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Perioperative complication management protocol for lung cancer ablation

Submission date
21/07/2025

Recruitment status
No longer recruiting

Registration date
23/07/2025

Overall study status
Completed

Last Edited
22/07/2025

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Perioperative complication management is a crucial component of lung cancer ablation, directly related to surgical outcomes and patient prognosis. Existing complication management methods have shortcomings in practical application, such as non-standardized management procedures, incomplete monitoring indicators, and the lack of targeted interventions, resulting in unsatisfactory complication rates and treatment outcomes. This study aims to develop a perioperative complication management protocol for lung cancer ablation to reduce the incidence of perioperative complications and evaluate its application effects.

Who can participate?
Lung cancer patients undergoing ablation

What does the study involve?
The control group received routine management; the experimental group received management using the constructed perioperative complication management protocol for lung cancer ablation.

What are the possible benefits and risks of participating?
The perioperative complication management protocol for lung cancer ablation constructed will improve quality of life and satisfaction, effectively reduce the incidence of perioperative complications, and alleviate patients' psychological pressure.

This protocol is not yet able to predict possible complications that may occur.

Where is the study run from?
Tongji University Affiliated Shanghai Pulmonary Hospital, China

When is the study starting and how long is it expected to run for?
September 2022 to October 2024

Who is funding the study?
The Three-Year Action Plan Project for Discipline Construction of Tongji University School of Nursing, China

Who is the main contact?
Dr Lihua Huang, huanglh2025lh@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
Nil known

Study information

Scientific Title
Construction and application of perioperative complication management protocol for lung cancer ablation

Study objectives
To construct a perioperative complication management protocol for lung cancer ablation and evaluate its application effects.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 28/10/2022, Shanghai Pulmonary Hospital Ethics Review Committee (No. 507 Zhengmin Road, Shanghai, 200000, China; +86-02165115006; Xuxiaoyan98@21cn.com), ref: Q22-368Y

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospice, Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Scientific management of perioperative complications in patients undergoing lung cancer ablation

Interventions
The control group received routine management, and the experimental group received management using the constructed perioperative complication management protocol for lung cancer ablation.

The method of randomisation involved using the coin flip method. Ward 4 of the Oncology Department was determined as the control group and Ward 2 as the experimental group.

The control group received routine management: Preoperatively, the responsible nurse informed patients about lung cancer ablation methods and precautions; the importance of intraoperative cooperation and compliance; medical staff were responsible for observing and managing adverse events or complications during surgery, with image acquisition and scanning supervised by other CT room technicians; postoperatively, patients returned to the ward where responsible nurses closely observed vital sign changes and complication occurrence, such as hemoptysis, respiration, heart rate, blood pressure indicators, and chest tightness or dyspnea discomfort; patients received telephone follow-up every 3 months after discharge.

The experimental group received management using the constructed perioperative complication management protocol for lung cancer ablation as follows:
1. Establishment of multidisciplinary team: A perioperative complication management team for lung cancer ablation was established, consisting of nursing, ablation, rehabilitation, and psychological nursing groups
2. Clarification of team member responsibilities:
2.1. Nursing group: Responsible for pre- and postoperative patient care and health education,

assisting with intraoperative supplies preparation and monitoring (closely observing for hypotension, chest tightness, dyspnea symptoms, monitoring for pneumothorax, bleeding complications, promptly notifying physicians, cooperating with emergency care when necessary)
2.2. Ablation group: Responsible for CT imaging, image analysis, lesion measurement, puncture site positioning, image post-processing, developing needle insertion paths, and performing lung cancer ablation
2.3. Rehabilitation group: Team members developed individualized perioperative rehabilitation plans based on patient conditions before enrollment
2.4. Psychological nursing group: Team members developed individualized psychological intervention plans based on actual patient conditions before enrollment. All personnel received unified training and assessment from senior staff within the research team, with all team members passing assessment.
3. Protocol implementation: The research team leader established a WeChat group and supervised and maintained its operation; responsible nurses conducted preoperative breathing training according to surgical requirements until patients could perform command breathing cooperation, contacted the multidisciplinary team by phone for perioperative preparation; work groups used the WeChat platform to establish contact, cooperate with each other, and timely understand surgical progress and patient conditions: the ablation group reported preoperative preparation or patient surgical process to the ward; responsible nurses reported postoperative patient conditions; during puncture by the ablation group, nurses cooperated with supply transfer, intraoperative patient guidance, and postoperative complication observation and management; responsible nurses conducted telephone follow-up every 3 months after patient discharge, inquiring, guiding, and answering relevant questions for their assigned patients.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Perioperative complication incidence (perioperative complication incidence = total number of perioperative complications / total number of lung cancer ablation patients) at 3 months after surgery measured using study data collected from case report forms
2. Quality of life measured using Functional Assessment of Cancer Therapy-General (FACT-G) scale before intervention and 3 months after surgery
3. Patient Satisfaction measured using a self-designed satisfaction questionnaire (Satisfaction rate for each group = (very satisfied + satisfied) / total cases in each group × 100%) at 3 months after surgery
4. Preoperative Anxiety Level using a Self-rating Anxiety Scale before surgery

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/09/2022

Completion date
31/10/2024

Eligibility

Key inclusion criteria

1. Patients meeting lung tumor diagnostic criteria scheduled for elective lung cancer ablation treatment
2. Clear consciousness, normal thinking, able to communicate verbally and in writing
3. Cooperative with the study and signed informed consent

Participant type(s)
Patient

Age group
Mixed

Lower age limit
54 Years

Upper age limit
77 Months

Sex
Both

Target number of participants
272

Total final enrolment
269

Key exclusion criteria
1. Severe bleeding tendency, platelets <50×10⁹/L and uncorrectable coagulation disorders (prothrombin time >18s, prothrombin activity <40%), anticoagulation therapy and/or antiplatelet drugs discontinued for less than 5-7 days before ablation
2. Severe comorbidities, infection period, immunocompromised, renal insufficiency
3. Cardiac pacemaker implantation, metal implants
4. Eastern Cooperative Oncology Group (ECOG) performance status score >3

Date of first enrolment
01/12/2023

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
China

Study participating centre
Tongji University Affiliated Shanghai Pulmonary Hospital
No. 507 Zhengmin Road, Yangpu District

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Sponsor information

Organisation
Shanghai Pulmonary Hospital

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No. 507 Zhengmin Road, Yangpu District
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Sponsor type
Hospital/treatment centre

Website
https://med.tongji.edu.cn/english/HOME.htm

ROR
https://ror.org/033nbnf69

Funder(s)

Funder type
University/education

Funder Name
Tongji University

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

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

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date