Research Proposal

Effects of ultrasound-guided recruitment manoeuvres on postoperative pulmonary complications in OSA patients undergoing total laparoscopic hysterectomy: a randomized controlled trial

Applicant: The First Affiliated Hospital of Henan Medical University

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Introduction

Atelectasis occurs during general anesthesia in up to 90% of patients[1]. Atelectasis can occur during anesthesia induction and persist for up to two days postoperatively[2]. Clinical evidence has established its role in precipitating postoperative pulmonary complications (PPCs), with commonly observed manifestations ranging from pneumonia and pleural effusion to more severe conditions like pneumothorax and ARDS[3]. The use of anesthetic agents, pneumoperitoneum, changes in body positioning, and other factors can contribute to and exacerbate the development of atelectasis[4-8]. Due to factors such as increased BMI and reduced alveolar surfactant production in obese patients, atelectasis is more likely to occur during surgery[9]. In addition, a proportion of patients undergoing total laparoscopic hysterectomy are obese and have concomitant obstructive sleep apnea (OSA). The occurrence of sleep apnea in OSA patients postoperatively is a major cause of PPCs [10]. The administration of opioids during the perioperative period is associated with an increased incidence of apnoea.[11], further exacerbating the onset and progression of PPCs[12].

Lung-protective ventilation strategies have been developed to mitigate ventilator-associated lung injury and protect pulmonary tissue[13]. These strategies mainly include low tidal volume ventilation, individualized PEEP, recruitment maneuvers (RMs), and low plateau pressure. Currently, sustained inflation and incremental PEEP methods are commonly used for RMs. However, the optimal lung recruitment pressure during RM remains controversial, and blind recruitment may result in inadequate recruitment or excessive alveolar distention[14]. Additionally, excessive airway pressure during RM can elevate intrathoracic pressure, reduce venous return, and lead to significant fluctuations in the patient's hemodynamics[15].

Computed tomography (CT) is widely regarded as the gold standard for evaluating the effectiveness of RMs. However, due to its radiation risks, high cost, and limited intraoperative feasibility, it is not routinely used for evaluating RM during surgery. In previous studies, researchers have proposed using methods such as X-ray and

Electrical Impedance Tomography (EIT) to assess the effectiveness of RM[16 17]. However, there is still a lack of authoritative guidelines for evaluating RM.

As a diagnostic tool, ultrasound offers the advantages of being portable, non-invasive, free of ionising radiation, and capable of producing real-time images. It has been widely employed in operating rooms, intensive care units, and emergency departments. Studies have demonstrated that pulmonary ultrasound is a rapid and reliable method for identifying perioperative atelectasis, with a sensitivity exceeding 85%, and both specificity and accuracy rates exceeding 90%[18]. Ultrasound-guided RM can adjust parameters such as lung recruitment pressure, duration, and others based on individual patient characteristics, ensuring timely adaptation to meet the specific needs of each patient[19].

End-Expiratory Lung Volume (EELV) is defined as the volume of gas retained in the lungs at the end of expiration during mechanical ventilation, which is an important indicator reflecting the effectiveness of lung recruitment. By calculating the difference of EELV under various conditions, the change of lung volume after recruitment can be quantitatively evaluated, the alveolar volume after recruitment can be estimated, and the effectiveness of RM can be evaluated[20].

Therefore, we aim to evaluate the lung-protective effects of ultrasound-guided lung recruitment maneuvers in patients with OSA undergoing total laparoscopic hysterectomy and to explore the efficacy of EELV measurement in assessing the effectiveness of these maneuvers.

Method and analysis

Trial status

This study has been reviewed and approved by the ethics committee of the First Affiliated Hospital of Henan Medical University. Participant recruitment is scheduled to commence in May 2025, with an anticipated completion date of August 2026.

Study design and setting

We conducted a single-center, randomized controlled trial aimed at determining whether ultrasound-guided lung recruitment provides better recruitment outcomes and reduces the incidence of PPCs. Additionally, the study will explore the effectiveness of EELV measurement in evaluating RMs. This study will be carried out at the First Affiliated Hospital of Henan Medical University.

Eligibility criteria

Inclusion criteria

- Age ≥ 18 years;
- Scheduled for elective total laparoscopic hysterectomy;
- American Society of Anesthesiologists (ASA) I to III;
- BMI > 28 kg/m²;
- STOP-BANG score ≥ 3.

Exclusion criteria

- Abnormal findings on preoperative chest X-ray or CT, such as atelectasis, pneumothorax, thoracic deformity, pleural effusion, or neuromuscular diseases;
- Pre-existing severe pulmonary diseases;
- Severe cardiac arrhythmias or a history of cardiac surgery;
- Allergy to any medications used in the study.

Withdrawal Criteria:

- Severe subcutaneous emphysema interfering with lung ultrasound examination;
- Postoperative transfer to the ICU with tracheal intubation in place;
- Conversion from laparoscopic to open surgery during the procedure;
- Perioperative hemodynamic instability.

Randomization and blinding

This study will adopt a randomized, single-blind controlled trial design. According to CONSORT guidelines, we will allocate patients randomly to one of three groups based on a computer-generated randomization list: the SRM group (sustained inflation recruitment maneuver, n=30), the PRM group (incremental PEEP recruitment maneuver, n=30), and the LRM group (lung ultrasound-guided recruitment maneuver, n=30). Patients will remain blinded to their group assignments throughout the study.

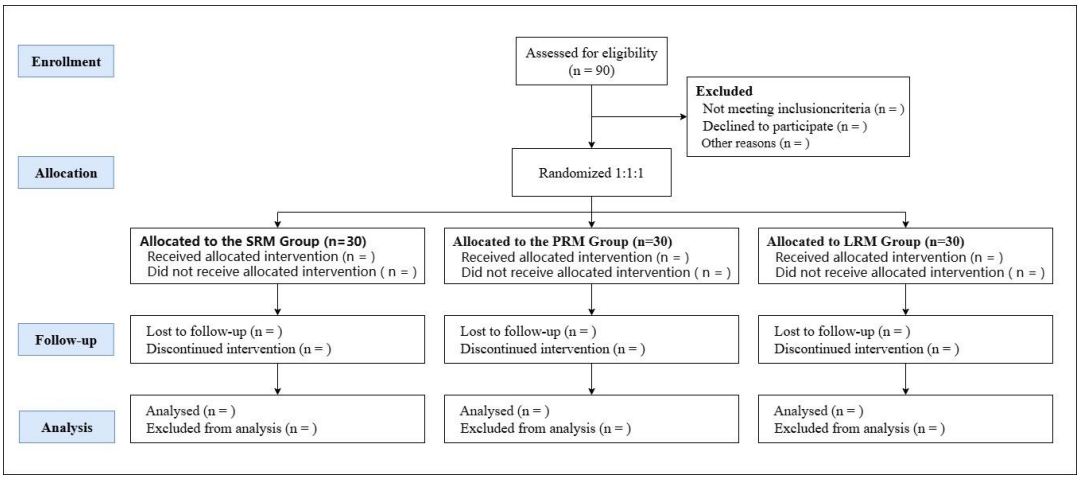

Fig. 1. CONSORT flow diagram

the SRM group (Sustained inflation recruitment maneuvers, n = 30);
the PRM group (Incremental PEEP recruitment maneuvers, n = 30);
the LRM group (Lung Ultrasound-guided recruitment maneuvers, n = 30)

Methods of the Trial

Anesthesia Protocol

Patients will not receive preoperative medication. Hemodynamic monitoring, including continuous electrocardiogram, non-invasive blood pressure, and pulse oximetry, is continuously monitored. After oxygenation with 100% oxygen via a face mask for 3 minutes, anesthesia induction will be performed with intravenous administration of midazolam (0.04–0.05 mg/kg), sufentanil (0.4–0.6 μg/kg), rocuronium (0.6 mg/kg), and etomidate (0.15–0.3 mg/kg). An appropriately sized reinforced endotracheal tube will be selected for intubation based on the patient's height.

During the maintenance of general anesthesia, 2% sevoflurane will be administered as the inhalation anesthetic, along with a continuous infusion of propofol (0.8–1.8 mg/kg/h) and remifentanil (0.1–0.3 μg/kg/h) using a micro-infusion pump. Rocuronium will be administered intermittently to maintain anesthesia. Intraoperative anesthetic dosing adjustments will be based on blood pressure, heart rate, and depth of anesthesia.

After tracheal intubation, the Dräger Primus anesthesia machine (Dräger, Germany) will be used in volume-controlled ventilation mode, with a tidal volume of 6-8 ml/kg of ideal body weight, FiO2 set to 0.5, I: E ratio set to 1:2, a respiratory rate of 12-18 breaths/min, and end-tidal carbon dioxide (PETCO2) maintained at 35-45 mmHg.

Radial artery puncture and catheterization for pressure monitoring will be performed at T1 (immediately after tracheal intubation), and 1 mL of arterial blood will be collected for blood gas analysis. An additional 1 mL of arterial blood will be collected for blood gas analysis at T5 (30 minutes after extubation).

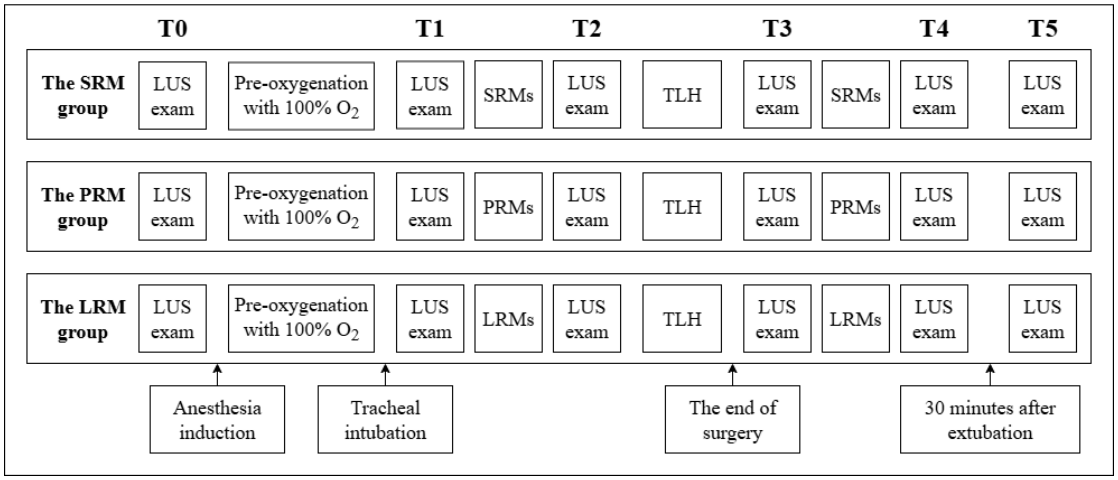

Fig. 2. Schematic diagram of the study protocol.

T0: before anesthesia induction; T1: immediately after tracheal intubation; T2: after the first lung recruitment; T3: immediately after the surgery; T4: after the second lung recruitment; T5: 30 minutes after extubation; SRMs: sustained inflation recruitment maneuver; PRMs: incremental PEEP recruitment maneuvers; LRMs: lung ultrasound-guided recruitment maneuvers; LUS: lung ultrasound; TLH: total laparoscopic hysterectomy.

Postoperative Follow-Up

Postoperative follow-up will monitor the occurrence of pulmonary complications, including pneumonia, atelectasis, and incision infections, within three days. The ARISCAT score, the Clinical Pulmonary Infection score, and the Quality of Recovery-15 scale will also be recorded.

Lung Recruitment Methods

The SRM group (Sustained inflation recruitment maneuver): The APL valve on the anesthesia machine will be adjusted to 30 cmH_2O, and the rapid oxygen inflow valve will be pressed to increase the pressure to the maximum, maintaining the pressure for 30 seconds.

The PRM group (Incremental PEEP recruitment maneuver): Starting from 5 cmH_2O, PEEP will be titrated upwards in 5 cmH_2O increments every 30 seconds until a

maximum of 30 cmH_2O is reached. After maintaining for 40 seconds, PEEP will be decreased by 5 cmH_2O every 30 seconds until it returns to the pre-recruitment level.

The LRM group (Lung ultrasound-guided recruitment maneuver): Lung ultrasound will be performed on patients. If any lung region has an LUS score ≥ 2, ultrasound-guided RM will be performed; otherwise, no operation will be conducted. After the ultrasound examination, the probe will be positioned over the lung region exhibiting the most severe aeration loss (highest LUS) to guide the RMs. The ventilator will be set to pressure-controlled ventilation (PCV), maintaining the inspiratory pressure at 40 cmH_2O. PEEP will be gradually increased from 5 cmH_2O, with increments of 5 cmH_2O every 5-10 seconds, until ultrasound shows no atelectatic areas. The pressure will be maintained at 40 cmH_2O for 40 seconds. An airway pressure ceiling of 40 cmH_2O will be established, and the pressure and the time used for the RM will be recorded.

Measurement of Recruitment Volume

After performing the RMs in the PRM group and LRM group, the respiratory rate will be adjusted to 6 breaths per minute. Record the PEEP ($PEEP_1$) used during RM. The exhaled tidal volume (VT_1) will be recorded. Then, PEEP will be adjusted to 5 cmH_2O ($PEEP_2$), and the expiratory tidal volume (VT_2) will be recorded. The difference between VT_1 and VT_2 will be calculated as ΔEELV. Baseline tidal volume and airway pressure will be recorded immediately before the RMs. The recruitment volume will be calculated using the following formula[20 21].

$$Recruitment\ volume = (VT_2 - VT_1) - [VT_1 / (Plat - PEEP_2)] \times (PEEP_1 - PEEP_2)$$

Lung Ultrasound Examination

Lung ultrasound will be performed on the patient by using a convex probe at the following time points: before anesthesia induction (T0), immediately after tracheal intubation (T1), after the first lung recruitment (T2), immediately after the surgery (T3), after the second lung recruitment (T4), and 30 minutes after extubation (T5).

Each lung will be divided into six regions (L1-L6, R1-R6) based on three vertical lines (the parasternal line, the anterior axillary line, and the posterior axillary line) and two horizontal lines (the nipple line and the diaphragm line). Each region will be scored by using the LUS Score proposed by Monastesse et al.[22], which has demonstrated sufficient sensitivity for detecting the occurrence of atelectasis during laparoscopic surgery. Lung ultrasound examination will be performed by two anesthesiologists independently, and the final score will be the average of the scores given by both anesthesiologists.

Outcome Assessment

The primary outcome is the lung ultrasound score (LUS), which will be measured at time points T1 through T5.

Secondary outcomes include the recruitment volume, as measured by the ΔEELV method.

Data collection

Data collection will adhere to standardized operating procedures to ensure accuracy and reliability. We will collect preoperative information, including age, ASA classification, height, weight, STOP-BANG score, and calculate BMI and ideal body weight. We will also record intraoperative information, including intraoperative fluid volume, blood loss, surgery duration, pneumoperitoneum duration, pneumoperitoneum pressure, anesthesia duration, mechanical ventilation time, PACU stay time, and pre- and post-recruitment blood pressure, heart rate, peak airway pressure, plateau airway pressure, arterial oxygen partial pressure, arterial carbon dioxide partial pressure, hospital length of stay, the ARISCAT score, the Clinical Pulmonary Infection score (CPIS), and the quality of recovery-15 scale (qor-15). Additionally, we will calculate the oxygenation index, dynamic lung compliance, alveolar-arterial oxygen pressure gradient, respiratory index, and dead space ventilation.

Statistical Analysis

Statistical analysis will be performed with the SPSS 26.0 software. Data for normally distributed continuous variables are presented as the mean ± standard deviation ($\bar{x} \pm s$). For non-normal data, express it as the median (*M*) and interquartile range (*IQR*). The paired sample t-test will be used to compare the repeated measurements of the normal distribution at different time points. Continuous variables that are not normally distributed will be compared using the rank-sum test. Categorical data will be expressed as frequencies and compared by the Chi-square test. Statistical significance will be defined as a *p*-value < 0.05.

Sample size estimation

The calculation of the sample size is based on the primary outcome. Based on the previous studies[23], at the end of the surgery, the LUS score of patients undergoing ultrasound-guided recruitment maneuver was 7.67±1.15, while that of patients using sustained inflation was 9.70±1.02. We assume that the recruitment effects of the incremental PEEP method and sustained inflation method are the same. Assuming a significance level of $\alpha = 0.05$, a power of $\beta = 0.1$, a dropout rate of 20%, a total of 90 participants were required, as calculated using PASS 15.0 software.

Ethics and dissemination

This study protocol was approved by the Ethics Committee of the First Affiliated Hospital of Henan Medical University on April 22, 2025 (EC-025-117). Written informed consent will be obtained from all participants. The results of this study will be disseminated through publication in internationally peer-reviewed scientific journals.

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