ISRCTN16446449 https://doi.org/10.1186/ISRCTN16446449

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

Registration date
26/10/2021

Overall study status
Completed

Last Edited
26/10/2021

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
Zhaoju Li, hellenanna@126.com

Contact information

Type(s)
Public

Contact name
Mrs Zhaoju Li

Contact details
Department of Anesthesiology
General Hospital of Southern Theatre Command of PLA
111 Liuhua Road
Yuexiu District
Guangzhou
China
510000
+86 15602405803
wftuyx02@163.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Quality of life

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 1mL/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(s)
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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
Department of Anesthesiology
General Hospital of Southern Theatre Command of PLA
111 Liuhua Road
Yuexiu District
Guangzhou
China
510000

Sponsor information

Organisation
General Hospital of Southern Theatre Command of PLA

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

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