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Association of preoperative spirometry tests with postoperative pulmonary complications after mediastinal mass resection: protocol for a retrospective cohort study

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ABSTRACT

Introduction Patients with a mediastinal mass are at risk of pulmonary complications in the perioperative period. Preoperative spirometry tests are recommended in patients scheduled for thoracic surgery. Our objective is to investigate the association between preoperative spirometry results and the incidence of postoperative pulmonary complications in patients following mediastinal mass resection, which may determine the usefulness of spirometry tests in the prediction of the perioperative respiratory risk.

Methods and analysis This protocol describes a retrospective cohort study of patients with mediastinal masses in Shanghai Pulmonary Hospital between 1 September 2021 and 1 September 2022, with a planned sample size of 660 patients. The primary aim of this study is to explore the association between preoperative spirometry results and the occurrence of postoperative pulmonary complications after mediastinal mass resection. Logistic regression analysis will be used to calculate the adjusted incidence rate difference and incidence rate ratios (with 95% CIs).

Ethics and dissemination The study was approved by the ethics committee of Shanghai Pulmonary Hospital (K21-372Y). The results of the study will be submitted to a peer-reviewed biomedical journal for publication and presented at relevant conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is one of the few studies that has evaluated the incidence of postoperative pulmonary complications in patients with mediastinal masses based on preoperative spirometry tests.
⇒ The study adopts a retrospective cohort study design in a high-volume thoracic centre in China.
⇒ Multivariate logistic regression following univariate analysis will be used.
⇒ This is a single-centre study with unknown generalisability, and validation of the findings will be necessary.
⇒ Residual, unidentified confounding cannot be fully excluded due to the retrospective design of the study.

INTRODUCTION

Postoperative pulmonary complications (PPCs) contribute to prolonged length of stay, increased costs of care and higher operative mortality, which are the leading causes of death after thoracic surgery.[1 2] Pulmonary complications after lung resection have already been established and are well described.[3 4] However, PPCs after mediastinal mass resection in thoracic surgery remain a separate problem, which is rarely an area of concern in the literature.

Masses of the mediastinum comprise a wide diversity of tumours afflicting patients of all ages.[5 6] Mediastinal masses represent different disease states, from asymptomatic lesions to severe life-threatening presentations.[7 8] For decades, surgical resection has been the preferred therapeutic approach for mediastinal masses.[9] Over recent years, great advancements in thoracic surgery, especially the application and popularisation of video-assisted thoracoscopic surgery (VATS) and robotic-assisted thoracoscopic surgery (RATS), have largely broadened the optional surgical approaches for mediastinal tumour resection. Compared with extensive surgery (thoracotomies and medial sternotomies), these minimally invasive approaches have the superiorities of less trauma, enhanced recovery and fewer perioperative complications.[9–12] However, insufficient studies explore the prevalence of PPCs after mediastinal mass resection and the risk factors for its occurrence.

The tumour-caused changes in the mediastinum lead to large variability in the respiratory and haemodynamic responses to anaesthesia in patients with mediastinal mass, and even a life-threatening situation

may occur due to the deficiency in the preoperative diagnosis, preparation and anaesthetic technique.[8 13 14] Therefore, exploring predictors of general anaesthesia risk for patients with a mediastinal tumour is critical and necessary. Accurate assessment of pulmonary function has been claimed to improve risk assessment of pulmonary complications.[15 16] Accordingly, preoperative pulmonary function tests (PFTs) are recommended in patients scheduled for lung resection,[17] cardiac[18] or non-thoracic surgery,[19] where spirometry, a specialised non-invasive test to measure lung function, may contribute to identifying patients at high risk of PPCs.[20] Especially, the prognostic value of forced expiratory volume in 1 s (FEV_1) and the ratio of FEV_1 to forced vital capacity (FVC) have been rationally well established in aortocoronary bypass surgery and lung resection, with a reduced FEV_1 and FEV_1/FVC strongly associated with postoperative mortality and complications.[21 22] However, the predictive capability of spirometry for complications after mediastinal mass resection surgery is unclear and has not been described in scientific literature.

Primary objective

The primary objective of this study is to investigate the association between preoperative spirometry results and the incidence of PPCs in patients following mediastinal mass resection.

Secondary objective

The secondary objectives are to evaluate the prevalence of PPCs after mediastinal mass resection surgery at our centre and to determine whether preoperative spirometry is related to 30-day readmission and mortality.

METHODS AND ANALYSIS

Study setting

This study will be a retrospective cohort study and will be conducted at Shanghai Pulmonary Hospital, one of the largest thoracic centres in China. The study was approved by the institutional review board of Shanghai Pulmonary Hospital (K21-372Y). The need for obtaining informed patient consent will be waived due to the retrospective nature of this study. We will adhere to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for reporting observational studies. All methods will be performed in accordance with the ethical principles of the 1964 Declaration of Helsinki and its later amendments. We will use the STROBE checklist and guidance when reporting our study findings.[23]

Eligibility criteria

Patients in receipt of mediastinal mass resection surgery at our centre between 1 September 2021 and 1 September 2022 and fulfilling the inclusion criteria will be included in the study (table 1). To be enrolled, only those who underwent preoperative PFTs will be included in the analysis, and the integrity of the data will be reviewed. A study flow diagram is provided in figure 1.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Age ≥18 years at the time of surgery	Age ≤17 years at the time of surgery
Accept preoperative spirometry test	Myasthenia gravis
	Bronchial compression was detected by preoperative fibreoptic bronchoscopy
	Impaired integrity of medical records
	Metastasectomy cases
	Surgery using median sternotomy

Data collection

Study data will be collected from electronic medical records at our institution from patients who had a mediastinal mass resection under VATS or RATS between 1 September 2021 and 1 September 2022. Metastasectomy cases and those surgery using median sternotomy will be excluded. The following information will be collected from electronic medical records:

Preoperative data

Preoperative data that will be collected are listed in table 2.

Intraoperative data

Intraoperative data will include the duration of surgery, blood loss, requirement for transfusion, whether hypoxaemia and hypotension occur, new-onset atrial fibrillation, utilisation of hydroxyethyl starch and vasopressors during operation.

Postoperative data

Postoperative data will be collected from the institutional thoracic surgery registry and include PPCs, new-onset arrhythmia, myocardial infarction, renal complication, cerebral infarction, seizure, pulmonary thromboembolism, surgical complications, the length of stay, 30-day and 90-day readmission, and 30-day mortality. The levels of a myocardial enzyme (cardiac troponin T, creatine kinase MB isoenzyme, myoglobin and brain natriuretic peptide) and inflammatory factors (interleukin (IL)-1β, IL-6 and tumour necrosis factor-α) in peripheral blood will also be recorded. The renal complication was defined as an Acute Kidney Injury Network classification ≥2. Surgical complications will include prolonged air leak (≥5 days), prolonged effusion (≥5 days), chylothorax, vocal cord palsy, empyema, wound infection, wound dehiscence and bronchopleural fistula.

Institutional protocol for perioperative care

Patients received standard perioperative care according to our institutional protocol. All patients received

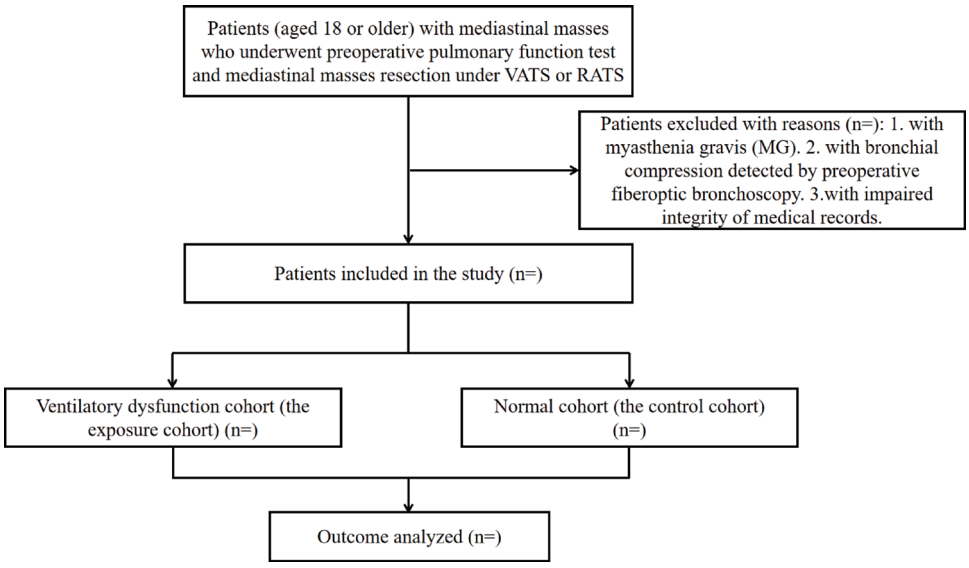

Figure 1 Study flow diagram. RATS, robotic-assisted thoracoscopic surgery; VATS, video-assisted thoracoscopic surgery.

general anaesthesia, which was performed using standard doses of midazolam, propofol, sufentanil and rocuronium bromide. Double-lumen tracheal intubation was performed when the patient lost consciousness. The anaesthetic, fluid volume, infusion speed and transfusion were adjusted according to haemodynamic monitoring conditions to maintain the haemodynamic parameters within 20% of the preoperative baseline values. A protective ventilation protocol was implemented for all patients. All patients were routinely extubated at the end of surgery unless the attending anaesthesiologists or surgeons decided not to. For postoperative pain management, we have implemented a protocol specific to each type of patient, mainly relying on patient-controlled intravenous analgesia and giving light intravenous or oral rescue analgesics. All patients underwent routine X-ray examinations on the first day after the operation.

Preoperative spirometry tests

All patients accepted preoperative spirometry tests within 1 week before the operation, which are routine preoperative tests among patients undergoing mediastinal mass resection through VATS or RATS at Shanghai Pulmonary Hospital. Preoperative spirometry results include FVC, FEV_1, %VC (FVC/predicted VC) and FEV_1/FVC (FEV_1%). FVC is defined as the maximal volume of air exhaled with a maximally forced effort from a maximal inspiration, which is the vital capacity performed with a maximally forced expiratory effort. FEV_1 is defined as the volume (L) of air exhaled in the first second of forced expiration, starting from a position of full inspiration. Both FEV_1 and FVC are presented as percentage-predicted values based on age, gender and height reference standards used by our institution, and the ratio of FEV_1/FVC is also presented as a percentage. A specialised technician from the Department of Pulmonology in the same centre will be appointed to perform the spirometry tests for every patient 1 week before surgery.

Table 2 Preoperative data

Demographic characteristic	Age, sex, body mass index, American Society of Anesthesiologists physical status, preoperative spirometry results, cardiac function, smoking, cancer cell types and clinical tumour, node, metastasis stages
Systemic comorbidities	Hypertension, diabetes mellitus, cardiac disease, cerebrovascular disease, renal dysfunction and pulmonary disease
Pre-surgical blood tests	Arterial oxygen partial pressure, peripheral blood haemoglobin content and inflammatory factor (IL-1β, IL-6 and TNF-α) levels

IL, interleukin; TNF-α, tumour necrosis factor-α.

Main exposures

According to the American Thoracic Society and the European Respiratory Society guidelines,[24] the cut-off point for FVC is 80% predicted, and that for FEV_1% is 70%. Spirometry assessment is determined by %FVC and FEV_1%, and subjects are divided into four categories (normal, obstructive, restrictive and combined), depending on whether %FVC and FEV_1% are normal or abnormal. Consequently, we will create a normal cohort and a ventilatory dysfunction cohort (including obstructive, restrictive and combined) (table 3).

Table 3 Study cohorts

Normal cohort	Ventilatory dysfunction cohort
%FVC ≥80, FEV_1% ≥70 (normal group)	%FVC ≥80, FEV_1% <70 (obstructive group) %FVC <80, FEV_1% ≥70 (restrictive group) %FVC <80, FEV_1% <70 (combined group)

FEV_1, forced expiratory volume in 1 s; FVC, forced vital capacity.

Table 4 Definitions of postoperative respiratory complications according to the European Perioperative Clinical Outcome consensus statement

Postoperative pulmonary complication	Definition
Atelectasis	A radiological finding of atelectasis in chest X-ray: lung opacification with shift of hilum, mediastinum, or hemidiaphragm towards affected area and compensatory inflation in adjacent lung
Pulmonary aspiration	Clear clinical history and radiological evidence
Postoperative pneumonia	US Centers for Disease Control definition of pneumonia One chest radiograph with at least one of the following (two or more serial chest X-rays for patients with underlying pulmonary or cardiac disease): (a) new or progressive and persistent infiltrates, (b) consolidation, (c) cavitation; AND at least one of the following: 1. Fever (>38°C) with no other recognised causes 2. Leucopenia (white cell count <4×10^9/L) or leucocytosis (white cell count >12×10^9/L) 3. For adults >70 years old, altered mental status with no other recognised causes AND at least two of the following: 1. New onset of purulent sputum or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements 2. New onset or worsening cough, or dyspnoea, or tachypnoea 3. Rales or bronchial breath sounds 4. Worsening gas exchange (hypoxaemia, increased oxygen requirement, increased ventilator demand)
Postoperative respiratory failure	Berlin definition of respiratory distress syndrome Timing: within 1 week of a known clinical insult or new or worsening respiratory symptoms AND Chest imaging: bilateral opacities not fully explained by effusions, lobar/lung collapse or nodules AND Origin of oedema: respiratory failure not fully explained by cardiac failure or fluid overload (requires objective assessment, for example, echocardiography, to exclude hydrostatic oedema), AND Oxygenation: mild PaO_2:FiO_2 between 26.7 and 40.0 kPa (200–300 mm Hg) with PEEP or CPAP 5 cmH_2O; moderate PaO_2:FiO_2 between 13.3 and 26.6 kPa (100e200 mm Hg) with PEEP 5 cmH_2O; severe PaO_2:FiO_2 13.3 kPa (100 mm Hg) with PEEP 5 cmH_2O. Mechanical ventilation The need for tracheal reintubation and mechanical ventilation after extubation, and within 30 days after surgery OR mechanical ventilation for more than 24 hours after surgery. The inclusion of non-invasive ventilation may be considered on a study-by-study basis.

CPAP, continuous positive airway pressure; FiO_2, fractional inspired oxygen; PaO_2, arterial oxygen pressure; PEEP, positive end-expiratory pressure.

Postoperative pulmonary complications

The PPCs will be assessed via symptoms and the chest X-ray on the first day after surgery. Bedside X-ray examinations are available for every patient to diagnose atelectasis and determine the location of the chest tube, which could assess PPCs. In this study, the PPCs will be defined as the composite of respiratory complications with common pathophysiological mechanisms covering pulmonary collapse and airway contamination,[25] which include (1) atelectasis detected on postoperative chest radiograph, (2) pulmonary aspiration recognised by clear clinical history and radiological evidence, (3) pneumonia using US Centers for Disease Control criteria,[26] and (4) acute respiratory distress syndrome covering Berlin consensus definition[27] and reinstitution of mechanical or non-invasive ventilation after extubation[28] (table 4). In addition, other complications associated with the physiological changes that follow surgery and anaesthesia, including (1) pulmonary embolism, (2) pleural effusion, (3) cardiogenic pulmonary oedema, (4) pneumothorax and (5) bronchospasm, were excluded. Any PPCs defined in table 4 during the hospital will be recorded. Even if the patient does not report symptoms, bedside X-ray examination can help rule out PPCs. The thoracic surgeon decides whether to carry out further CT examination, if necessary, and all the results are available in the electronic medical record.

Furthermore, the definition of PPCs we used incorporates an assessment of severity[25]:

1. None: planned use of supplemental oxygen or mechanical respiratory support as part of routine care, but not in response to a complication or deteriorating physiology. Therapies that are purely preventive or prophylactic, for example, high-flow nasal oxygen or continuous positive airway pressure (CPAP) should be recorded as none.
2. Mild: therapeutic supplemental oxygen ≤0.6 fractional inspired oxygen (FiO_2).
3. Moderate: therapeutic supplemental oxygen ≥0.6 FiO_2, requirement for high-flow nasal oxygen or both.

4. Severe: unplanned non-invasive mechanical ventilation, CPAP or invasive mechanical ventilation requiring tracheal intubation.

Sample size

To our knowledge, there have been no studies examining rates of PPCs for patients after mediastinal mass resection precisely as we have defined them here. It has been reported that the incidence of PPCs is about 10.5% in adults with mediastinal mass.[29] Based on our pilot study, the incidence of PPCs is about 30% in an abnormal cohort of spirometry tests. Assuming 80% power to detect a proportion of 0.105 in the normal cohort and 0.3 in the abnormal cohort with a one-sided α of 0.05, this would require 300 patients per group, with an overall sample of n=600. We aim to include 660 patients to allow a loss to follow-up rate of 10%. During the 1-year observational window, there should be approximately 700 patients undergoing mediastinal mass resection surgery in our centre, a high-volume thoracic centre in China.

Statistical analysis

Descriptive statistics were used to characterise the cohort. Categorical variables were described using counts and frequencies, and continuous variables were described using means with SDs and medians with IQRs. Significant differences between the two cohorts were tested by χ^2 or Fisher's exact test for categorical variables and Student's t-test for continuous variables. Skewed distributed data will be compared using a non-parametric test.

Logistic regression analysis will be used to calculate the adjusted incidence rate difference and incidence rate ratios (with 95% CIs). Univariate analysis for odds of any PPCs will be performed by logistic regression for every confounder from our database. Furthermore, a multivariable model will be built considering significant (p<0.05) variables from the univariate regression combined with partial preoperative and intraoperative variables in the Assess Respiratory Risk in Surgical Patients in Catalonia Score[30] (age, preoperative SpO_2, preoperative anaemia and duration of surgery).

Two-tailed p values of less than 0.05 will be considered statistically significant. All statistical analyses will be performed using SPSS V.26.0 (IBM SPSS).

Data management and monitoring

All data will be analysed through ResMan (www.medresman.org.cn/), an online website for data management, in linked, anonymised form. The conduct of the trial conduction will be supervised by the study supervisor (ZW), with monthly audits of the trial performed. The datasets will be available from the chief investigator upon reasonable request.

Study status

Our data collection is ongoing and it is expected to be completed in July 2023. Data analysis is due to begin in August 2023 and we plan to complete the study by the end of 2023.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

The study was approved by the ethics committee of Shanghai Pulmonary Hospital (K21-372Y). On completion, the results of the study will be submitted to a peer-reviewed biomedical journal for publication and presented at relevant conferences.

DISCUSSION

PPCs encompass a series of respiratory diseases, ranging from asymptomatic atelectasis to respiratory failure,[1 31] which are challenging to perioperative management for patients undergoing major surgery and relevant to prolonged hospital stays and elevated mortality.[32] The incidence of PPCs is multifactorial, varied considerably, and is usually dependent on surgical factors and individual characteristics. Besides, increased age, extensive surgical range and thoracic surgery are strongly associated with a higher risk of PPCs.[32] The pain disrupting the performance of respiratory muscles and the anaesthesia, to a lesser extent, adversely affecting lung function are also the causes of PPCs. Advances in perioperative care ensure the diversity of effective interventions covering preoperative, intraoperative and postoperative periods to minimise the adverse effects of surgery and anaesthesia. However, the prediction and treatment of PPCs are multidisciplinary challenges, with infrequent or outdated consensus guidelines aimed to reduce the risk of PPCs compared with those for postoperative cardiovascular complications.[33 34]

Accurate assessment of lung function has been regarded as vital for patients presenting for thoracic surgery, which usually have lung or bronchial carcinoma, a mediastinal mass or oesophageal disease. Most of these patients are elderly, with a history of smoking and consequent comorbid conditions. Moreover, unique features of thoracic surgery including the special cardiopulmonary physiology caused by position, ventilation/perfusion mismatch, one lung ventilation and hypoxic pulmonary vasoconstriction lead to a large challenge for thoracic anaesthesia and perioperative management.[15] All these factors together contribute to the necessity of PFTs. Spirometry is the gold-standard method for the detection of airflow limitations and is recommended in patients with chronic obstructive pulmonary disease (COPD).[35] However, surgery is increasingly being carried out in patients with undiagnosed COPD, which is a major risk factor for PPCs.[36] Anaesthesia and surgery may aggravate pre-existing airway obstructions due to the influence on the respiratory system. FEV_1, which predicts the degree of respiratory impairment in patients with COPD, is a critical tool to evaluate a patient for thoracic surgery with preoperative FEV_1 less than 60% predicted strongly indicating PPCs and 30-day mortality.[37] The value of spirometry in

predicting PPCs after lung resection has been demonstrated by several retrospective studies.[19 38–40] However, the association between spirometry and perioperative respiratory complications in adults with mediastinal mass remains unclear.

One retrospective study evaluated the incidence of life-threatening perioperative respiratory complications in adult patients with mediastinal mass and studied the usefulness of PFTs in the determination of the perioperative risk.[41] A combination of obstructive and restrictive patterns was associated with a high rate of postoperative respiratory complications. However, the patients all had extensive surgery (thoracotomies and medial sternotomies). Currently, minimally invasive surgery has replaced median sternotomy for mediastinal masses and is performed by various approaches. Thus, the primary purpose of this study is to evaluate the association between preoperative spirometry tests and PPCs to provide targets for PPC prediction in patients scheduled for mediastinal mass resection surgery.

This study has several limitations. First, as clinical data were collected from electronic medical records, partially significant data will be lost and some patients will be excluded. However, the high-volume thoracic surgery centre ensures sufficient samples and credibility, which cover this deficiency to some extent. Although the retrospective cohort design will increase case numbers and statistical power, it may lead to selection and information bias. In addition, the study results will have unknown generalisability, in view of the single-centre setting, and may not be applicable outside of China. Nevertheless, our results can provide a clinical reference for other centres to predict PPC after mediastinal mass resection.

Contributors ZZ and YF contributed equally to conceiving this project, facilitating protocol and drafting this manuscript. Conceptualisation—ZZ, YF and NZ. Funding acquisition—ZW. Investigation and resources—ZZ, YF and JY. Project administration, validation, visualisation, writing of the original draft, review and editing—ZZ. Supervision—ZW.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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