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Postoperative chronic operation-related symptoms after minimally invasive lung surgery: a prospective observational protocol

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ABSTRACT

Introduction Significant numbers of patients undergoing minimally invasive lung surgery develop chronic symptoms such as chronic pain and chronic cough after surgery, which may lead to a reduced quality of life (QoL). Despite this, there remains a dearth of high-quality prospective studies on this topic. Therefore, our study aims to systematically investigate the incidence and progression of long-term chronic symptoms following minimally invasive lung surgery, as well as changes in patient's psychological status and long-term QoL.

Methods This is a single-centre, observational, prospective study that included patients with stage I non-small cell lung cancer or benign lesions. Prior to surgery, patients' baseline levels of chronic pain, chronic cough and sleep will be documented. Anxiety, depression and QoL assessments will be conducted using the Hospital Anxiety and Depression Scale (HADS) and the European Organisation for Research and Treatment of Cancer (EORTC) 30-item QoL Questionnaire (QLQ-C30). Following surgery, pain and cough will be evaluated during the initial 3 days using the Numeric Pain Rating Scale and Visual Analogue Scale score, with assessments performed thrice daily. Additionally, sleep status will be recorded daily during this period. Subsequently, postoperative chronic symptoms and QoL will be assessed at weeks 1, 2, 4, 12, 26 and 52. Chronic cough will be evaluated using the Leicester Cough Questionnaire, chronic pain will be assessed via the Brief Pain Inventory and McGill Pain Questionnaire while the EORTC QLQ-C30 questionnaire and HADS will provide continuous monitoring of QoL, anxiety and depression statuses. Data will also include the timing of chronic symptom onset, predisposing factors, as well as aggravating and relieving factors.

Ethics and dissemination Ethical approval was obtained from the Ethics Committees of Fujian Medical University Union Hospital. The findings will be disseminated in peer-reviewed publications.

Trial registration number NCT06016881.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will be the first prospective investigation of chronic symptoms and long-term quality of life in patients after minimally invasive lung surgery.
⇒ Sample size is large enough to give some conclusive results.
⇒ Detailed assessments of preoperative and postoperative psychological status are included.
⇒ Single-centre design may limit generalisability to broader patient populations.
⇒ Lack of psychiatric clinical interviews may underestimate psychological disorders at baseline.

INTRODUCTION

With the implementation of lung cancer screening programmes using CT and low-dose CT in high-risk patients, more and more lung nodules are being detected.[1] The vast majority of malignant nodules are early-stage lung cancers that are predominantly ground glass lesions on CT images. Histologically, adenocarcinoma in situ (AIS) and minimally invasive adenocarcinoma (MIA) are defined as cancers with no or limited tissue infiltration.[2] Studies have shown that patients with AIS or MIA have a 100% probability of being free of recurrence within 5 years after surgery and have disease-specific survival rates of 100% and 100%, respectively.[3] In patients with early-stage lung cancer and benign lesions, long-term postoperative survival and tumour recurrence are non-priorities. Therefore, postoperative quality of life (QoL) is increasingly emphasised by patients and clinicians. However, a significant proportion of patients undergoing minimally invasive lung surgery still develop chronic pain and chronic cough in the postoperative period, the severity of which can lead to reduced QoL.[4–6]

Studies have shown that chronic pain after video-assisted thoracoscopic surgery (VATS) is significantly improved compared with open thoracic surgery, but the overall incidence is still 35.3%,[7 8] and postoperative pain makes patients fearful of coughing, which increases the rate of pulmonary complications and negatively affects the patient's psyche, which

seriously affects the patient's postoperative recovery. Chronic cough is a common chronic symptom after pulmonary resection, and chronic cough has been reported in the literature to occur in approximately 30%–40% of patients postoperatively.[6 9] A persistent cough can lead to organic complications such as fatigue, insomnia, hoarseness, urinary incontinence, rib fractures and spontaneous pneumothorax. In addition, coughing after lung surgery, especially chronic coughing, exacerbates patients' postoperative incisional pain, doubts about the effectiveness of treatment and may even lead to depressive symptoms in some patients, which seriously reduces the quality of patients' postoperative life.[10] However, long-term chronic postoperative symptoms have not received sufficient clinical attention and there is still a lack of relevant high-quality prospective studies. Most of the previous studies had methodological limitations and most used retrospective or cross-sectional studies. Moreover, the vast majority did not assess patients' preoperative pain, psychological disorders and QoL at baseline and did not systematically document the duration of the onset of chronic postoperative symptoms, treatment outcomes, course regression and long-term changes in postoperative QoL, as well as lacked long-term follow-up data.

The aim of this prospective observational study is to systematically examine the incidence and development of long-term chronic symptoms related to minimally invasive lung surgery, as well as changes in preoperative and postoperative psychological status and long-term QoL in patients undergoing minimally invasive lung surgery.

METHODS AND ANALYSIS

Study design and population

This single-centre, observational, prospective study includes patients with stage I lung cancer or benign lesions. Patients will undergo ongoing screening at admission and prior to surgery. Preoperatively, patients will undergo lung CT, ECG, cardiac ultrasound and pulmonary function tests to assess their baseline condition. Baseline levels including chronic pain, chronic cough and sleep and anxiety and depression status are also recorded. Patients with well-defined pulmonary nodules who were assessed to be surgical pointers will be included in the study. We anticipate that 500 patients can be successfully recruited. The study pathway is illustrated in figure 1. The Ethics Committee of Fujian Medical University Union Hospital has approved this trial (No. 2023KY144), and the trial protocol has been registered on ClinicalTrials.gov (NCT06016881).

Study setting

All participants will be recruited from the Department of Thoracic Surgery, Fujian Medical University Union Hospital, from October 2023 to March 2024, and each patient will be followed for at least 1 year.

Inclusion criteria

The inclusion criteria are as follows: (a) 18 years of age or older; (b) undergo single-port thoracoscopic surgery; (c) be diagnosed with stage I lung cancer or benign lesions on histological examination and (d) voluntarily participate in the study and sign an informed consent form.

Exclusion criteria

The exclusion criteria are as follows: (a) history of previous chest surgery; (b) any type of chronic pain requiring daily analgesics; (c) any type of chronic cough requiring daily medication; (d) pregnancy; (e) breast feeding; (f) contraindication to Non-Steroidal Anti-Inflammatory Drug (NSAID) use and (g) other tumours that require chemotherapy or radiotherapy in combination.

Surgical procedures

The range of surgical resection is determined based on each patient's preoperative evaluation and surgeon's judgement. All patients underwent single-port thoracoscopic surgery with a 3.5–4.0 cm operative hole incised in the fourth or fifth intercostal space in the midaxillary line. Intraoperative mediastinal lymph node dissection or mediastinal lymph node sampling will be performed at the discretion of the surgeon on a case-by-case basis. At the end of the operation, drains (22–24F drains and/or 8-F ultrafine drains) will be placed in the chest cavity. Pleural adhesions, mediastinal lymph node dissection (sampling or sweeping) and vagus nerve dissection will be fully documented.

Anaesthesia procedures

Anaesthesia will be induced by 1% propofol 1–2 mg/kg, sufentanil 0.4–0.5 µg/kg and rocuronium bromide 1 mg/kg. Tracheal intubation will be performed by visual laryngoscopic placement of a double-lumen tube or a single-lumen occlusion tube, and the exact method of intubation and the number of intraoperative adjustments of tracheal intubation will be fully recorded. Anaesthesia maintenance will be carried out using propofol at a dosage of 4–12 mg/kg and remifentanil at a dosage of 0.05–0.2 µg/kg. Intraoperative monitoring of bispectral index (BIS) will be conducted, with the BIS value targeted and maintained between 50 and 60. Dosages of propofol and remifentanil will be adjusted according to the BIS value. Train of four (TOF) monitoring will also be performed, and adjustments to rocuronium bromide dosage will be made accordingly. Neostigmine antagonism will be routinely administered at the conclusion of the operation to ensure a TOF greater than or equal to 70%. Volume-controlled positive-pressure mechanical ventilation will be used for two-lung ventilation, with a tidal volume of 8–10 mL/kg, a respiratory rate of 12–16 breaths/min, an inspiratory/expiratory ratio of I/E of 1:2 and an end-expiratory partial pressure of carbon dioxide maintained at 35–45 mm Hg. Intravenous self-contained analgesia pumps will be used with a combination of sufentanil 1 µg/mL, ondansetron 8 mg and dexmedetomidine 10 mg. The utilisation of preoperative or postoperative nerve blocks will be documented.

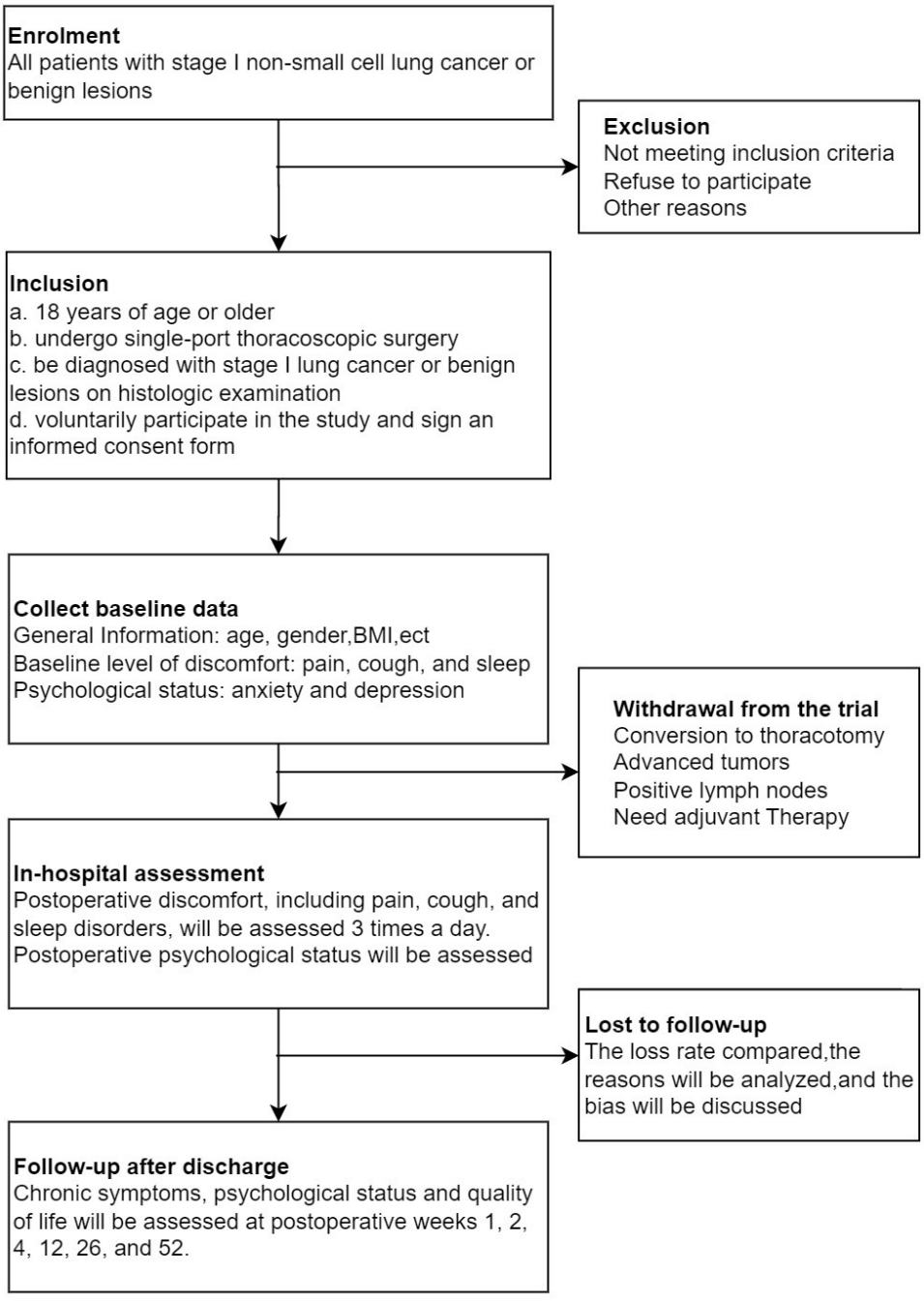

Figure 1 Flow chart of the study. BMI, body mass index.

Outcomes and measures

The primary outcome is the occurrence and development of long-term chronic symptoms, such as chronic pain and chronic cough, after minimally invasive lung surgery. Secondary outcomes include the assessment of long-term QoL and changes in anxiety and depression status over time. The schedule of enrolment and assessments is shown in table 1.

Preoperative phase

Prior to surgery, baseline assessments will be conducted to establish a reference point for comparison postoperatively. These assessments will include demographic data, medical history and baseline measurements of relevant parameters.

Postoperative phase

During the initial 3 days following surgery, assessments of pain and cough frequency will be conducted using the Numeric Pain Rating Scale (NRS) and Visual Analogue Scale score, respectively. These assessments will be performed thrice daily (every 8 hours), and sleep status will be recorded daily. The methods of assessment will include direct patient reporting and clinical observation.

Table 1 Patient assessment schedule

	Study period					
	Enrolment	Hospitalisation period		Follow-up		Close-out
Time point	0	Before surgery	After surgery	1 week	2, 4, 12, 26 and 52 weeks	t_x
Enrolment						
Eligibility screen	X					
Informed consent	X					
Assessments						
Baseline patient characteristics	X	X				
Nodules characteristics	X	X	X			
Baseline level of discomfort	X	X				
Postoperative complications			X	X		
Postoperative discomfort*			X	X		
Anxiety and depression	X	X	X	X	X	
Chronic symptoms†				X	X	
Quality of life measure	X	X	X	X	X	

*Postoperative discomfort—pain, cough and sleep status.
†Chronic symptoms—chronic pai and chronic cough.

Follow-up phase

Postoperative chronic symptoms and QoL will be assessed at specified intervals: postoperative weeks 1, 2, 4, 12, 26 and 52. Assessment tools will include the Leicester Cough Questionnaire (LCQ) for chronic cough, Brief Pain Inventory and McGill Pain Questionnaire for chronic pain, and the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 for overall QoL. The Hospital Anxiety and Depression Scale will be used for continuous assessment of anxiety and depression status.

Data analysis

All statistical analyses will be performed by using SPSS V.20.0 (or higher). All statistical tests will be performed using a two-sided 0.05 hypothesis test of superiority, and 95% CIs and p values will be given for comparisons between groups. Measurement information will be statistically described using mean±SD or median (minimum, maximum) unless otherwise stated. Count data will be statistically described using frequencies (percentages). Depending on the distribution of the variables, between-group tests will be performed using independent t-tests or Mann-Whitney U-tests. The χ^2 test or Fisher's exact test will be applied to categorical variables.

Patient and public involvement

Neither patients nor the public will be involved in the design, recruitment, outcome measures and conduct of the study. Trial results will be disseminated via peer-reviewed scientific journals and conference presentations rather than specifically notified to a single patient.

ETHICS AND DISSEMINATION

The study was approved by the Ethics Committees of Fujian Medical University Union Hospital (No.2023KY144). The study is performed in compliance with the Declaration of Helsinki and the principles of Good Clinical Practice. All patients will sign an informed consent before study entry.

DISCUSSIONS

For individuals with early-stage lung cancer and benign lesions, long-term postoperative survival and tumour recurrence are no longer the primary focus. Instead, there is a growing concern among patients and clinicians regarding the long-term chronic postoperative symptoms and overall QoL. While enhanced rapid rehabilitation management after VATS aims to minimise the impact of surgery on patients, a significant number still experience persistent issues such as chronic pain and cough. The severity of these issues can significantly diminish the overall QoL. Additionally, there is a limited body of research exploring the psychological state of patients undergoing surgery for pulmonary nodules, a factor we consider pivotal in influencing overall QoL.

Chronic postsurgical pain (CPSP) is a common and often disabling complication of many surgical procedures. CPSP is defined as pain that develops after a surgical procedure and persists for at least 3 months after the procedure, excluding all other causes of pain (infections, recurrent malignant tumours) as well as pain caused by pre-existing pain problems.[11] Chronic postoperative pain occurs in approximately 10% of patients undergoing surgery,[12] however, in lung surgery, this percentage is as high as 20%–50%.[7 13 14] A prospective

study by Bendixen *et al* randomly assigned 206 patients with stage I non-small cell lung cancer to the VATS group and the anterolateral thoracotomy group, both of which underwent lobectomy, and the VATS group had less postoperative pain and better QoL in the first year postoperatively compared with the anterolateral thoracotomy group.[15] This landmark study, which confirmed video-assisted thoracoscopy as the surgical procedure of choice for lobectomy for stage I non-small cell lung cancer, did not report on the nature of postoperative pain, time of onset of pain, its intensity and duration, treatment modalities,and outcomes. In another large-sample long-term retrospective study reported by Yoon *et al* which included 3200 patients, 459 (14.3%) and 558 (17.4%) patients developed postoperative chronic pain at 3 and 36 months postoperatively, respectively.[16] However, the study did not exclude patients with advanced lung cancer, ignored pain that may be caused by the progression of the cancer itself and did not assess baseline levels before surgery.

Several retrospective studies have shown that female sex, age and acute pain are risk factors for chronic pain after VATS, and the number of incisions, duration of surgery, duration of drainage, and inadequate analgesia have also been identified as predictors.[17 18] This study was prospectively designed to assess pain intensity during the first 3 days of postoperative hospitalisation using the Numeric Rating Scale (NRS) and to assess the incidence of postoperative chronic pain using the Brief Pain Scale and the McGill Pain Questionnaire,[19] to identify its potential predictors and to explore the mechanisms of pain onset and effective interventional treatments. The baseline pain level was assessed preoperatively, and the characteristics of chronic pain were focused on postoperatively, and the different treatment options and efficacy were analysed through long-term follow-up, in the hope of eliminating bias, more comprehensively discovering the risk factors, exploring effective treatments and providing a basis for further clinical studies.

Chronic cough is a common chronic symptom after pulmonary resection, and chronic cough is reported in the literature to occur in about 30%–40% of patients after surgery, but it has not received sufficient clinical attention.[6 9] Currently, there is still a lack of guidelines and consensus for the management of chronic cough after lung surgery, and there is no standardised and uniform treatment for chronic cough after lung surgery. Previously reported risk factors for chronic cough after lung surgery include female, history of Chronic Obstructive Pulmonary Disease (COPD), airway obstruction, right lung cancer and mediastinal lymph node dissection. In addition, studies have suggested that anaesthesia modalities, intubation methods and anaesthesia medications may have an effect on postoperative chronic cough[20]; therefore, anaesthesia factors were included in the analysis of this study. The LCQ has been shown to be well suited as an indicator of outcomes in clinical practice and research therapies that affect cough. The LCQ was used in this study to assess the impact of chronic cough after pulmonary surgery and the efficacy of different treatment modalities. The LCQ is short and easy to administer and consists of 19 items with scores ranging from 1 to 7. It is divided into three subscales, physical, psychological and social, with lower LCQ scores implying a poorer QoL the more one is affected by cough.[21]

Psychological distress has been reported in more than 40% of patients with lung cancer, one of the highest prevalence rates of any cancer.[22] Psychological distress, including anxiety and depression, may adversely affect postoperative chronic pain, postoperative sleep and QoL.[23–25] The study used the Generalised Anxiety Disorder Screening Scale[26] and the Beck Depression Inventory,[27] which have been shown to have good diagnostic accuracy for anxiety and depressive states in patients with cancer, to screen anxious and depressed patients presenting within 1 year of surgery, with a view to exploring changes in preoperative and postoperative psychological distress and its impact on the quality of long-term postoperative survival. For some patients with psychological distress, further psychological evaluation was performed by a credentialed psychologist, and systematic treatment was recommended for patients with severe symptoms.

Patients with early-stage lung cancer already have significantly lower QOL and significantly impaired physical and emotional functioning compared with the normal population before surgical treatment. Lung cancer resection leads to further deterioration of QOL, especially in the 3–6 months following surgery. While some studies have shown that QOL returns to baseline levels 6–9 months after surgery, other studies have shown that QOL remains significantly impaired at 6 months and 1 year after surgery.[28] Most studies did not include long-term chronic symptoms and psychological factors in the analysis of long-term quality of survival, so more high-quality studies are needed to accurately characterise the potential influencing factors of QOL and the long-term trend of QOL change in patients with lung cancer, which will be beneficial for the perioperative guidance of subsequent surgeries and the long-term postoperative care.

The primary limitation of this study lie in its single-centre design. Additionally, the study does not involve psychiatric clinical interviews, potentially omitting patients with initial anxiety disorders. The exclusion criteria may limit the applicability of the findings to a broader patient population. Finally, the study is limited to a 1-year follow-up period, which may not capture all long-term outcomes.

We initiated the first prospective observational trial to investigate the prevalence of long-term chronic symptoms after minimally invasive lung surgery, risk factors, efficacy of treatment received, duration of disease and eventual regression, preoperative and postoperative psychological status, and long-term postoperative QOL. Our aim is to furnish evidence to support further multicentre cohort studies and randomised controlled trials.

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Contributors BZ and CC conceived and designed the study. BZ is responsible for the overall content as guarantor. YH, MC and ZW developed the study protocol. YH, PL and SZ drafted and revised the manuscript. All authors collected and analysed the data. All authors read and approved the final manuscript.

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