevant treatments based on the situation.

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