

Clinical study protocol

Program name: Ultrasound-guided serratus anterior plane block combined with erector spinae plane block versus thoracic paravertebral block for postoperative analgesic effect and recovery after thoracoscopic surgery

NCT number: 1000012129

Date of applicant: August 29, 2022

1. Research Background and Significance:

Thoracoscopic surgery is becoming increasingly popular because it has several advantages compared with thoracotomy of small incision, fast postoperative recovery, fewer perioperative complications, short hospital stay, and improved postoperative quality of life.^[1] However, patients are still faced with moderate to severe pain after thoracoscopic surgery. How to control pain effectively and promote postoperative recovery is still a challenging problem.^[2-3]

Opioids usage, epidural analgesia, thoracic paravertebral block, intercostal nerve block, erector spinal plane nerve block, and serratus anterior plane block are commonly used to control pain after thoracoscopic surgery. Although the use of opioid analgesics can effectively control pain, with the increase of the dose of opioids, the adverse effects will become more pronounced, such as respiratory depression, which is not conducive to the postoperative recovery. Regional anesthesia techniques are more effective in relieving pain than opioids alone and can reduce opioid dosage, thus helping to reduce opioid-related adverse effects.^[4] Epidural analgesia was once considered as the gold standard for post-thoracotomy pain control,^[5] but it is not widely used for pain management after thoracoscopic surgery because it is related to high potential risks of nerve lesions, rupture of spinal dura mater, epidural hematoma, hypotension and difficult to operate for the inexperienced.

Thoracic paravertebral block is effective in controlling pain after thoracoscopic surgery, but it also carries risks such as difficulty of operation and perforation of the pleura. Intercostal nerve block has a certain effect on postoperative pain control after thoracotomy,^[6-7] and has the advantages of safe and simple operation, but its analgesia time is short and it is difficult to relieve visceral pain. In recent years, erector spinae plane block and serratus anterior plane block have been applied to postoperative thoracoscopic analgesia.^[7-8] They are easy to operate and far away from the spinal cord and pleura and other important tissues, but they are still lacking in analgesic effect compared with thoracic paravertebral block. Single erector spinae plane block or serratus anterior plane block is difficult to replace thoracic paravertebral block in postoperative analgesia. Therefore, it is of great significance to find a simple and sufficient analgesic nerve block to replace the thoracic paravertebral block with many risks.

ESPB is a new technique used to provide thoracic anesthesia, and in clinical trials of non-inferiority tests, erector spinae plane block is non-inferior to thoracic paravertebral block in terms of analgesia,^[9] and also has a potential visceral analgesic effect.^[10] SAPB was first used in breast surgery and is now commonly used in cardiothoracic surgery.^[11] SAPB, as part of a multimodal analgesia, is a non-inferior regional anesthesia technique compared to PVB in terms of analgesic efficacy, especially in reducing opioid use.^[12] Postoperative analgesia can be achieved by erector spinae plane block in a variety of ways. Local anesthetics can enter the paravertebral space, diffuse along the fascial plane below the erector spinae muscle, diffuse backward to the erector spinae muscle, and also diffuse laterally.^[13] However, compared with thoracic paravertebral block, the diffusion of local anesthetics in the paravertebral space is limited. Serratus anterior plane block could

block the lateral cutaneous branches of intercostal nerves, the long thoracic nerve and the thoracodorsal nerve, and the dermatome of sensory block could be up to T2-9.

Therefore, from the existing clinical researchs and the principle of nerve block, it is reasonable to replace thoracic paravertebral block with serratus anterior plane block combined with erector spinae plane block for postoperative thoracoscopic analgesia.

There is no research on the analgesic effect of erector spinae plane combined with serratus anterior plane block after thoracoscopic surgery. The purpose of this study is to explore whether the serratus anterior plane block combined with erector spinae plane block can replace thoracic paravertebral block to provide better analgesic effect after thoracoscopic surgery, so this study has very important clinical significance.

2. Research purpose:

To investigate whether serratus anterior combined with spinal erector plane block can provide adequate analgesia after thoracoscopic surgery.

3 Research Design

3.1 Research Type

Single-center, prospective, randomized, double-blind, controlled study.

3.2 Sample size estimation

According to an preliminary experiment (7 patients in the serratus anterior plane block combined with erector spinae plane block group and 7 patients in the thoracic paravertebral block group), the results showed that the 24h postoperative morphine consumption was 23.7 ± 4.8 mg in the SAPB & ESPB group and 28.7 ± 4.2 mg in the PVB group. A difference of 2.5 mg in the 24h postoperative morphine consumption was chosen as the minimum expected difference between the two groups. 1:1 enrollment would require 41 patients in each group to achieve a significance level of 0.05 for a one-sided test and performance test of 80%. A total sample size of 92 subjects was required if the dropout rate was set at 10%.

3.3 Randomization and double- blinded study

Patients were allocated randomly to SAPB & ESPB group and PVB group according to computer-generated random number table. All patients and an investigator who was responsible for follow-up during 48 postoperative hours were blinded to the randomization groups. The investigator instructed the patients to use a patient-controlled intravenous analgesia (PCA) device for postoperative pain management, the visual analog scale to assess pain at rest and during coughing, and the correct use of a pulmonary function meter.

Serratus anterior plane block combined with erector spinae plane block were performed in the experimental group after anesthesia, while thoracic paravertebral nerve block was performed in the control group .

4 Subject selection and withdrawal

4.1 Inclusion criteria:

1. American Society of Anesthesiologists (ASA) physical status I-II
2. Age from 18–75 years
3. BMI 19–28 kg/m²;
4. Selective thoracoscopic partial pneumonectomy under general anesthesia;
5. Informed consent has been signed.

4.2 Exclusion criteria:

1. Daily use of opioid analgesics or history of opioid abuse
2. Reoperation in ipsilateral thorax
3. Allergic to any of the drugs used in the study, or have a history of drug allergy
4. Have mental or nervous system diseases, motor or sensory defects;
5. Coagulation dysfunction
6. Have cognitive dysfunction, unable to cooperate with the research;
7. Severe renal, liver or heart dysfunction
8. Chest wall and spine trauma, infection, deformity and other conditions where nerve block cannot be carried out
9. Participated in other clinical trials within 3 months prior to study inclusion
10. Other reasons considered unsuitable for clinical trials by the investigator
11. Refusal to participate.

4.3 Exit criteria:

1. Conversion to thoracotomy unrelated to anesthesia;
2. The operation lasted more than 4 hours;
3. The consciousness in PACU was completely awake, and there was no effect in plane block;
4. Serious adverse events, complications or special physiological changes are not suitable for further study;
5. The patient or his/her guardian requests to withdraw;
6. Other researchers cited reasons to stop the study

5 Research process

The anesthesiologist went to the ward one day before the operation to evaluate the anesthesia of the patients who were going to undergo thoracoscopic pulmonary resection, signed the informed consent form, and selected the subjects according to the inclusion criteria and exclusion criteria. They were randomly divided into SAPB & ESPB group(test group) and PVB group(control group). Patients were also taught how to use the spirometer, patient-controlled intravenous analgesia(PCA), and visual analogue scale (VAS). (VAS: a 100 mm horizontal line, with 0 mm at one end of the line, indicating no pain. The other end is 100mm, indicating severe pain. The middle portion indicates varying degrees of pain.)

- 1) All patients were forbidden to drink and eat before operation without preoperative medication
- 2) After the patients entered the operating room, the investigator measured the

VAS score of the patient at rest and coughing in the sitting position. FVC (L), FEV₁ (L) and FEF 25% -75% (L/sec) were measured by spirometer for three times. Patients were assessed preoperatively using the QoR-15 Patient Questionnaire (see attached page).

- 3) Blood pressure, pulse, oxygen saturation and ECG were monitored. Anesthesia induction was performed after mask oxygenation: parecoxib sodium 40 mg, penehyclidine hydrochloride 0.5 mg, tropisetron 2 mg and sufentanil 0.5 μ g \cdot kg $^{-1}$, propofol 1.5–2.0 mg \cdot kg $^{-1}$ and rocuronium 0.8 mg \cdot kg $^{-1}$.
- 4) Performing tracheal intubation, ultrasound-guided radial artery cannulation to monitor ambulatory blood pressure and internal jugular central venous catheterization to establish a central venous channel.
- 5) Ultrasound-guided serratus anterior plane block combined with erector spinae plane block was performed in the experimental group. The erector spinae plane block was performed at T5 and T7 segments, with 10 ml 0.4% ropivacaine in each segment and 20 ml 0.4% ropivacaine in serratus anterior plane block. The control group received ultrasound-guided thoracic paravertebral block at T5 and T7 with 20 ml of 0.4% ropivacaine in each segment.
- 6) Anesthesia maintenance: 1-2% sevoflurane, dexmedetomidine 0.5 μ g \cdot kg $^{-1}$ \cdot h $^{-1}$ and remifentanil 0.1-0.2 μ g \cdot kg $^{-1}$ \cdot min $^{-1}$. Maintain the stability of intraoperative vital signs. Volume control ventilation mode: tidal volume was 6-8ml/kg, airway pressure was maintained within 25cmH₂O, end-expiratory CO₂ was maintained within 35-45mmHg, and lungs were dilated once every 1 hour. ECG, HR, BP, SpO₂, PetCO₂, body temperature, liquid intake and output were monitored. During the operation, vasoactive drugs were used as needed to maintain blood pressure, heart rate was maintained within \pm 20% of the preoperative basic level. Correct acid-base imbalance and electrolyte disturbance according to arterial blood gas analysis.
- 7) analgesic connection: intravenous injection of 5mg oxycodone 30 minutes before the end of surgery.
- 8) At the end of the operation, the endotracheal tube was removed when the patient was awake. Measure the level of nerve block when the patient is conscious. If there was no nerve block plane, the patient was withdrawn from the trial. The patient-controlled intravenous analgesia, which equipped with 0.5mg/ml oxycodone, 1ml/h background infusion, 3ml additional infusion and locked for 5min, was used immediately after extubation.
- 9) The patients were observed in the PACU for one hour, and the PCA could be applied for additional analgesia according to the needs of the patients. The patient was given rescue analgesia, a single intravenous dose of 2 mg of oxycodone, if the pain was not relieved or the patient requested it. Patients took a sitting position and measured the VAS scores of the patients at rest and coughing at 1h postoperatively. FVC (L), FEV₁ (L) and FEF 25% -75% (L/sec) were measured by spirometer for three times., and three indexes of FVC (L), FEV₁ (L) and FEF 25% -75% (L/sec) were recorded by spirometer for three times. Ask the patient if there are any adverse reactions, such as nausea, vomiting, itching, dizziness, headache, shoulder pain, respiratory depression, etc.

10) After returning to the ward, the patient can press the PCA for additional analgesia according to the needs. The patient was given rescue analgesia, a single use of diclofenac sodium suppository, if the pain was not relieved or the patient requested it. Investigators conducted postoperative visits at 2h, 4h, 8h and 24h postoperatively, the dosage of PCA, the times of rescue analgesia, VAS scores at rest and cough and adverse reactions were recorded. FVC (L), FEV1 (L) and FEF 25% -75% (L/sec) were recorded for three times by spirometer in the sitting position at 4h and 24h postoperatively. Patients were assessed postoperatively using the QoR-15 Patient Questionnaire at 24h postoperatively.

6. Outcome measurements

6.1 The primary outcome :

Cumulative morphine consumption at 24h postoperatively

6.2 The secondary outcomes:

- (1) The cumulative morphine consumption at 1h, 2h, 4h and 8h postoperatively.
- (2) The times of remedial analgesia at 1h, 2h, 4h, 8h and 24h postoperatively.
- (3) VAS score at rest and cough at 1h, 2h, 4h, 8h and 24h postoperatively.
- (4) The changes of FVC (L), FEV₁ (L) and FEF 25% - 75% (L / sec) were observed before operation, 1h, 4h and 24h after postoperatively.
- (5) Changes of QoR-15 questionnaire scores before and 24h postoperatively.
- (6) Postoperative complications and rehabilitation time nodes (including drainage tube removal time, discharge time, etc.).

7 Security

7.1 Adverse Events

The investigator shall truthfully fill in the Adverse Event Record Form, record the occurrence time, severity, duration, measures taken and outcome of the adverse event, and explain the criteria for judging the severity of the adverse event and the five-level classification criteria for judging the relationship between the adverse event and the test drug (definitely related, possibly related, possibly unrelated, unrelated and unable to determine). All adverse events should be followed up until they are resolved or stable.

Preventive measures for adverse events:

- ① Ultrasound-guided nerve block can visualize the puncture needle tip, effectively and greatly reduce the risk of local anesthetic poisoning and the damage caused by the puncture.
- ② Poisoning of local anesthetics: strict control of drug dosage and close intraoperative monitoring. Once it occurs, it should be treated immediately according to the treatment process of local anesthetic poisoning, such as ECG monitoring, respiratory tract management, volume control, the use of sedative anticonvulsant and corresponding vasoactive drugs.
- ③ Puncture injury: Ultrasound visualization and careful operation to ensure that tissue damage is minimized. Once it occurs, surgical intervention can be carried out

according to the severity.

Physicians will do their best to prevent and treat injuries that may result from this study. If an adverse event occurs in a clinical trial, a committee of medical experts will determine whether it is related to the intervention. The sponsor will provide the cost of treatment and corresponding economic compensation for the damage related to the test in accordance with the provisions of Good Clinical Practice (GCP) .

7.2 Serious Adverse Events

Serious adverse events were defined as adverse events that resulted in one of the following outcomes: death, prolonged hospitalization, disability, fatal reaction, or teratogenicity. Any serious adverse event occurring during the clinical trial must be reported to the principal investigator of the Department of Anesthesiology of Tongji Hospital and the Ethics Committee of the Drug Clinical Research Base of Tongji Hospital within 24 hours.

7.3 Safety monitoring

The data security management committee is composed of anesthesiologists. An interim analysis was conducted by the committee when half of the patients were enrolled. The study was discontinued if the interim analysis revealed a significant increase in mortality rate in the test group, or if there were significantly more complications.

8 Matters of Medical Ethics

8.1 Responsibilities of the investigator

The investigator is responsible for the trial and ensures that the study is conducted in accordance with the study protocol and ethical guidelines at home and abroad. Before the trial, the clinical study protocol and written informed consent were submitted to the Independent Ethics Committee of Drug Clinical Trial of Tongji Hospital of Huazhong University of Science and Technology for review, and the trial could be started only after approval.

8.2 Subject Information and Informed Consent

The investigator shall obtain the written informed consent of the subject before the subject participates in the study. The investigator shall explain the nature, purpose and risks of the clinical trial to the subject, and make sure that the subject has the right to withdraw at any time after agreeing to participate in the trial. After full consideration, the subject voluntarily participated in the clinical trial, and both the subject and the investigator signed and dated the Informed Consent Form.

9. Dropout cases

9.1 Definition of dropout cases

All patients who have filled in the informed consent form and qualified to enter the trial have the right to withdraw from the clinical trial at any time, no matter when and for any reason, as long as the subjects fail to complete the observation cycle

specified in the protocol, they are called dropout cases

9.2 Treatment of dropout cases

Patients drop-out due to adverse reactions which were judged to be relevant for trial intervention after follow-up must be recorded and notified to the sponsor. The dropout due to violation of the test protocol shall be recorded and explained.

9.3 Reasons for dropout

For any dropout case, the investigator must record the reasons for the dropout. In general, there are five reasons, namely, adverse events, violation of the trial protocol, loss to follow-up (including self-withdrawal of the subject), discontinuation of the sponsor and others.

10. Statistical analysis

Measurement data were analyzed and compared by t-test or Mann-Whitney U test, depending on whether the data were distributed normally or not. Repeated measures data (e.g., morphine consumption, VAS scores, pulmonary function measures) were analyzed using one-way analysis of variance(ANOVA). Enumeration data were compared by χ^2 or Fisher's exact test. $p < 0.05$ was considered significant.

11. Summary of lab report

Unblinding is performed when the statistical analysis is completed and the statistical analysis report is written by the statistical analyst. The statistical analysis report after Unblinding shall be delivered to the main researchers of the experiment to write the research report.

12 Data preservation

The research data related to this clinical trial were kept by the Department of Anesthesiology of Tongji Hospital.

References:

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3. Elmore, B., et al., *Pain Management Following Thoracic Surgery*. Thorac Surg Clin, 2015. 25(4): p. 393-409.
4. Kumar, K., et al., *A Review of Opioid-Sparing Modalities in Perioperative Pain Management: Methods to Decrease Opioid Use Postoperatively*. Anesth Analg, 2017. 125(5): p. 1749-1760.

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6. Zhu, M., et al., *Ultrasound-Guided Intercostal Nerve Block Following Esophagectomy for Acute Postoperative Pain Relief in the Postanesthesia Care Unit*. Pain Pract, 2018. 18(7): p. 879-883.
7. Chen, N., et al., *The effect of ultrasound-guided intercostal nerve block, single-injection erector spinae plane block and multiple-injection paravertebral block on postoperative analgesia in thoracoscopic surgery: A randomized, double-blinded, clinical trial*. J Clin Anesth, 2020. 59: p. 106-111.
8. De Cassai, A., et al., *Serratus anterior plane block for video-assisted thoracoscopic surgery: A meta-analysis of randomised controlled trials*. Eur J Anaesthesiol, 2021. 38(2): p. 106-114.
9. Taketa, Y., Y. Irisawa, and T. Fujitani, *Comparison of ultrasound-guided erector spinae plane block and thoracic paravertebral block for postoperative analgesia after video-assisted thoracic surgery: a randomized controlled non-inferiority clinical trial*. Reg Anesth Pain Med, 2019.
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12. Hanley, C., et al., *Ultrasound-guided continuous deep serratus anterior plane block versus continuous thoracic paravertebral block for perioperative analgesia in videoscopic-assisted thoracic surgery*. Eur J Pain, 2020. 24(4): p. 828-838.
13. Chin, K.J. and K. El-Boghdadly, *Mechanisms of action of the erector spinae plane (ESP) block: a narrative review*. Can J Anaesth, 2021. 68(3): p. 387-408.

Informed Consent Form · Notification Page

Dear Patient:

The doctor has confirmed that you need a thoracoscopic partial pneumonectomy under general anesthesia. You will be invited to participate in a study

Ultrasound-guided serratus anterior plane block combined with erector spinae plane block versus thoracic paravertebral block for postoperative analgesic effect and recovery after thoracoscopic surgery. The study protocol has been reviewed by the Medical Ethics Committee of Tongji Medical College of Huazhong University of Science and Technology, and the clinical study has been approved.

Please read the following as carefully as possible before you decide whether or not to participate in this study. It will help you understand the study, the reasons for doing it, the procedures and duration of the study, and the benefits, risks, and discomforts that may occur to you if you participate in the study. If you like, you can also discuss it with your relatives and friends, or ask your doctor for an explanation to help you make a decision.

1. Research background and purpose

1.1 Burden of disease and treatment status

Thoracoscopic surgery has the advantages of small incision, quick postoperative recovery, fewer perioperative complications, shorter hospital stay, and improved postoperative quality of life. However, patients are still faced with moderate to severe pain after thoracoscopic surgery. Opioid analgesics and nerve blocks are often used to control pain after thoracoscopic surgery. Opioids have significant adverse effects and are not conducive to post-operative recovery. Therefore, opioids combined with nerve blocks for multimodal analgesia can reduce the use of opioids.

Nerve block is a common form of regional anesthesia, which is often used as an auxiliary anesthesia method for small-scale surgery or general anesthesia.

Ultrasound-guided nerve block, which can visualize the target area, can be more accurate and safer. The investigators wanted to explore whether a serratus anterior plane block combined with erector spinae plane block could provide adequate analgesia after thoracoscopic surgery.

1.2 Research objective:

To investigate whether serratus anterior combined with spinal erector plane block can provide adequate analgesia after thoracoscopic surgery.

1.3 Research Participating Units and expected number of participant cases

The study will be conducted at Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology, and 92 subjects are expected to volunteer to participate.

2. Who should not participate in the study?

1) Daily use of opioid analgesics or history of opioid abuse

- 2) reoperation in ipsilateral thorax
- 3) Allergic to any of the drugs used in the study, or have a history of drug allergy
- 4) have mental or nervous system diseases, motor or sensory defects;
- 5) Coagulation dysfunction
- 6) Have cognitive dysfunction, unable to cooperate with the research;
- 7) Severe renal,liver or heart dysfunction
- 8) chest wall and spine trauma, infection, deformity and other conditions where nerve block cannot be carried out
- 9) participated in other clinical trials within 3 months prior to study inclusion
- 10) Other reasons considered unsuitable for clinical trials by the investigator

3. What will you need to do if you participate in the study?

- 3.1 Before you are enrolled in the study, your doctor will ask about and take your medical history and perform relevant tests.
- 3.2 If you volunteer to participate in the study, the following steps will be followed.
 - 1) All patients were forbidden to drink and eat before operation
 - 2) After entering the operating room, the VAS score was measured, the pulmonary function was recorded by spirometer for three times, and the QoR-15 patient questionnaire was filled in.
 - 3) Routine monitoring of electrocardiogram, blood pressure, pulse oxygen saturation.
 - 4) Routine induction of general anesthesia with tracheal intubation and controlled breathing.
 - 5) You will likely be assigned by means of a random number table to either a test group with serratus anterior plane block combined with erector spinae plane block or a control group with thoracic paravertebral block.
 - 6) General anesthesia was maintained until the end of the operation, and the patient was extubated after recovery and sent to PACU.
 - 7) After the procedure, you will be followed up by the investigator to learn about the use of the PCA, measure your VAS score, pulmonary function, and complete the QoR-15 patient questionnaire.

4. Possible benefits of participating in the study

You may already know about your condition and will have routine general anesthesia even if you do not participate in the clinical trial. According to the defined protocol, when you are eligible to participate in this trial, your treatment data will be recorded in a more scientifically credible manner. Do serratus anterior plane blocks combined with erector spinae plane blocks differ from thoracic paravertebral block in reducing postoperative analgesic use? The exploration of this issue requires your participation and that of other subjects. The clinical results obtained in this study may contribute significantly to the treatment of patients with baobao yao the same disease in the future.

During your treatment, you will receive proper care and treatment from doctors. We have perfect medical facilities to help and serve you at any time. In the event of adverse reactions related to the trial, prompt and necessary treatment is provided free

of charge.

5. Participate in the study of possible adverse reactions and risks

Definition and reporting system of serious adverse events: Nerve block has the risk of local anesthetic poisoning and puncture injury. The correlation between the nature and severity of any adverse event occurring in the course of the experiment and the clinical treatment study must be determined and strictly recorded in the case report form. In case of serious adverse reactions, they should be handled immediately according to the management process of our hospital and reported to the research group within 24 hours.

Preventive measures for adverse events:

① Ultrasound-guided nerve block can visualize the puncture needle tip, effectively and greatly reduce the risk of local anesthetic poisoning and the damage caused by the puncture.

② Poisoning of local anesthetics: strict control of drug dosage and close intraoperative monitoring. Once it occurs, it should be treated immediately according to the treatment process of local anesthetic poisoning, such as ECG monitoring, respiratory tract management, volume control, the use of sedative anticonvulsant and corresponding vasoactive drugs.

③ Puncture injury: Ultrasound visualization and careful operation to ensure that tissue damage is minimized. Once it occurs, surgical intervention can be carried out according to the severity.

The doctor will closely observe the changes in your condition to ensure your health, and will tell you the truth about any changes and adverse reactions during the study.

If you are injured as a result of your participation in this study, or if there is anything unexpected, whether or not it is related to the intervention, your doctor will make a judgment and medical treatment.

Physicians will do their best to prevent and treat injuries that may result from this study. If an adverse event occurs in a clinical trial, a committee of medical experts will determine whether it is related to the intervention. The sponsor will provide the cost of treatment and corresponding economic compensation for the damage related to the test in accordance with the provisions of Good Clinical Practice (GCP)

6. Related costs

6.1 During the study period of this project, you will receive the following free medical treatments:

- ① Ultrasound examination of superficial tissues 2 times.
- ② Ultrasound-guided serratus anterior plane block combined with erector spinae plane block.
- ③ Preoperative and postoperative pulmonary function monitoring.
- ④ Postoperative pain-related assessment (visual analogue pain scale).
- ⑤

6.2 The rest of the anesthesia operation, monitoring and drug costs involved were

borne by the subjects themselves.

7. Confidentiality of personal information

Your medical records will be kept intact at the hospital where you are visiting. Your doctor will record the results of your laboratory and other tests in your medical record. The investigator, the ethics committee, and the drug administration will be allowed to access your medical records. Any public report on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data to the extent permitted by law.

8. How to get more information?

You can ask any question about this study at any time and get an answer. Your doctor will let you know if there is any important new information in the course of the study that may affect your willingness to continue with the study.

9. Voluntary participation in and withdrawal from the study

Participation in the study is entirely up to you. You may refuse to participate in this study, or withdraw from the study at any time during the course of the study, without affecting your medical or other interests and relationship with the doctor.

Your physician or investigator may suspend your participation in this study at any time during the course of the study for your best interest.

10. What to do now? It is up to you (and your family) to decide whether to participate in this study.

Ask your doctor as many questions as possible before you make the decision to participate in the study.

Thank you for reading the above material. If you decide to participate in this study, tell your doctor and he/she will arrange everything for you about the study. Please keep this information.

Informed Consent Form · Signature Page

Clinical Research Project Title: Ultrasound-guided serratus anterior plane block combined with erector spinae plane block versus thoracic paravertebral block for postoperative analgesic effect and recovery after thoracoscopic surgery

Subject undertaking unit: Department of Anesthesiology, Tongji Hospital, Tongji Medical College, Huazhong University of Science and Technology

Declaration of Consent:

I have read the above description of this study and have had the opportunity to discuss and ask questions about this study with my doctor. All of the questions I asked were answered to my satisfaction.

I am aware of the risks and benefits of participating in this study. I understand that participation in the study is voluntary, and I confirm that I have had sufficient time to consider it and understand that:

- I can always ask my doctor for more information.
- I can withdraw from the study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I am equally aware that if I were to withdraw from the study, especially due to medication, it would be very beneficial to the whole study if I were to inform my doctor of any changes in my condition and complete the appropriate physical and physico-chemical examinations.

If I need to take any other medication because of a change in my condition, I will ask my doctor for advice in advance or tell my doctor truthfully afterwards.

I agree that the representative of the ethics committee of the drug supervision and administration department should consult my research data.

I will be provided with a signed and dated copy of the informed consent form.

In the end, I decided to agree to participate in the study and promised to follow the doctor's advice as much as possible.

Participant's Signature: _____

Cell phone: _____

Date: _____

I confirm that I have explained the details of this trial to the patient, including his rights and possible benefits and risks, and have given him a copy of the signed informed consent form.

Researcher in Charge Signature: _____

Cell phone: _____

Date : _____