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

Submission date
02/12/2024

Recruitment status
No longer recruiting

Registration date
14/01/2025

Overall study status
Completed

Last Edited
13/12/2024

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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-α (TNF-α), 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 measure
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-α, 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

Secondary outcome measures
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

Overall study start date
01/12/2022

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

Age group
Mixed

Lower age limit
30 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
120

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
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Sponsor information

Organisation
The Second Affiliated Hospital of Shandong First Medical University

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Sponsor type
Hospital/treatment centre

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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Second Affiliated Hospital of Shandong First Medical University

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/12/2024

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?
Protocol file			13/12/2024	No	No