

# Efficacy of oxycodone combined with thoracic paravertebral nerve block for postoperative analgesia in esophageal cancer surgery

<b>Submission date</b> 02/12/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 14/01/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/12/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study focuses on improving pain management after thoracoscopic esophagectomy, a minimally invasive surgery for esophageal cancer. Despite its advantages, patients often experience significant postoperative pain, which can hinder recovery. Effective pain control is essential to reduce complications, enhance recovery, and improve overall quality of life. This research aims to evaluate a combination of oxycodone-based intravenous patient-controlled analgesia (PCIA) and thoracic paravertebral nerve block (TPVB) as a multimodal pain relief strategy. The goal is to determine whether this method provides better pain relief, reduces inflammation, and supports the immune system compared to other commonly used pain control methods.

### Who can participate?

Patients aged 30 to 70 years undergoing thoracoscopic esophagectomy for esophageal cancer between June 2023 and June 2024. Participants must be classified as American Society of Anesthesiologists (ASA) grade I or II, meaning they are generally healthy or have only mild systemic conditions.

### What does the study involve?

Patients were chosen and split into four groups of 30. Each group received different combinations of pain relief: Group A got oxycodone with a nerve block, Group B got sufentanil with a nerve block, Group C got only oxycodone, and Group D got only sufentanil. The researchers measured pain levels at various times after surgery and recorded any side effects. They also took blood samples to check for inflammation and immune response markers. This helped them understand how each pain relief method affected the body.

### What are the possible benefits and risks of participating?

Participants may experience improved pain control with fewer side effects due to the use of advanced multimodal analgesia. The study could also contribute to better postoperative care for future patients undergoing similar surgeries.

Potential side effects include nausea, dizziness, or allergic reactions to the study drugs. Serious risks, such as respiratory depression, are rare but will be carefully monitored by the research team.

**Where Is This Study Taking Place?**

The Second Affiliated Hospital of Shandong First Medical University, China

**When is the study starting and how long is it expected to run for?**

December 2022 to December 2024

**Who is funding the study?**

The Second Affiliated Hospital of Shandong First Medical University, China

**Who is the main contact?**

Wensheng Zhang, liweiweicool@163.com

## Contact information

**Type(s)**

Public, Scientific, Principal investigator

**Contact name**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

J202202E

## Study information

**Scientific Title**

The application of intravenous patient-controlled analgesia (PCIA) with oxycodone combined with thoracic paravertebral nerve block in postoperative analgesia for thoracoscopic esophagectomy

## Study objectives

The combination of oxycodone-based patient-controlled intravenous analgesia (PCIA) and thoracic paravertebral nerve block (TPVB) provides superior postoperative pain relief, anti-inflammatory and immune-protective effects, promoting faster recovery while reducing complications and opioid-related side effects in thoracoscopic esophagectomy.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 17/04/2023, Ethics Review Committee of the Second Affiliated Hospital of Shandong First Medical University (No.366, Taishan Street, Taian, 271000, China; +86 0538-6236905; tyfykyk@163.com), ref: 2023-056

## Study design

Randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Quality of life, Treatment, Safety, Efficacy

## Health condition(s) or problem(s) studied

Esophageal cancer surgery

## Interventions

This study selected postoperative patients undergoing thoracoscopic esophagectomy as the research subjects to compare outcomes in terms of analgesic efficacy, inflammatory mediators, and immune function. The aim was to investigate the application of oxycodone combined with thoracic paravertebral nerve block in postoperative analgesia for thoracoscopic esophagectomy patients, optimize multimodal analgesia strategies, and promote rapid recovery.

From June 2023 to June 2024, 120 patients undergoing thoracoscopic esophagectomy were selected as study subjects and randomly divided using a computer-generated random number table into four groups, with 30 patients in each group: Group A (oxycodone PCIA + ropivacaine thoracic paravertebral nerve block), Group B (sufentanil PCIA + ropivacaine thoracic paravertebral nerve block), Group C (oxycodone PCIA), and Group D (sufentanil PCIA). At specific time points after the initiation of PCIA—2 hours (T1), 4 hours (T2), 8 hours (T3), 12 hours (T4), 24 hours (T5), and 48 hours (T6)—the Visual Analog Scale (VAS) was used to assess patients' pain levels, and postoperative adverse reactions were recorded for each group. Peripheral blood samples were collected from the forearm at 15 minutes before anesthesia induction (T0), as well as at 12 hours (T4), 24 hours (T5), and 48 hours (T6) postoperatively. Serum levels of tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), interleukin-6 (IL-6), interleukin-10 (IL-10), and plasma high mobility group box 1 (HMGB1) were measured using enzyme-linked immunosorbent assay (ELISA). Flow cytometry was employed to evaluate T lymphocyte subsets (CD4+, CD8+) and natural killer (NK) cell levels.

## Intervention Type

Mixed

### **Primary outcome(s)**

1. Resting and activity-related pain levels measured using the Visual Analog Scale (VAS) at specific time points after PCIA pump connection: 2 hours (T1), 4 hours (T2), 8 hours (T3), 12 hours (T4), 24 hours (T5), and 48 hours (T6)
2. Serum levels of inflammatory markers, including TNF- $\alpha$ , IL-6, IL-10, and HMGB1, measured using enzyme-linked immunosorbent assay (ELISA) at T0, T4, T5, and T6
3. T lymphocyte subsets (CD4+, CD8+) and natural killer (NK) cell levels measured using flow cytometry at T0, T4, T5, and T6

### **Key secondary outcome(s)**

1. The incidence and severity of nausea, vomiting, pruritus, and dizziness measured using direct observation and documentation between 2 to 48 hours postoperatively
2. Urinary retention was recorded by direct observation and reporting the number of cases, between 2 to 48 hours postoperatively
3. The sedation score was measured using the Ramsay Sedation Score at 2, 4, 8, 12, 24, and 48 hours postoperatively.
4. PCIA-related adverse events, including allergic reactions, bronchospasm and unconsciousness were continuously monitored and reported using Case Reporting throughout the postoperative observation period
5. The occurrence of hypotension was documented by monitoring the patients' postoperative blood pressure levels and their changes throughout the postoperative observation period
6. The occurrence of respiratory depression was reported through postoperative observations and clinical assessments throughout the postoperative observation period

### **Completion date**

01/12/2024

## **Eligibility**

### **Key inclusion criteria**

1. Patients undergoing thoracoscopic esophagectomy from June 2023 to June 2024
2. Classified as ASA grade I-II
3. Aged between 30 and 70 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Lower age limit**

30 years

### **Upper age limit**

70 years

### **Sex**

All

### **Total final enrolment**

120

### **Key exclusion criteria**

1. Patients who have previously participated in similar studies or refused to participate in this study, those with psychiatric disorders, or a history of sedative dependence
2. Patients with visual or hearing impairments, difficulties communicating in Mandarin, chronic pain syndromes, severe hepatic, renal, or cardiac diseases, or those whose surgery was converted to open thoracotomy
3. Patients with coagulation disorders or infections at the injection site
4. Patients with known allergies to ropivacaine, oxycodone, or sufentanil

### **Date of first enrolment**

01/06/2023

### **Date of final enrolment**

01/06/2024

## **Locations**

### **Countries of recruitment**

China

### **Study participating centre**

**The Second Affiliated Hospital of Shandong First Medical University**

No.366, Taishan Street

Taian

China

271000

## **Sponsor information**

### **Organisation**

The Second Affiliated Hospital of Shandong First Medical University

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

## Funder Name

The Second Affiliated Hospital of Shandong First Medical University

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Wensheng Zhang, Department of Anesthesiology, The Second Affiliated Hospital of Shandong First Medical University. Email: Zhwsh1968@sina.com. The type of data that will be shared is anonymised raw data in Excel.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			13/12/2024	No	No