

BMJ Open Longitudinal patient-reported outcomes 1 year after thoracoscopic segmentectomy versus lobectomy for early-stage lung cancer: a multicentre, prospective cohort study protocol

Xin Gao ,¹ Wei Dai ,¹ Qi Zhang ,^{1,2} Wenwu Liu,¹ Yangjun Liu ,³ Lingjia Yang,⁴ Xing Wei ,¹ Qiuling Shi ,^{5,6} Cecilia Pompili ,^{7,8} Yang Pu,⁶ Shaohua Xie,¹ Run Xiang,¹ Bo Tian ,¹ Bin Hu,¹ Xiaozun Yang,¹ Xiang Wang,¹ Xiaojun Yang,¹ Tianpeng Xie,¹ Yong Tang,⁹ Guibin Qiao,⁹ Nan Sun,¹⁰ Shan Gao,¹¹ Guangjian Zhang,¹¹ Dan Chen,¹² Yue Cui,¹³ Xiaobo Chen,¹³ Yu He,¹⁴ Rong Zhang,¹⁴ Qiang Li,¹ Xiang Zhuang¹

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XG, WD and QZ contributed equally.

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For numbered affiliations see end of article.

Correspondence to

Dr Xiang Zhuang;
13882191333@139.com

ABSTRACT

Introduction Segmentectomy and lobectomy are the main surgical procedures for early-stage lung cancer. However, few studies have analysed patient-reported outcomes after segmentectomy versus lobectomy. This study aims to compare patient-reported outcomes—such as symptoms, daily functioning and quality of life—between thoracoscopic segmentectomy and lobectomy for early-stage lung cancer during the 1 year after surgery.

Methods and analysis Overall, 788 newly diagnosed patients with early-stage lung cancer (tumour size ≤ 2 cm), who are scheduled to undergo thoracoscopic segmentectomy or lobectomy, will be recruited in this multicentre, prospective cohort study. The patients will receive standardised care after surgery. The Perioperative Symptom Assessment for Lung Surgery—a validated lung cancer surgery-specific scale—will be used to assess the symptoms and functions at baseline, at discharge and monthly after discharge for 1 year. The European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 and Lung Cancer module 29 will be used to assess the patients' quality of life at the same time points. The primary outcome will be the shortness of breath scores during the first year after thoracoscopic segmentectomy and lobectomy and will be compared using mixed-effects models. The secondary outcomes will include other symptoms, indicators of daily functioning, quality of life scores and traditional clinical outcomes. These will be compared using mixed-effects models and the Student's t-test, non-parametric test or X^2 test. Propensity score matching will be used to ensure an even distribution of known confounders between the groups.

Ethics and dissemination The Ethics Committee for Medical Research and New Medical Technology of Sichuan Cancer Hospital approved this study (approval number: SCCHEC-02-2022-002). All participants will be instructed to provide informed consent. The manuscript is based on protocol version 3.0. The study results will be presented

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is a multicentre, prospective, cohort study with an adequate sample size.
- ⇒ Data related to patient-reported outcomes will be collected at multiple time points within 1 year after thoracoscopic segmentectomy and lobectomy.
- ⇒ Two lung cancer surgery-specific scales will be used to assess the patients' symptom burden and quality of life.
- ⇒ This study will use propensity score matching to improve comparability between the groups.
- ⇒ This observational study may be associated with selection, information and confounding bias.

at medical conferences and published in peer-reviewed journals.

Trial registration number ChiCTR2200060753.

INTRODUCTION

Since 1995, lobectomy has been considered as the standard surgical procedure for treating early-stage lung cancer.¹ However, the increase in early-stage lung cancer cases with ground-glass opacity, along with recent advancements in surgical techniques, have led to a growing interest in whether segmentectomy can replace lobectomy for early-stage lung cancer. Some retrospective studies have demonstrated that segmentectomy had an overall survival rate similar to that of lobectomy for early-stage lung cancer.^{2,3} Moreover, the latest multicentre, randomised controlled trial (JCOG 0802) in this field showed that segmentectomy was associated with better survival than lobectomy in patients with

small-sized peripheral non-small cell lung cancer.⁴ However, the lack of research into long-term quality of life after surgery has limited the implementation of patient-centred decision-making.^{5,6}

Patient-reported outcomes (PROs) are outcomes that are reported directly by patients and are primarily related to symptoms, functioning and quality of life.⁷ As one of the four indicators of clinical outcome recommended by the US Food and Drug Administration,⁷ PROs have been increasingly used in thoracic surgery.^{8,9} PROs can facilitate decision-making for both patients and clinicians, especially when traditional outcome measures—such as postoperative complications and survival—are similar between two different treatment options.¹⁰ For example, Bendixen *et al*¹¹ reported that video-assisted thoracoscopic surgery resulted in similar postoperative complications as open surgery for lobectomy in early-stage lung cancer, but was associated with lower levels of pain and a better quality of life. This suggested that video-assisted thoracoscopic surgery should be the optimal surgical approach for early-stage lung cancer.

To our knowledge, few studies have specifically compared segmentectomy and lobectomy based on PROs. One randomised trial showed that during the first year after surgery, segmentectomy resulted in a better quality of life than lobectomy.¹² However, the results of most patients who underwent open surgery may not be interpreted in the current era of minimally invasive surgery. Another retrospective study by our team did not find a significant difference in symptom burden and functional status between patients who received thoracoscopic segmentectomy versus lobectomy during the first month after surgery.¹³ However, it is unclear whether thoracoscopic segmentectomy and lobectomy result in differences in long-term PROs. Therefore, in this multicentre, prospective cohort study, we aim to compare the 1-year trajectories of PROs after thoracoscopic segmentectomy versus lobectomy for early-stage lung cancer. We hypothesise that patients undergoing thoracoscopic segmentectomy will have similar or better PROs during the first year after surgery compared with those undergoing thoracoscopic lobectomy.

METHODS AND ANALYSIS

Study design and population

This multicentre, prospective cohort study will use a non-inferiority design. The inclusion and exclusion criteria that will be used in this study are summarised in [table 1](#). The flow diagram of this study is shown in [figure 1](#).

Setting

This study will be initiated by the Sichuan Cancer Hospital. It will be conducted in seven hospitals in China including the Sichuan Cancer Hospital, Guangdong Provincial People's Hospital, Liaoning Cancer Hospital, The First Affiliated Hospital of Xi'an Jiaotong University, The First Affiliated Hospital of Chongqing Medical

Table 1 Inclusion and exclusion criteria

Criteria	
Inclusion criteria	Age ≥ 18 years
	Clinical or pathological diagnosis of early-stage non-small cell lung cancer (maximum tumour diameter ≤ 2 cm and tumour with no lymph nodes or distant metastases)
	Patients scheduled to undergo intentional thoracoscopic segmentectomy or lobectomy
	Ability to understand the details of the study and content of the questionnaire
Exclusion criteria	Willing to sign the informed consent form
	History of chest surgery
	History of neoadjuvant therapy
	History of other malignancies
	Daily use of analgesics
	Patients scheduled to undergo surgery using the subxiphoid thoracoscopic approach
	Patients scheduled to undergo bilobectomy or lobectomy combined with sublobar resection (segmentectomy, subsegmentectomy or wedge resection)
Patients scheduled to undergo simultaneous bilateral surgery	
Participation in other interventional studies	

University, The First Affiliated Hospital of Kunming Medical University and Ya'an People's Hospital. Patients will be continuously screened for enrolment at the time of admission and before surgery. Patient recruitment will be conducted from August 2022 to March 2023, and each patient will be followed up for at least 1 year. This study is ongoing. Since each participating centre performs an average of 1000 lung cancer surgeries per year, we expect that 788 patients can be successfully recruited within the aforementioned study period.

Surgical procedures

Because of the observational nature of this study, the selection of segmentectomy or lobectomy will be determined based on each patient's preoperative assessment and the surgeon's discretion. The surgical approach will be either uniportal or multiportal. A uniportal thoracoscopic incision usually involves a 3–4 cm incision at the fourth or fifth intercostal space between the anterior and middle axillary lines.¹⁴ In contrast, multiportal thoracoscopic incisions usually involve 2–4 incisions, each of which measures 0.5–4 cm and is usually performed at the fourth, seventh, or ninth intercostal space along the anterior, middle, or posterior axillary lines. Segmentectomy requires the dissection of the arteries and bronchi of the

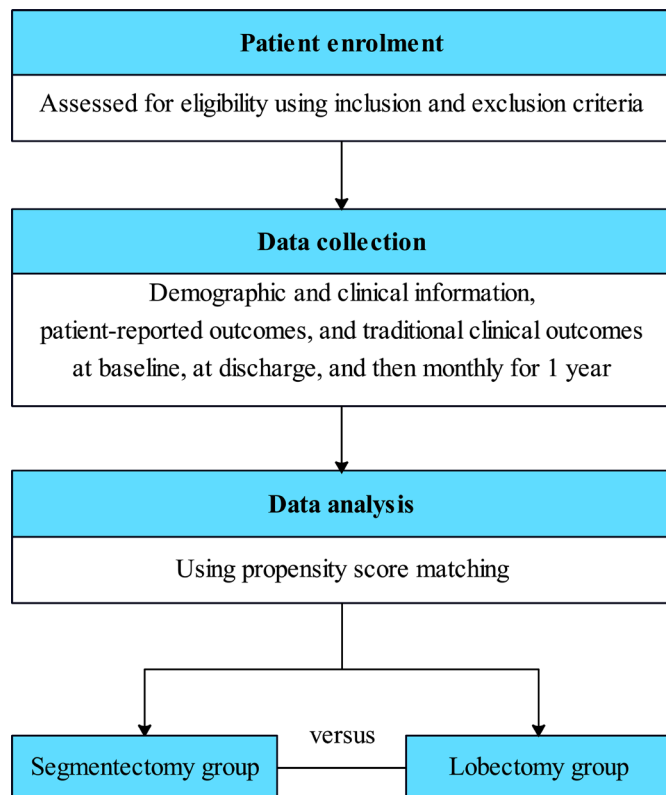


Figure 1 Flow chart of the study.

target segment and can include single subsegmentectomy, single segmentectomy, combined subsegmentectomy, combined segmentectomy, segmentectomy combined with subsegmentectomy, segmentectomy combined with wedge resection and subsegmentectomy combined with wedge resection. Lobectomy requires the dissection of the arteries, veins and bronchi of the target lobe, and will not include bilobectomy or lobectomy combined with sublobar resection (segmentectomy, subsegmentectomy or wedge resection). Lymph node dissection or sampling will be performed at the surgeons' discretion. Patients will receive standardised care after surgery, and the enhanced recovery protocol will not be used.

Outcomes and measures

The primary objective of this study is to compare the shortness of breath scores of patients over a period of 1 year after thoracoscopic segmentectomy or lobectomy. Shortness of breath was chosen as the primary outcome for two main reasons. First, the major difference between lobectomy and segmentectomy is the extent of parenchymal resection, which can theoretically be measured based on lung function. However, the renowned JCOG 0802 trial did not find clinically significant differences in lung function between patients who received segmentectomy versus lobectomy.⁴ Therefore, shortness of breath may be used as an alternative indicator of lung function in these patients. Second, PROs such as shortness of breath are more patient-centred and sensitive indicators than traditional clinical outcomes.¹⁰

The shortness of breath score will be measured using the Perioperative Symptom Assessment for Lung Surgery (PSA-Lung) Scale, which is a validated lung cancer surgery-specific instrument developed based on a Chinese population.¹⁵ The PSA-Lung Scale includes seven symptoms (pain, cough, shortness of breath, disturbed sleep, fatigue, drowsiness and distress) and two functional items (difficulty in walking and impairment in activities of daily living). Each item is rated on a scale of 0–10 points, with 0 representing no symptoms or no functional impairment and 10 representing the most severe symptoms or functional impairment. The recall period for the PSA-Lung Scale is 24 hours.

The secondary outcomes will include symptom and daily functioning scores other than short of breath scores on PSA-Lung, quality of life scores, conversion rate (thoracoscopic to open surgery), operative time, intraoperative blood loss, number of lymph nodes dissected, number of lymph node stations dissected, days until chest drain removal after surgery, postoperative hospital stay, postoperative in-hospital complications and complications within 30 days after surgery (based on the Clavien-Dindo grading system).¹⁶ Quality of life scores will be measured using the European Organization for Research and Treatment Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30)¹⁷ and Lung Cancer module (QLQ-LC29).^{18 19} All items of the EORTC QLQ-C30 and QLQ-LC29 are rated using a 4-point Likert scale (1, not at all; 2, a little; 3, quite a bit and 4, very much). The recall periods for the EORTC QLQ-C30 and QLQ-LC29 are 1 week.

The JCOG 0802 trial reported robust results related to the lung function and survival of patients.⁴ Accordingly, we will examine the following as exploratory outcomes in this study: the rate of decline in the forced expiratory volume in 1 s (FEV1) from baseline to 1 year postoperatively, 5-year recurrence rate, 5-year recurrence-free survival rate, 5-year survival rate and 10-year survival rate.

Data collection, management and monitoring

The collected data will include the demographic and baseline clinical information of patients, PROs and traditional clinical outcomes (see above). PRO data will be collected at baseline (before surgery), at discharge (± 1 day) and once every month (± 7 days) after discharge for 1 year. These data will be collected using electronic questionnaires, paper questionnaires or telephone follow-ups, depending on the patient's choice. Patients will be instructed to complete the questionnaire on their own (unless they require assistance). Other data will be obtained from the electronic medical record system or through telephone follow-ups.

An electronic data capture (EDC) system will be used to design the case report form (CRF) and for database establishment and data management. The EDC system will be deployed in the server of the principal research centre (Sichuan Cancer Hospital). Each researcher will use a personal password-protected account to access the EDC system for patient enrolment and data entry. This

programme will include a data manager, data monitor, and data and safety monitoring board (DSMB). The data manager will be responsible for organising the CRF design, establishing the database, producing the standard operating procedure (SOP) and training researchers, and will also perform daily data management. The data monitor will be responsible for performing data checks every 3 months. The DSMB will consist of three senior clinicians and a statistician who will independently monitor the safety of the participants, quality of the data and progress of the study.

Quality control

This study will be conducted by a multidisciplinary team that includes the principal investigator, subcentre principal investigator, research coordinators, research assistants, clinical research methodologists, information technology specialists, data managers, data monitors, project monitors and the DSMB. Before patient enrolment, all investigators will receive SOP training. Regular and unscheduled data checks will be performed during the patient recruitment process. In addition, the automatic logical verification function of the EDC database will assist researchers in correcting errors. After patient recruitment has been completed, all data will be subjected to a final verification, including checks for completeness and accuracy. To verify key indicators in the CRF, all the cases will be double-checked. For non-key indicators, 10% of the cases will be randomly selected for double-checking. Acceptable error rates will be no more than 0.2% for numerical variables and no more than 0.5% for text variables. If an error rate exceeds these limits, 100% double-checking will be performed.

Sample size calculation

This study will use a non-inferiority design. According to the formula shown in figure 2,^{20 21} we will assume that the one-sided α is 0.025, the β is 0.1, the minimum measurable change in the shortness of breath score is an SD of 20%, the non-inferiority margin is an SD of 10%, the number of time points after surgery is 13 and the correlation between repeated measures is 0.4. A minimum of 105 patients will be required in each group. Considering an attrition rate of 20% (including invalid data and withdrawal data) and a propensity score matching (PSM) attrition rate of 2/3, each group will be required to have at least 394 patients. Therefore, the total sample size will be at least 788.

$$N = \frac{2(z_{\alpha} + z_{\beta})^2 (1 + (n-1)\rho)}{n[(\mu_1 - \mu_2) + \delta] / \sigma^2}$$

Figure 2 Sample size calculation formula for the study.

Data analysis

Patients whose surgery is cancelled or converted to thoracotomy, those who undergo non-segmentectomy or non-lobectomy surgery, those whose postoperative pathology is not lung cancer, those who require postoperative adjuvant treatment or those who request to withdraw from the study will not be included in the final analysis. We will perform PSM to minimise the differences between groups. To calculate the propensity score, variables that can potentially impact decision-making related to the extent of surgery will be selected based on expert opinion and literature review.²² The potential variables include age, sex, FEV1, FEV1%, body mass index, smoking status, Charlson Comorbidity Index, American Society of Anesthesiologists physical status classification, tumour diameter, surgical approach, type of lymphadenectomy, number of chest tubes and tumour stage.^{13 23 24} All potential variables will be modelled using a univariate logistic regression model with surgical extent (segmentectomy vs lobectomy) as the dependent variable. Variables with a p value of <0.1 will be used for propensity score calculation using a multivariate logistic regression model.

Based on the calculated propensity scores, we will use greedy matching to pair patients undergoing thoracoscopic segmentectomy with patients undergoing thoracoscopic lobectomy using a 1:1 ratio with a proximity SD of 0.25 of the logit of the propensity score. Less than 10% of the standardised mean difference between the groups will be considered an adequate balance for matching. Using this matched dataset, the primary outcome and secondary outcomes related to PRO data will be analysed using a mixed-effects model to evaluate whether there are differences between the two groups during the first year after surgery. Sensitivity analysis will be performed using all samples, with an adjustment for potential confounders. The secondary and exploratory outcomes related to clinical measures will be analysed using the Student's t-test, non-parametric test or X^2 test, as appropriate. A one-sided p value will be calculated for the primary outcome, and all other outcomes will be two sided. Statistical significance will be set at a p value of <0.05. The data will be analysed independently by data analysts using SAS V.9.4 (SAS Institute).

Patient and public involvement

Patients will be invited to participate in study design, patient recruitment and study implementation. The general public will not be invited to participate in study design, recruitment and implementation. Patients will not be informed of the results of the study unless they request it at the time of enrolment.

ETHICS AND DISSEMINATION

This study is approved by the Ethics Committee for Medical Research and New Medical Technology of Sichuan Cancer Hospital on 4 January 2022 (number: SCCHEC-02-2022-002). Prior to patient enrolment, the

subcentres (Guangdong Provincial People's Hospital, Liaoning Cancer Hospital, The First Affiliated Hospital of Xi'an Jiaotong University, The First Affiliated Hospital of Chongqing Medical University, The First Affiliated Hospital of Kunming Medical University and Ya'an People's Hospital) will also submit this research protocol to the ethics committees of their respective institutions for approval. All participants will be instructed to provide electronic or written informed consent. The results of this study will be disseminated to the participating centres, presented at appropriate conferences and published in peer-reviewed medical journals.

Author affiliations

¹Department of Thoracic Surgery, Sichuan Cancer Hospital & Institute, Sichuan Cancer Center, University of Electronic Science and Technology of China, Chengdu, Sichuan, China

²Graduate School, Chengdu Medical College, Chengdu, Sichuan, China

³Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden

⁴College of Medical and Dental Science, University of Birmingham, Birmingham, UK

⁵Center for Cancer Prevention Research, Sichuan Cancer Hospital & Institute, Sichuan Cancer Center, University of Electronic Science and Technology of China, Chengdu, Sichuan, China

⁶School of Public Health, Chongqing Medical University, Chongqing, China

⁷Thoracic Surgery Unit, University and Hospital Trust - Ospedale Borgo Trento, Verona, Italy

⁸Section of Patient Centered Outcomes Research, Leeds Institute of Medical Research at St James's, University of Leeds, Leeds, UK

⁹Department of Thoracic Surgery, Guangdong Provincial People's Hospital, Guangzhou, Guangdong, China

¹⁰Department of Thoracic Surgery, Liaoning Cancer Hospital & Institute, Shenyang, Liaoning, China

¹¹Department of Thoracic Surgery, The First Affiliated Hospital of Xi'an Jiaotong University, Xi'an, Shaanxi, China

¹²Department of Thoracic Surgery, The First Affiliated Hospital of Chongqing Medical University, Chongqing, Chongqing, China

¹³Department of Thoracic Surgery, First Affiliated Hospital of Kunming Medical University, Kunming, Yunnan, China

¹⁴Department of Thoracic Surgery, Ya'an People's Hospital, Ya'an, Sichuan, China

Twitter Xing Wei @SurgeronXingWEI

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Competing interests None declared.

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ORCID iDs

Xin Gao <http://orcid.org/0000-0002-3089-2279>

Wei Dai <http://orcid.org/0000-0003-1650-1590>

Qi Zhang <http://orcid.org/0000-0003-2215-7538>

Yangjun Liu <http://orcid.org/0000-0002-3540-5361>

Xing Wei <http://orcid.org/0000-0002-3035-5633>

Qiuling Shi <http://orcid.org/0000-0003-0660-3809>

Cecilia Pompili <http://orcid.org/0000-0001-6746-5441>

Bo Tian <http://orcid.org/0000-0003-1283-3045>

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