

Effect of epidural anesthesia on the quality of short-term rehabilitation in hospital after surgery for cancer

Submission date 09/10/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/10/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/10/2021	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Patients with cancer are often accompanied by a variety of diseases and internal milieu disturbance, surgical resection is still confronted by many issues. Thoracic epidural anesthesia (TEA) (an injection in your back to stop you feeling pain in part of your body) and postoperative analgesia (pain medication) are often used in surgery to remove cancer. However, there are also some problems with the practical application of TEA, especially the difficulty of puncture and catheter detachment and displacement, which constitute the main factors affecting epidural analgesia that greatly compromise the patient's satisfaction.

The aim of this study is to perform a retrospective study on the postoperative short-term rehabilitation quality of patients with cancer undergoing minimally invasive radical resection based on the TEA combined with general anesthesia in comparison with general anesthesia alone.

Who can participate?

Patients aged 18 to 80 years undergoing minimally invasive surgery for cancer under general anesthesia.

What does the study involve?

Patients undergoing minimally invasive surgery with cancer under general anesthesia were selected sequentially from our database. According to whether TEA was used in anesthesia, the patients were divided into two groups, namely the TEA group and the control group (general anesthesia alone). The general anesthesia regimen was identical for both groups. In the TEA group, ropivacaine was given before general anesthesia, and the same dose of medicament was supplied at an intraoperative interval of 2h to maintain the block level. The epidural catheter was removed after surgery. Both groups were subjected to patient-controlled intravenous analgesia (PCIA). We will analyze the patient's conditions during and after surgery.

What are the possible benefits and risks of participating?

The application of TEA in minimally invasive radical resection of cancer can significantly reduce

the dosages of intraoperative anesthetic drugs and postoperative opioid drugs, which is beneficial to the postoperative recovery of patients.

Where is the study run from?

General Hospital of Southern Theatre Command of PLA (China)

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

February 2021 to December 2021

Who is funding the study?

Natural Science Foundation of Guangdong Province (China)

Who is the main contact?

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Contact information

Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

A retrospective study on the postoperative short-term rehabilitation quality of patients with cancer undergoing minimally invasive radical resection based on thoracic epidural anesthesia (TEA) combined with general anesthesia in comparison with general anesthesia alone

Study objectives

The application of TEA in minimally invasive radical resection of cancer can significantly reduce the dosages of intraoperative anesthetic drugs and postoperative opioid drugs, lower analgesia-related adverse reactions, which is beneficial to rehabilitation of patients after surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single-center retrospective cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not applicable (retrospective study)

Health condition(s) or problem(s) studied

Effect of intraoperative thoracic epidural anesthesia on the quality of hospital short-term rehabilitation after minimally invasive radical resection of cancer

Interventions

Patients undergoing minimally invasive surgery with cancer under general anesthesia according to whether TEA was used in anesthesia, the patients were divided into two groups, namely the TEA group and the control group (general anesthesia alone). The general anesthesia regimen was identical for both groups. In the TEA group, 0.15% ropivacaine (0.05 mL/kg) was given before general anesthesia, and the same dose of medicament was supplied at an intraoperative interval of 2 h to maintain the block level. The epidural catheter was removed after surgery. Both groups were subjected to patient-controlled intravenous analgesia (PCIA) using sufentanil (3 µg/kg), dexmedetomidine (2.5 µg/kg), and 2.5 mg of haloperidol in 150 mL of normal saline 30 min before the end of the surgery. The continuous basal dose was 1 mL/h, and the single-dose was 2.5 mL.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ropivacaine, sufentanil, dexmedetomidine, haloperidol

Primary outcome measure

Measured using patient records:

1. Dosage of anesthesia and vasoactive drugs used throughout the procedure
2. Postoperative analgesic information, including the time of the first pressing (i.e., the time when the surgery is over), the consumption of analgesic drugs, and the resting and motorial analgesic scores (R-VAS and M-VAS) at 24, 48 and 72 h postoperatively

Secondary outcome measures

Measured using patient records:

1. Demographic information: sex, age, height and weight, smoking and drinking history, preoperative complication of cardiovascular disease, diabetes mellitus, before the operation
2. Duration of the operation (min)

Overall study start date

01/02/2021

Completion date

01/12/2021

Eligibility**Key inclusion criteria**

Patients aged 18 - 80 years undergoing minimally invasive surgery with cancer under general anesthesia

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Total final enrolment

100

Key exclusion criteria

1. Patients with abnormal blood coagulation indices through the laboratory examination 48 h before operation
2. Patients with the operation time exceeding 12 h
3. Patients with operative method changed to thoracotomy or laparotomy
4. Patients with exploratory thoracotomy or laparotomy within 48 h after the operation

Date of first enrolment

01/01/2018

Date of final enrolment

01/01/2021

Locations

Countries of recruitment

China

Study participating centre

The Southern Theater General Hospital of the Chinese People's Liberation Army

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Government

Funder Name

Natural Science Foundation of Guangdong Province

Alternative Name(s)

Guangdong Provincial Natural Science Foundation, Natural Science Foundation of Guangdong, Guangdong Natural Science Foundation, Natural Science Fund of Guangdong Province,

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Publication and dissemination plan

A study is planned for publication in a medical journal.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other