Postoperative analgesic effect of acupotomy combined with patient-controlled intravenous analgesia in patients undergoing video-assisted thoracoscopic surgery: A study protocol for a randomized controlled trial

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Abstract
Background: Postoperative acute pain is a common issue following thoracic surgery. Acupotomy is a common and safe intervention method for pain treatment in the clinic. In previous preliminary experiments, we found that acupotomy has a good clinical effect and safety in the treatment of pain after thoracoscopic surgery. However, due to a lack of rigorous design and adequate sample size, the efficacy still needs to be further confirmed. The purpose of this study will be to explore the efficacy and safety of acupotomy combined with patient-controlled intravenous analgesia (PCIA) for the treatment of pain after video-assisted thoracic surgery (VATS).

Methods: The study will be a single-centre, parallel group, randomized controlled trial. Seventy patients with significant pain after thoracoscopic surgery with a visual analogue scale (VAS) score ≥7 will be included and randomly distributed into two groups: G1, the acupotomy combined with PCIA group; or G2, the conventional PCIA group. The primary outcome measure is pain scores at rest and coughing evaluated with the VAS by a blinded observer in the PACU and postoperatively at 1, 2, 4, 8, 12, 24, 48 and 72 h. The secondary outcome measures are postoperative requirements for rescue analgesia, the cumulative amount of self-administered analgesics, the level of sedation (LOS), Bruggemann comfort scale (BCS), and functional activity score (FAS) concerning adverse effects and patient satisfaction.

Discussion: This trial has the potential to identify a novel strategy for postoperative pain management in VATS. Findings may advocate for the inclusion of the treatment of comorbid pain after thoracoscopy in current pain management practice guidelines.

1. Introduction
Postoperative acute pain is a common issue following thoracic surgery[1]. Although minimally invasive compared to the thoracotomy approach, postoperative pain arising from intercostal muscle, fascia, nerve, and visceral tissue injury after video-assisted thoracoscopic lung surgery must still be considered moderate to severe[2, 3]. Poor postoperative analgesia is not only related to a reduction of patient satisfaction but also leads to the impairment of postoperative cardio-pulmonary function and further deterioration of the condition[4, 5]. For example, severe postoperative pain will increase
the risk of chronic pain; sympathetic activation may lead to cardiovascular adverse events; slow activity will increase the risk of thromboembolism events; and if the patient does not recover for a long time, they may have anxiety, depression and other psychological problems[6]. The medical costs and hazards of postoperative pain, including health care costs and medical resource utilization, daily activity restrictions, reduced quality of life, and increased risk for mortality, inflict a considerable burden on patients, families, and health care systems.

Patient-controlled intravenous analgesia (PCIA) is a personalized strategy involving various opioids that allows patients to administer analgesics as needed and has been demonstrated to be effective for postoperative pain management under diverse conditions[7, 8]. In addition, a series of reports have shown that there are other effective analgesic techniques, including intraspinal block, peripheral nerve block, wound infiltration, and systemic nonsteroidal anti-inflammatory drug (NSAID) administration[9-11].

However, most of these modalities are technically complex, present a high risk and/or carry a high risk of serious side effects such as epidural haematomas, dural puncture, nerve injuries, pneumothorax, hypotension, infection, respiratory depression, cough suppression, coagulopathy, local anaesthetic toxicity and renal impairment[12, 13]. Therefore, to date, no analgesic drug can be used alone to effectively treat severe pain without side effects. Enhanced Recovery After Surgery (ERAS) is a multimodal, multidisciplinary approach to the treatment of surgical patients with the aim of enhancing the quality of recovery after surgery[14]. The role of pain management in ERAS pathways is fundamental, considering the importance of containing surgical stress, reducing pain-related complications and speeding recovery[15-17]. In regard to pain management, ERAS promotes the adoption of a multimodal strategy that is tailored to the patients[18]. However, there is currently no consensus on the best strategy for treating pain after video-assisted thoracic surgery (VATS).

Acupotomy, widely used in Korea and China, a special form of acupuncture with characteristics of surgical procedures, is widely used for musculoskeletal conditions and is considered an excellent treatment for pain relief[19]. The analgesic effect of acupotomy has been recognized by many clinicians[20]. Moreover, in the previous preliminary experiments, we found that acupotomy has a
good clinical effect and safety in the treatment of pain after thoracoscopic surgery. However, due to a lack of a rigorous design and an adequate sample size, the efficacy still needs to be further confirmed.

Thus, in this trial, we combined acupotomy with PCIA to form a multimodal analgesia regimen and designed a randomized controlled trial to explore its efficacy and safety in the treatment of pain after VATS.

2. Methods
2.1. Study design and setting
This study will use a single-centre, parallel group, randomized controlled trial to explore the efficacy and safety of acupotomy combined with PCIA for the treatment of pain after VATS. It will be carried out at Fujian Provincial Hospital and has been registered with the Chinese Clinical Trial Registry (ChiCTR1900027191).

After eligibility screening and signing informed consent, eligible participants after thoracoscopic surgery will be randomly distributed into two postoperative analgesia groups: G1, the acupotomy combined with PCIA group; or G2, the conventional PCIA group. In addition to the abovementioned analgesic regimen, all subjects will receive conventional postoperative treatment, including health education and conventional medical therapy. The primary outcome measure is pain scores at rest and coughing evaluated with the VAS by a blinded observer in the PACU and postoperatively at 1, 2, 4, 8, 12, 24, 48 and 72 h.

The secondary outcome measures are the time to the first postoperative analgesic use, postoperative requirements for rescue analgesia, the cumulative amount of self-administered analgesics, the level of sedation (LOS), Bruggemann comfort scale (BCS), and functional activity score (FAS) concerning adverse effects and patient satisfaction. The flow diagram for this trial is presented in Fig. 1.

2.2. Sample size
Based on the results of our preliminary experiments, the mean difference ± SD are 3.21 ± 1.473 in the acupotomy combined with PCIA group and 4.48 ± 1.343 in the conventional PCIA group. We expect an effect size of at least 0.9 for this outcome after the intervention. A sample size of 56 participants is required to sufficiently detect a target effect size with a type 1 error of 5% (α = 0.05) and 80% power
(β = 0.20) using Gpower 3.1.9.2 software. Considering a 20% attrition rate, 70 participants are necessary, with 35 participants in each group.

2.3. Participants and eligibility criteria
Seventy patients with lung cancer, American Society of Anesthesiologists physical status I-II, aged 30-70 years old, elected for VATS lobectomy with a VAS score ≥ 7 will be recruited in this clinical study. They will also be required to be able to communicate well and understand how to score their pain level. All eligible participants who meet the study inclusion criteria will be identified through the Division of Thoracic Surgery. The study exclusion criteria are coagulation disorders; neuropathy; infections at the site of acupotomy; obesity (body mass index, BMI > 30 kg/m²); clinically significant neurological, cardiovascular, renal, and hepatic diseases; inability to remove the tracheal catheter or to correctly use the PCIA pump after surgery; psychiatric illnesses that would interfere with the perception and assessment of pain; and pain-killer use within a week before surgery.

We will have dedicated researchers to screen existing institutional registry records and databases and to work closely with the thoracic surgeons to identify qualified participants. Once eligibility is established, the research staff will contact eligible participants or their families and explain the purpose and significance of this study, fully provide explanations to remove participants’ doubts, and ascertain interest in enrolment. If the participant agrees to enrol, informed consent will be obtained. Participants will undergo baseline assessments following informed consent. A CONSORT diagram of participant recruitment is shown in Table 1.
Table 1
Trial processes chart

| Items                          | Before enrollment (week) | PACU | Postoperative 1 h. | Postoperative 2 h. | Postoperative 4 h. | Postoperative 8 h. | Postoperative 12 h. | Postoperative 24 h. | Postoperative 48 h. | Postoperative 72 h. |
|-------------------------------|--------------------------|------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Inclusion criteria            | x                        |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Exclusion criteria            | x                        |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Informed consent              | x                        |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Randomization and allocation  | x                        |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Pain scores (VAS)             |                          |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Postoperative requirements for rescue analgesia | × | × | × | × | × | × | × | × | × | × |
| LOS                           |                          |      |                    |                    |                    |                    |                    |                    |                    |                    |
| BCS                           |                          |      |                    |                    |                    |                    |                    |                    |                    |                    |
| FAS                           |                          |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Cumulative amount of self-administered analgesics | | | | | | | | | | | |
| Adverse events                |                          |      |                    |                    |                    |                    |                    |                    |                    |                    |
| Patients’ satisfaction        |                          |      |                    |                    |                    |                    |                    |                    |                    |                    |

2.4. Randomization and blinding

In this study, we will use SAS (SAS 9.2) statistical software to create a randomization sequence by an independent statistician. The randomization sequence will assign patients on the basis of a 1:1 ratio to either the intervention group (acupotomy combined with PCIA group) or the control group (conventional PCIA group). Competent doctors will strictly screen qualified subjects according to inclusion criteria and exclusion criteria.

The allocation sequence (containing random numbers, allocation and intervention information) will be concealed from the researchers who are responsible for enrolling and assessing participants in sequentially numbered, opaque, sealed and stapled envelopes. The project manager will evaluate the baseline information of eligible participants and then inform them which group they are assigned to.
Study personnel involved in recruitment, screening, data collection, and data entry will be blinded to group assignment.

2.5. Study intervention
2.5.1 Interventions, anaesthesia, and patient-controlled intravenous analgesia
Patients in both groups will receive intravenous inhalation combined with general anaesthesia. After entering the operating room, clinicians will regularly monitor their blood pressure, electrocardiography, SpO$_2$, and PETCO$_2$ and then open the vein.

General anaesthesia will be induced with 0.05 mg/kg of midazolam, 2–4 µg/kg of fentanyl, and 2 mg/kg of propofol intravenously. Tracheal intubation will be facilitated with rocuronium bromide 0.6 mg/kg. If necessary, we will repeat intubation. We will use 1-2% sevoflurane to maintain anaesthesia. During the surgery, patients will intravenously receive propofol and remifentanil at doses of 2-2.5 µg/kg and 3-4 µg/kg, respectively. In addition, we will continuously administer cisatracurium besylate to maintain muscle relaxation. The oxygen concentration will be adjusted according to the arterial blood gas value of the partial arterial blood oxygen concentration value. PETCO$_2$ will be controlled between 35 and 40 mmHg. A left-sided double-lumen endobronchial tube will be inserted under the premise of the tube size matches for the left mainstem bronchial diameter. We will confirm the correct tube position with the help of stethoscope and flexible fibreoptic bronchoscopy. At 30 min before the end of the operation procedure, we will give the patients 5–10 mg dezocine intravenously. Patients in the conventional PCIA group will be immediately connected to an intravenous self-control analgesia pump that contains 2 µg/ml of sufentanil and 8 mg of ondansetron diluted in 100 ml of 0.9% saline after surgery. The initial loading dose is 2 ml, the background dose is 2 ml/h, the single PCIA dose is 0.5 ml, and the locking time is 15 min. Patients in the acupotomy combined with PCIA group will be treated with acupotomy before the PCIA treatment.

2.5.2 Acupotomy treatment
Senior TCM doctors with nearly 30 years of clinical experience in acupuncture and 5 years of acupotomology experience will perform all acupotomy operations. The doctors will not be involved in evaluating the effects of treatment. A flat-head-screw-driver-shaped stainless-steel disposable acupotomy needle (0.6 mm in diameter and 50 mm in length, Lejiu Acupotomy Company, China) will
be used. Acupotomy will be performed in the lateral position. An iodine antiseptic will be used to sterilize the area for acupotomy. We will not anaesthetize the skin. The needle will be inserted at a position of 0.5–1.5 inches away from the spinous process at the T4-T7 level on the painful side of the chest, 50–60 mm under the skin and in a direction parallel to the muscle fibres. The practitioner will stop the acupotomy needle when resistance at the needle point is felt. The practitioner will move the needle point around in different directions to stimulate the soft tissue 3-5 times until the tenderness disappears. Then, the needle will be pulled out, and gauze will be applied to the site to prevent bleeding.

2.6 Outcome measures
When the patients are transferred to the post-anaesthesia care unit (PACU), vital signs (heart rate, noninvasive blood pressure, respiratory rate, and SpO₂) will be monitored and recorded every 5 minutes for at least 30 minutes. When the patients’ vital signs are stable and they are able to communicate easily, a series of clinical-scale evaluations and analgesia will be evaluated and recorded. The primary outcome measure of this study is the postoperative pain intensity scores. The pain scores (VAS) in the PACU and postoperatively at 1, 2, 4, 8, 12, 24, 48 and 72 h at rest and coughing will be assessed.

The secondary outcome measures are postoperative requirements for rescue analgesia, the cumulative amount of self-administered analgesics, the LOS, BCS, and FAS concerning adverse effects and patient satisfaction.

The time to the first rescue analgesic use and the cumulative amount of self-administered analgesics in the first 48 and 72 hours will be recorded. The BCS, LOS, and FAS will be recorded at 1, 4, 8, 16, 24, 48, and 72 hours after surgery. The LOS is recorded on a 5-point scale, with 0 indicating fully awake, 1 indicating drowsy/closed eyes, 2 indicating asleep/easily aroused with light tactile stimulation or a simple verbal command, 3 indicating asleep/arousable only by strong physical stimulation, and 4 indicating unarousable. The BCS is scored as 0, persistent pain; 1, severe pain while deep breathing or coughing; 2, mild pain while deep breathing or coughing; 3, painless while deep breathing; and 4, painless while coughing. The FAS is scored as A, not restricted; B, mild-to-moderately restricted; and
C, severely restricted. Postoperative adverse effects such as nausea, vomiting, hypotension, hypoxemia, cardiac arrhythmia and the complications from the drugs and technique will be recorded and treated.

Patients’ satisfaction will be assessed verbally at 24, 48 and 72 hours after surgery using a 5-point Likert scale (5 = completely satisfied, 4 = quite satisfied, 3 = slightly dissatisfied, 2 = dissatisfied, 1 = very dissatisfied). The observer who records the postoperative data will also be blinded to the group assignment.

2.7 Statistical analysis
The statistical analysis will be carried out using SPSS software (released 2011; IBM SPSS Statistics for Windows, Version 20.0, IBM Corp., Armonk, NY). All allocated subjects with available data will be analysed, i.e., on the basis of the intention-to-treat. The continuous variables will be presented as the means ± SD (standard deviations) or medians (25th to 75th centiles) and compared using the two-tailed Mann-Whitney or Student’s t-test, as appropriate. Categorical variables will be presented as numbers and percentages and analysed by Fisher’s exact or the chi-squared test. All statistical tests will be performed with a bilateral test, and $P \leq 0.05$ will be considered as statistically significant.

3. Discussion
This prospective randomized control study aims to evaluate the effects of acupotomy combined with PCIA (compared to conventional PCIA) on postoperative pain, functional recovery, postoperative adverse effects and patient satisfaction among patients undergoing VATS with not well-controlled postoperative pain. Despite the application of minimally invasive techniques, improved administration of analgesic drugs, and the combined use of analgesic drugs, the postoperative pain of some patients after thoracoscopic surgery has not been well controlled[21].

As the concept of a multimodal perioperative analgesic regimen, the options for postoperative analgesia must be effective, with minimal side effects, and aim to decrease the potentially harmful consequences of thoracic surgery on the immediate and long-term patient well-being[22, 23]. Moreover, as improving patients’ recovery after surgery and reducing patients’ hospital stay are key aims of fast-track surgery, there is an urgent need to consider other pain-relieving strategies to
complement the analgesics currently used[24-26].

PCIA is a common analgesic method after thoracoscopic surgery in clinics[27, 28], and acupotomy is a traditional Chinese acupuncture treatment that focuses on the pain treatment of clinical diseases[29, 30]. The combination of acupotomy and conventional PCIA can provide new insights into complicated postoperative pain management and functional rehabilitation of patients after thoracoscopy. In this study, we will use a combination of patient-reported subjective evaluation scales and objective statistical evaluation indicators of the effect of analgesic use to verify the effect of acupotomy combined with PCIA on pain after thoracoscopy, making the research results more reliable. In addition, early rehabilitation of postoperative limb function is also an important part of evaluating the effect of surgical treatment. In this study, the FAS scale will be used to evaluate the recovery of upper limb motor function in patients after thoracoscopic surgery. At the same time, we will also focus on the evaluation of adverse reactions and patient satisfaction. To the best of our knowledge, this will be the first randomized controlled trial to study the effect of a combination of acupotomy and PCIA on the management of postoperative pain and functional recovery in this population.

The major limitation of this protocol is its non-double-blind design. Nevertheless, we have taken some remedial measures to further ensure the quality of the research. For instance, patients will be allocated using a computerized randomization schedule to receive either of two techniques, which may control for selection bias. Moreover, the outcome assessors and statistical analysts will be blind to the intervention, which may control for report bias. This study also lacks long-term follow-up observations and assessments. The 3-day continuous observation period reflects the real-world clinical practice of the observation of acute analgesia after thoracoscopy and is sufficient to confirm the clinical efficacy and safety of acupotomy combined with PCIA in the short-term treatment of pain after thoracoscopy.

In conclusion, our results could offer an innovative strategy for improving postoperative pain control that could have a substantial impact on postoperative care and quality of life for patients who undergo VATS.

Trial Status
Protocol number: version 2.0-2019.12.01. Recruiting start date: December 5, 2019. Expected study completion date: December 2020.

Abbreviations
PCIA: patient-controlled intravenous analgesia; VATS: video-assisted thoracic surgery; VAS: visual analogue scale; LOS: the level of sedation; BCS: Bruggemann comfort scale; NSAID: systemic nonsteroidal anti-inflammatory drug; FAS: functional activity score; ERAS: Enhanced Recovery After Surgery.

Declarations

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Availability of data and materials
Not applicable.

Authors’ contributions
LZH, JC, LXM, and GMM conceived of the study, designed the study protocol, and drafted the manuscript. JC, LYY wrote the manuscript. LZH is in charge of coordination and direct implementation. YSX, GJH, JC and LYY helped to develop the study measures and analyses. All authors contributed to drafting the manuscript and have read and approved the final manuscript.

Ethics approval and consent to participate
This study will exactly adhere to the recommendations of the Declaration of Helsinki. All participants
will be completely informed of the study and will sign the informed consent form before participation.

This trial has been approved by the Ethics Board of Fujian Provincial Hospital (K2018-06-007).

**Consent for publication**

Not applicable.

**Competing interests**

The authors declare that they have no competing interests.

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Figures
Figure 1 Flow diagram of participants

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