Research Protocol

Effect of Different Inspired Oxygen Concentrations on Intraoperative Lung Recruitment Efficacy in Patients Undergoing Abdominal Surgery

Sponsoring Institution: Northern Jiangsu People's Hospital

Leading Institution: NA

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1. Protocol Summary

Item	Details
Project Name	Effect of Different Inspired Oxygen Concentrations on Intraoperative Lung Recruitment Efficacy in Patients Undergoing Abdominal Surgery
Research Objective	To investigate the effect of different inspired oxygen concentrations on intraoperative lung recruitment efficacy in patients undergoing abdominal surgery
Study Design	A single-center, prospective, randomized controlled studyStudy population: Patients undergoing elective abdominal surgeryTrial protocol: Primary outcome measure: Time to recovery of lung compliance; Secondary

	outcome measures: Comparison of oxygenation index before anesthesia induction and after extubation, degree of atelectasis at the end of surgery, incidence of hypoxemia during PACU stay, and incidence of pulmonary complications within 3 days after surgery.
Sample Size	88 casesSample size calculation process Based on preliminary experimental results, sample size was calculated using PASS, with a 20% dropout rate, resulting in a total sample size of 88 cases (22 cases in each group). Input： Power and Alpha Power 0.95 Alpha 0.05 Group 4 Group Allocation Equal Effect size Means 30 34 50 53 K 1 σ 7 6 15 19 **Numeric Results** Means: 30 34 50 53 **Power** / **Average n** / **G** / **Total N** / **K** / **Std Dev of Means σm** / **Standard Deviation σ** / **Effect Size** / **Alpha** 0.9707 / 3.00 / 4 / 12 / 1.00 / 9.91 / 6.00 / 1.6515 / 0.0500 0.9875 / 4.00 / 4 / 16 / 1.00 / 9.91 / 7.00 / 1.4156 / 0.0500 0.9526 / 11.00 / 4 / 44 / 1.00 / 9.91 / 15.00 / 0.6606 / 0.0500 0.9526 / 17.00 / 4 / 68 / 1.00 / 9.91 / 19.00 / 0.5215 / 0.0500 **One-Way Analysis of Variance F-Tests** **Dropout-Inflated Sample Size (Continued)** **Average Group Sample Size n** / **Group** / **Dropout Rate** / **Sample Size Ni** / **Dropout-Inflated Enrollment Sample Size Ni'** / **Expected Number of Dropouts Di** 17.00 / 1 - 4 / 20% / 17 / 22 / 5 Total / 68 / 88 / 20
Case Selection	Target population: Patients undergoing abdominal surgery
	Inclusion CriteriaPatients with ASA physical status Ⅰ-Ⅱ;Patients who voluntarily participate in the study and sign the informed consent form;Patients undergoing elective abdominal surgery under general anesthesia;Gender 不限，aged 18-64 years, BMI 18-25 kg/m²;Expected operation time ≥1.5 hours, and intraoperative blood loss ≤500 ml.

	Exclusion CriteriaPrevious thoracic surgery; chest X-ray or CT indicating pneumothorax or pulmonary bullae;Pulmonary diseases: chronic bronchitis, asthma, moderate to severe obstructive ventilatory dysfunction; preoperative pulse oxygen saturation (SpO2) <90% in room air or <95% with oxygen inhalation; contraindications to lung recruitment: high intracranial pressure, hypovolemic shock, right heart failure;Severe heart disease (New York Heart Association, NYHA class III or IV; acute coronary syndrome or persistent ventricular tachyarrhythmia);Participation in other interventional studies or refusal to enroll.
Treatment Protocol	None
Efficacy Evaluation	Efficacy evaluation indicators (primary and secondary efficacy indicators)Primary outcome indicator: Time for dynamic lung compliance (Cdyn) to return to baseline after lung recruitment;Secondary outcome indicators: Degree of atelectasis immediately after extubation, evaluated by lung ultrasound; oxygenation index at T0-T5; incidence of hypoxemia and duration of oxygen therapy during PACU stay; pulmonary complications within 3 days after surgery, evaluated by postoperative chest X-ray or CT, with atelectasis assessed by lung ultrasound.
	Safety evaluation indicators: None
Statistical Methods	Descriptive statistics, Mann-Whitney U test, t-test, Chi-square test, etc.

2. Research Background

During perioperative mechanical ventilation, high fractional inspired oxygen (FiO2) is usually administered to prevent hypoxemia. Although numerous studies have shown that the use of high FiO2 during surgery can improve oxygen supply to vital organs such as the heart, brain, and kidneys, inhalation of high-concentration oxygen is also a risk factor for postoperative pulmonary complications. Therefore, there is no consensus on the optimal intraoperative FiO2 setting[1].

Lung recruitment typically includes manual lung recruitment and ventilator-driven lung recruitment, with the latter including vital capacity maneuver, pressure-controlled method, and volume-controlled method. Various lung recruitment methods can effectively open alveoli and improve oxygenation[3].

Evaluation of lung recruitment efficacy includes pressure-volume (P-V) curve, electrical impedance tomography (EIT), and lung ultrasound (LUS).

The P-V curve describes the relationship between airway pressure and tidal volume, reflecting the mechanical properties of the lungs and chest wall, and can assist in judging the

ventilation status of the lungs. A normal P-V curve is "S"-shaped, with the zero point representing functional residual capacity (FRC), and the volume change range being tidal volume. The P-V curve is an effective bedside tool for evaluating respiratory mechanics and lung recruitment efficacy.

The basic principle of EIT is to apply weak voltage and current to the human body through local electrodes, sense changes in internal bioelectrical impedance, and reconstruct internal structure images using algorithms. High extracellular fluid content, high electrolyte concentration, large cell volume, and multiple intercellular connections reduce impedance, while adipose tissue, bone, and air increase impedance. This method is non-invasive, simple, and provides rich information, and can be used for bedside detection and monitoring. Gas has high impedance, and blood flow has low impedance; thoracic impedance changes with ventilation and blood flow. Moreover, lung tissue is close to the body surface, so changes in lung volume and conductivity can be easily detected. In animal models, indicators such as ventilation center shift, compliance of dependent and non-dependent lung regions, and tidal distribution index on EIT can assist in judging changes in local ventilation distribution during lung recruitment[4]. Spadaro et al. dynamically monitored the ventilation status of the gravity-dependent static lung zone (DSS) using EIT and evaluated lung recruitment efficacy using the P-V curve. During lung recruitment, with the increase of PEEP, DSS decreased while lung recruitment volume increased. The opposite change occurred when PEEP decreased. DSS was correlated with changes in lung recruitment volume ($r=0.734$, $P<0.001$). EIT can calculate the compliance of local lung regions to judge the impact of PEEP on local alveolar ventilation and can also be used for titrating individualized PEEP.

Although computed tomography (CT) is considered the "gold standard" for evaluating lung recruitment efficacy, its high requirements for equipment and site, as well as large radiation dose, limit its use. LUS can also be used to check the ventilation status of the lungs, because diseases change the ratio of gas to fluid in the lungs, and LUS shows corresponding signs such as tissue-like changes and "fragment sign". Quantitative evaluation can also be performed using LUS scores. Song et al.[5] used ultrasound-guided lung recruitment in children under 1 year old, which significantly reduced the incidence of atelectasis. Wu et al.[6] compared the effects of ultrasound-guided lung recruitment, manual lung recruitment, and mechanical ventilation without lung recruitment in laparoscopic gynecological surgery, and the results showed that lung recruitment improved intraoperative oxygenation and reduced LUS scores, with the ultrasound-guided group having the best effect. Even 30 minutes after tracheal extubation, the difference in LUS scores between groups remained significant. However, no differences were observed in PPC, postoperative pain, or postoperative hospital stay, which may be related to normal preoperative lung function and short operation time in all patients.

Most current studies tend to inhale low-concentration oxygen while ensuring adequate oxygenation. Studies have shown that inhalation of high-concentration oxygen during surgery and before extubation can lead to postoperative atelectasis and even impair postoperative oxygenation function. However, blindly reducing FiO_2 before extubation may bring troubles to crisis management after extubation, and it is not beneficial to blindly reduce FiO_2 without ensuring adequate airway patency[7]. Studies have shown that applying 10 cmH_2O continuous positive airway pressure before and during induction, and 10 cmH_2O

PEEP during surgery can improve oxygenation function in patients undergoing laparoscopic surgery. This seems to suggest that if high-concentration oxygen is inhaled during surgery, alveolar patency can be maintained by applying continuous positive airway pressure, and then FiO2 can be gradually reduced to reduce the risk of postoperative atelectasis and hypoxemia.

Dynamic lung compliance can monitor alveolar changes in real-time, which is of great significance for evaluating intraoperative lung function. The value of compliance represents the number of gas-containing alveoli; the more alveoli collapse, the less gas-containing tissue, and the lower the compliance, which can objectively reflect lung function. With the continuous development of medical technology, laparoscopic surgery has become increasingly popular. Studies have found that intraoperative pneumoperitoneum can increase intra-abdominal pressure, cause diaphragmatic elevation, significantly reduce end-expiratory lung volume, and abnormal distribution of ventilation/perfusion ratio. In gynecological laparoscopic surgery, patients usually adopt the Trendelenburg position. Under the influence of gravity, the Trendelenburg position further exacerbates the compression of the diaphragm, leading to alveolar collapse, further reduction of functional residual capacity and dynamic lung compliance, and increased risk of postoperative atelectasis[2].

As part of the lung-protective ventilation strategy, lung recruitment has been widely used. However, there is no unified consensus on lung recruitment strategies in current international guidelines. The time for lung compliance to return to baseline after lung recruitment is unclear, and the optimal inspired oxygen concentration that can benefit patients from lung recruitment is uncertain. Based on this, this study intends to evaluate the effect of different inspired oxygen concentrations on lung recruitment efficacy in patients undergoing abdominal surgery.

3. Research Objectives

3.1 Primary objective: To investigate the effect of different inspired oxygen concentrations on the time for lung compliance to return to baseline after lung recruitment in patients undergoing abdominal surgery;

3.2 Secondary objectives: To explore the comparison of oxygenation index before anesthesia induction and after extubation, incidence of hypoxemia during PACU stay, incidence of atelectasis after extubation, and incidence of pulmonary complications within 3 days after surgery in patients undergoing abdominal surgery with different inspired oxygen concentrations after lung recruitment;

4. Study Design, Principles, and Procedures

4.1 Study Design

Study design type: A single-center, prospective, randomized controlled study

Grouping method: Patients were randomly divided into 4 groups using a random number table method: Group A, Group B, Group C, and Group D, with 22 cases in each group.

Randomization was generated by computer using R software (version 3.5.1, R Foundation for Statistics Computing, Vienna, Austria). An assistant not involved in the study concealed the allocation in opaque envelopes and handed them to the attending anesthesiologist before general anesthesia induction. The ultrasound examiner (BRK or HB) was completely blinded to group allocation.

Blinding level: Blinding was applied to subjects and data collectors

Study center: Northern Jiangsu People's Hospital

Rationality of indications: Lung recruitment is a mechanical ventilation scheme proposed for alveolar collapse, which fully opens alveoli by means of continuous high airway pressure or intermittent increase of alveolar peak pressure, and applies appropriate positive end-expiratory pressure to maintain alveolar patency to improve oxygenation in patients.

4.2 Study Procedures

Study population: Patients undergoing elective abdominal surgery

Grouping: Group A: FiO2=30% (if SpO2<94%, increase FiO2; if FiO2≥40%, the patient was excluded); Group B: FiO2=40%; Group C: FiO2=60%; Group D: FiO2=80%. Inspired oxygen concentrations were adjusted to the respective group levels after the start of surgery.

Trial protocol: Patients entered the operating room, preoxygenated for 3 minutes, followed by anesthesia induction. After the drugs took full effect, tracheal intubation was performed. Inspired oxygen concentrations were adjusted to the respective group levels after the start of surgery. The first lung recruitment was performed 10 minutes later. The second lung recruitment was performed after lung compliance returned to baseline. All patients underwent lung recruitment immediately at the end of surgery. Respiratory mechanics parameters, hemodynamic parameters, etc., were recorded. The incidence of hypoxemia during PACU stay and postoperative atelectasis evaluated by ultrasound were recorded.

4.3 Indications

Atelectasis after general anesthesia

4.4 Study Endpoints

Incidence of pulmonary complications within 3 days after surgery.

5. Study Subjects

5.1 Study Population

Patients undergoing elective abdominal surgery;

5.2 Inclusion Criteria

Patients with ASA physical status Ⅰ-Ⅱ;

Patients who voluntarily participate in the study and sign the informed consent form;

Patients undergoing elective abdominal surgery under general anesthesia;

Gender unlimited, aged 18-64 years, BMI 18-25 kg/m²;

Expected operation time ≥1.5 hours, and intraoperative blood loss ≤500 ml.

5.3 Exclusion Criteria

Previous thoracic surgery; chest X-ray or CT indicating pneumothorax or pulmonary bullae;

Pulmonary diseases: chronic bronchitis, asthma, moderate to severe obstructive ventilatory dysfunction; preoperative pulse oxygen saturation (SpO2) <90% in room air or <95% with oxygen inhalation; contraindications to lung recruitment: high intracranial pressure, hypovolemic shock, right heart failure;

Severe heart disease (New York Heart Association, NYHA class III or IV; acute coronary syndrome or persistent ventricular tachyarrhythmia); participation in other interventional studies or refusal to enroll.

5.4 Exclusion Criteria

In Group A (FiO2=30%), if SpO2<94%, FiO2 was increased; if FiO2≥40%, the patient was excluded.

5.5 Recruitment Process

Subjects were visited one day before surgery to understand whether their medical history met the inclusion and exclusion criteria. After confirmation, the experimental process and anesthesia method were communicated with the family members. If the subjects and their families agreed, the anesthesia consent form and clinical trial informed consent form were signed. Eligible subjects were enrolled and randomly grouped.

5.6 Criteria for Terminating the Study

Considerations for the safety of subjects. For example, situations where it is inappropriate to continue the study, including: worsening of the condition, serious adverse events, poor compliance, etc. Postoperative occurrence of surgery-related complications such as postoperative bleeding requiring reoperation should result in termination of the study.

6. Research Methods and Technical Route

6.1 Study Grouping

Grouping: Group A: FiO2=30% (if SpO2<94%, increase FiO2; if FiO2≥40%, the patient was excluded); Group B: FiO2=40%; Group C: FiO2=60%; Group D: FiO2=80%. Inspired oxygen concentrations were adjusted to the respective group levels after the start of surgery.

6.2 Intervention Measures

Lung recruitment

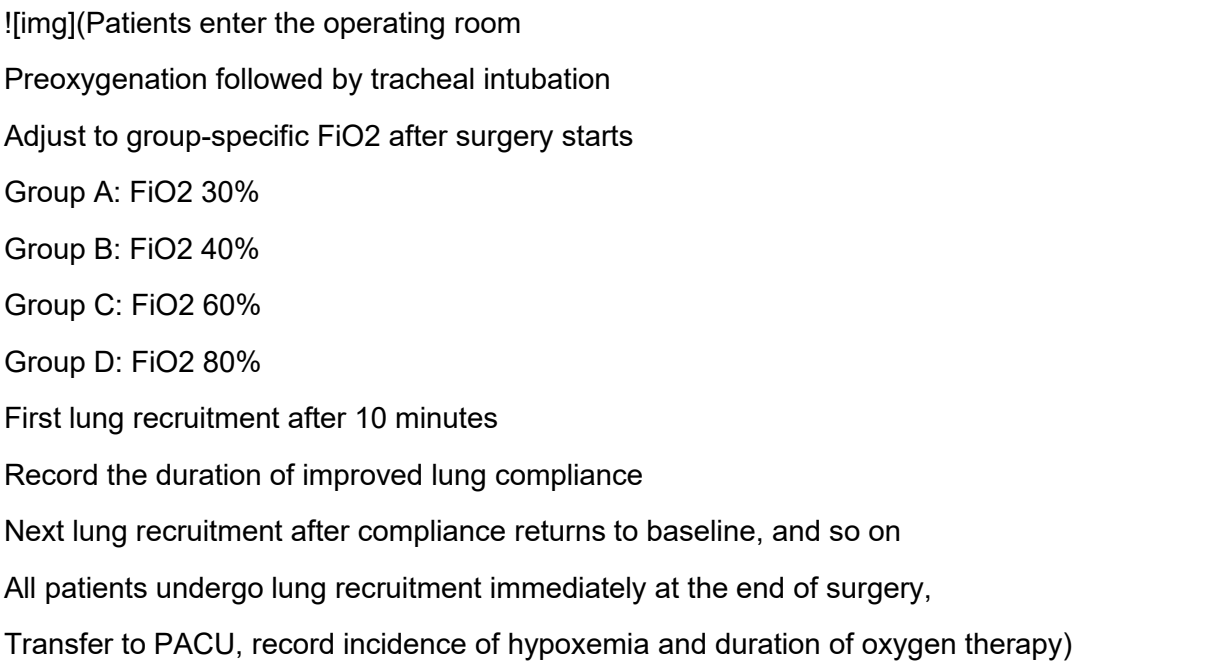
6.3 Study Intervention Protocol

Patients entered the operating room, preoxygenated for 3 minutes, followed by anesthesia induction. After the drugs took full effect, tracheal intubation was performed. Inspired oxygen concentrations were adjusted to the respective group levels after the start of surgery. The first lung recruitment was performed 10 minutes later. The second lung recruitment was performed after lung compliance returned to baseline. Respiratory mechanics parameters, hemodynamic parameters, etc., were recorded. The incidence of hypoxemia during PACU stay and postoperative atelectasis evaluated by ultrasound were recorded.

6.4 Concomitant Medications

There were no concomitant medications in this study.

6.5 Study Flowchart



6.6 Study-Related Laboratory Tests

Liver and kidney function, blood routine, coagulation function, blood gas analysis

6.7 Study-Related Imaging Examinations

Electrocardiogram

7. Efficacy Evaluation Criteria

Observation of primary outcome indicators: Time for dynamic lung compliance (Cdyn) to return to baseline after lung recruitment. Respiratory mechanics parameters and hemodynamic parameters at T1-T5 were recorded, including Cdyn, PIP, Ppeak, Pplat, Vt, PEEP, MP, Pdrive, BP, HR;

Observation of secondary outcome indicators: Degree of atelectasis immediately after extubation, evaluated by lung ultrasound; oxygenation index at T0-T5; incidence of hypoxemia and duration of oxygen therapy during PACU stay; pulmonary complications within 3 days after surgery, evaluated by postoperative chest X-ray or CT, with atelectasis assessed by lung ultrasound.

8. Observation Items and Detection Time Points

Before the first lung recruitment (RM1) after surgery starts (T1), immediately after RM1 (T2), before RM2 (T3), immediately after RM2 (T4), and immediately at the end of surgery (T5). Primary and secondary outcome indicators were observed. Degree of atelectasis immediately after extubation, evaluated by lung ultrasound; oxygenation index at T0-T5; incidence of hypoxemia and duration of oxygen therapy during PACU stay; pulmonary complications within 3 days after surgery, evaluated by postoperative chest X-ray or CT, with atelectasis assessed by lung ultrasound.

9. Observation of Adverse Events

9.1 Definition and Assessment of Adverse Events

Adverse Event (AE) refers to any untoward medical event that occurs after a subject receives the investigational product, which may present as symptoms, signs, diseases, or abnormal laboratory tests, but is not necessarily causally related to the investigational product.

Serious Adverse Event (SAE) refers to an adverse medical event that occurs after a subject receives the investigational product, including death, life-threatening conditions, permanent or severe disability or functional loss, need for hospitalization or prolongation of hospitalization, and congenital anomalies or birth defects.

Adverse Drug Reaction (ADR) refers to any harmful or unintended reaction that may be related to the investigational product in clinical trials. There is at least a reasonable possibility of a causal relationship between the investigational product and the adverse event, i.e., the correlation cannot be excluded.

Suspected Unexpected Serious Adverse Reaction (SUSAR) refers to a suspected and unexpected serious adverse reaction whose nature and severity exceed the information in the investigator's brochure, labeling, or product characteristic summary of the investigational drug.

Investigators will closely observe adverse events in subjects. All adverse events reported by subjects or observed by investigators from randomization to the end of the study or early withdrawal must be recorded in medical records or CRFs, including laboratory and auxiliary examinations, and at least include the name of the AE, time of occurrence, end time,

severity, whether corrective treatment was given, outcome, and causal relationship with the study.

During the study, changes in vital signs, physical examinations, clinical manifestations, and laboratory tests of subjects should be evaluated. When signing the informed consent form, the name and phone number of the researcher whom the subject can contact in case of emergency, or when reporting any medical symptoms or subject-related AEs, must be provided. Pre-existing toxic reactions or AEs in subjects before participating in the clinical study are only recorded as AEs if the grade increases by one or more levels compared with the baseline assessment results during the study.

CTCAE Grade	Equivalent	Definition
Grade 1	Mild	Mild physical discomfort, not affecting daily life and function
Grade 2	Moderate	Physical discomfort, affecting daily life and function, no indication for treatment
Grade 3	Severe	Symptomatic, affecting daily life and function, with indication for treatment
Grade 4	Life-threatening/disability/functional loss	Life-threatening, with indication for emergency treatment, physical disability or intellectual impairment
Grade 5	Death	Adverse event resulting in death

AE and Study Correlation Analysis Table

	Definite	Probable	Possible	Suspected	Impossible
Reasonable time sequence with	+	+	+	+	-

medication/intervention					
Known drug/reaction type	+	+	+	+	-
Symptom relief or disappearance after stopping intervention	+	+	±	±	-
Recurrence of reaction after re-intervention	+	?	?	?	-
Cannot be explained by disease or concomitant medication	+	+	-	±	-

9.2 Recording and Handling of Adverse Events

9.2.1 Recording of Adverse Events

While observing efficacy, investigators should pay attention to adverse events or reactions. Investigators should explain to subjects and require them to truthfully report changes in their condition after medication, avoiding leading questions.

All adverse events, whether related to the trial drug or not, should be recorded in detail. Investigators should closely monitor clinical and laboratory evidence of adverse events in each patient, including the date of occurrence, symptoms, laboratory test results, severity, outcome, duration, and results of the event, and fill in the "Adverse Event Form". Investigators should promptly judge the causal relationship between the adverse event and the study drug and analyze the correlation between the adverse event and the trial drug. Concomitant medications should be recorded in detail, along with signatures and dates.

9.2.2 Handling of Adverse Events

9.2.3 Reporting of Adverse Events

Adverse events include intraoperative hypotension, bradycardia, hypoxemia, etc.

10. Quality Control and Quality Assurance

Investigators visited subjects one day before surgery to understand their medical history. Eligible subjects were enrolled only after obtaining their informed consent in strict accordance with the inclusion and exclusion criteria. If serious adverse events occurred during surgery, the trial should be stopped immediately.

11. Data Safety Monitoring

A data safety monitoring plan corresponding to the risk level will be formulated for the clinical study. All adverse events are recorded in detail, properly handled, and followed up until they are properly resolved or the condition is stable. Serious adverse events and unexpected events are reported to the ethics committee, competent authorities, sponsors, and drug regulatory authorities in a timely manner in accordance with regulations; the principal investigator regularly reviews all adverse events cumulatively, and if necessary, holds an investigator meeting to evaluate the risks and benefits of the study; emergency unblinding can be performed in double-blind trials to ensure the safety and rights of subjects; studies with greater than minimal risk will arrange independent data monitors to monitor study data, and high-risk studies will establish an independent data safety monitoring committee to monitor accumulated safety and efficacy data to make recommendations on whether to continue the study.

12. Statistical Analysis

12.1 Statistical Methods

All data were statistically analyzed using SPSS 26.0 software, with $P<0.05$ indicating a statistically significant difference. Count data were expressed as cases or percentages and analyzed using the Chi-square test or Fisher's exact test. Normality of measurement data was evaluated using the Kolmogorov-Smirnov test or Shapiro-Wilk test. Measurement data conforming to a normal distribution were expressed as mean ± standard deviation ($x\pm s$) and analyzed using the t-test; count data with repeated measurements were analyzed using one-way ANOVA; skewed or unknown-distribution measurement data were expressed as median (interquartile range) [median (IQR)] and analyzed using the Mann-Whitney U test.

12.2 Sample Size Calculation Process

88 casesSample size calculation process Based on preliminary experimental results, sample size was calculated using PASS, with a 20% dropout rate, resulting in a total sample size of 88 cases (22 cases in each group).

Input：

Power and Alpha

Power 0.95

Alpha 0.05

Group 4

Group Allocation Equal

Effect size

Means 30 34 50 53

K 1

σ 7 6 15 19

Numeric Results
Means: 30 34 50 53

Power	Average n	G	Total N	K	Std Dev of Means σm	Standard Deviation σ	Effect Size	Alpha
0.9707	3.00	4	12	1.00	9.91	6.00	1.6515	0.0500
0.9875	4.00	4	16	1.00	9.91	7.00	1.4156	0.0500
0.9526	11.00	4	44	1.00	9.91	15.00	0.6606	0.0500
0.9526	17.00	4	68	1.00	9.91	19.00	0.5215	0.0500

One-Way Analysis of Variance F-Tests

Dropout-Inflated Sample Size (Continued)

Average Group Sample Size n	Group	Dropout Rate	Sample Size Ni	Dropout-Inflated Enrollment Sample Size Ni'	Expected Number of Dropouts Di
17.00	1 - 4	20%	17	22	5
	Total		68	88	20

13. Ethics of Clinical Research

The clinical study will follow the World Medical Association Declaration of Helsinki and other relevant regulations. Before the start of the study, the trial protocol will be implemented only after approval by the ethics committee. Before each subject is enrolled in the study, the investigator is responsible for fully and comprehensively introducing the purpose, procedures, and possible risks of the study to the subject or their agent, and a written informed consent form will be signed. Subjects should be informed that they have the right to withdraw from the study at any time. The informed consent form should be retained as a clinical study document for reference. The privacy and data confidentiality of subjects will be protected during the study.

14. Collection and Storage of Samples/Specimens

None.

15. Study Progress

Not available.

16. References

[1] Young CC, Harris EM, Vacchiano C, Bodnar S, Bukowy B, Elliott RRD, Migliarese J, Ragains C, Trethewey B, Woodward A, Gama de Abreu M, Girard M, Futier E, Mulier JP, Pelosi P, Sprung J. Lung-protective ventilation for the surgical patient: international expert panel-based consensus recommendations. Br J Anaesth. 2019 Dec;123(6):898-913. doi: 10.1016/j.bja.2019.08.017. Epub 2019 Oct 3. PMID: 31587835.

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laparoscopic pelvic surgery in children: a prospective observational study. Can J Anaesth. 2015 Jul;62(7):798-806. doi: 10.1007/s12630-015-0369-0. Epub 2015 Apr 23. PMID: 25902890.

[3] Young CC, Harris EM, Vacchiano C, Bodnar S, Bukowy B, Elliott RRD, Migliarese J, Ragains C, Trethewey B, Woodward A, Gama de Abreu M, Girard M, Futier E, Mulier JP, Pelosi P, Sprung J. Lung-protective ventilation for the surgical patient: international expert panel-based consensus recommendations. Br J Anaesth. 2019 Dec;123(6):898-913. doi: 10.1016/j.bja.2019.08.017IF: 9.1 Q1 . Epub 2019 Oct 3. PMID: 31587835.

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Applicant's Commitment:

I guarantee the authenticity of the application content. I will perform the duties of the principal investigator, strictly abide by the relevant national regulations on clinical research, effectively ensure the time for research work, conscientiously carry out the work, submit relevant materials on time, and consciously submit relevant reports during the research process in accordance with the requirements of the ethics committee approval. I will bear full responsibility for any false information and violations of regulations.

Principal Investigator's Signature:

Date:

Informed Consent Form

Dear Lady/Sir,

We are about to conduct a study on the impact of different inhaled oxygen concentrations on the efficacy of intraoperative lung recruitment in patients undergoing abdominal surgery. You may meet the inclusion criteria for this study, so we invite you to participate. This study has been reviewed and approved by the (Medical Ethics Committee of Subei People's Hospital). The department responsible for conducting the study is the Department of Anesthesiology, and the principal investigator is Gao Ju.

This informed consent form will introduce you to the purpose, steps, benefits, risks, inconveniences or discomforts you may bear, and major matters of the study. It will also inform you of other available treatment options and your right to withdraw from the study at any time. Please read it carefully and make a prudent decision on whether to participate. When the responsible doctor explains and discusses the informed consent form with you, you can ask questions at any time and ask him/her to explain what you don't understand. You can discuss it with your family, friends and your doctor before making a decision. Your signature will not deprive you of any legal rights. The original signed informed consent form will be kept by the researcher, and you will receive a copy.

I. Research Background

During perioperative mechanical ventilation, a relatively high FiO is usually given to prevent hypoxemia. Although many studies have shown that the use of a high intraoperative FiO can improve oxygen supply to important organs such as the heart, brain and kidneys, inhalation of high-concentration oxygen is also a risk factor for postoperative pulmonary complications. Therefore, there is no consensus on the optimal setting of intraoperative FiO . Dynamic lung compliance can monitor alveolar changes in real time, which is of great significance for evaluating the lung function of patients during surgery. The value of compliance represents the number of gas-containing alveoli. The more alveoli collapse, the fewer gas-containing tissues, and the lower the compliance, which can objectively reflect the lung function.

Lung recruitment, as part of the lung-protective ventilation strategy, has been widely used. However, the duration of improved lung compliance after lung recruitment is unclear, and the optimal inhaled oxygen concentration that can benefit patients from lung recruitment is uncertain. Based on this, this study intends to evaluate the impact of different inhaled oxygen concentrations on the efficacy of lung recruitment in patients undergoing abdominal surgery.

II. Research Purpose

To explore the impact of different inhaled oxygen concentrations on the efficacy of intraoperative lung recruitment in patients undergoing abdominal surgery.

III. Eligibility Criteria for Participating in the Study

1. Patients with ASA classification Ⅰ-Ⅱ;
2. Those who voluntarily participate in this study by signing the informed consent form;
3. Patients undergoing elective general anesthesia for abdominal surgery;
4. No gender restriction, aged 18-64 years, with BMI 18-25 kg/m^2;
5. Expected operation time ≥ 1.5 hours, and intraoperative bleeding ≤ 500 ml.

Exclusion criteria:

6. Previous thoracic surgery; chest X-ray or CT indicating pneumothorax or pulmonary bulla;
7. Pulmonary diseases: chronic bronchitis, asthma, moderate to severe obstructive ventilatory dysfunction; preoperative pulse oxygen saturation (SpO_2) < 90% in room air or SpO_2 < 95% with oxygen inhalation; contraindications to lung recruitment: high intracranial pressure, hypovolemic shock, right heart failure;
8. Severe heart disease (New York Heart Association, NYHA III or IV; acute coronary syndrome or persistent ventricular tachyarrhythmia);
9. Participation in other interventional studies or refusal to enroll.

IV. Number of Participants in the Study

This study plans to recruit 88 subjects.

V. Is It Mandatory to Participate in and Complete This Study?

Your participation in this study is entirely voluntary. If you decide to participate, you will be required to sign the informed consent form and receive a copy. If you participate, you can still request to withdraw at any time, and your withdrawal will not affect your standard treatment.

VI. Research Process

Research Objects: Patients undergoing elective abdominal surgery.

Grouping: Group A: FiO_2 = 30%. If SpO_2 < 94%, increase FiO_2; if FiO_2 ≥ 40%, the patient will be excluded. Group B: FiO_2 = 40%; Group C: FiO_2 = 60%; Group D: FiO_2 = 80%. The inhaled oxygen concentration of each group will be adjusted 10 minutes after the start of the operation.

Experimental Protocol: After the patient enters the operating room, preoxygenation is performed for 3 minutes, followed by induction of anesthesia. After the drugs have fully taken effect, tracheal intubation is performed. The inhaled oxygen concentration of each group is adjusted 10 minutes after the start of the operation. The first lung recruitment is performed

10 minutes later, and the second lung recruitment is performed after lung compliance returns to the baseline level. Respiratory mechanics parameters, hemodynamic parameters, etc., are recorded. The incidence of hypoxemia during PACU and postoperative atelectasis assessed by ultrasound are recorded.

Primary Outcome Indicator: Duration of improved lung compliance; **Secondary Outcome Indicators**: Atelectasis at the end of surgery, incidence of hypoxemia during PACU, and incidence of pulmonary complications within 3 days after surgery.

VII. Things You Need to Cooperate with in the Study

10. Provide accurate information about past medical history and current condition.
11. Inform the responsible doctor of any health problems that occur during the study.
12. Inform the responsible doctor of any new drugs, medications, vitamins or herbs you take during the study.
13. Do not take any drugs or treatments, including prescription drugs and over-the-counter drugs (including vitamins and herbs), unless permitted by the responsible doctor.
14. Do not participate in other clinical studies.
15. Take appropriate contraceptive measures (during the study and within 7 days after the last administration).
16. Follow the instructions of researchers and research doctors.
17. You can ask questions at any time if you have any unclear points.

VIII. Alternative Treatment Options If You Do Not Participate in This Study

This study is a randomized controlled study comparing the impact of different inhaled oxygen concentrations on the efficacy of intraoperative lung recruitment in patients undergoing abdominal surgery. Even if you participate in this study, we will not impose any interventions beyond routine diagnosis and treatment activities. You can also choose not to participate in this study, which will not have any adverse impact on your general anesthesia surgery under routine procedures.

IX. Possible Adverse Reactions, Risks and Discomforts of Participating in the Study

Participating in the study will not cause side effects or risks beyond the routine anesthesia process.

X. Possible Benefits of Participating in the Study

Participating in this study may improve intraoperative oxygenation, reduce the incidence of postoperative atelectasis and pulmonary complications, but this cannot be guaranteed.

XI. New Information During the Study

During the conduct of the research project, new information about the research protocol may emerge. If new information appears, your research doctor will inform you in a timely manner and discuss with you whether you are still willing to continue participating in the study. If you decide to discontinue participation, your research doctor will arrange follow-up treatment for you. If you decide to continue participating, you may be required to sign a new informed consent form. Or if your research doctor believes that withdrawing from the study is in your best interest, he/she will explain the reasons to you and arrange follow-up treatment for you.

XII. Your Rights

Your participation in the study is entirely voluntary. You can refuse to participate or withdraw from the study at any time during the process, and your medical treatment or legal rights will not be affected. If you do not participate or withdraw from the study midway, there are many other alternative treatment drugs, and you do not have to participate in this study to treat your disease. If you need to withdraw from the study, for your safety and the objective evaluation of the drug's effect, please cooperate with the research doctor to complete the relevant evaluations and laboratory tests after the end of the study.

If you have any questions during the study, you can consult your research doctor at any time.

XIII. Costs of Participating in the Study

Participants in this study will not incur any costs beyond routine clinical diagnosis and treatment.

XIV. Handling of Research-Related Injuries

If your health is harmed due to participating in this study, please inform the researcher, and we will take necessary medical measures. If you do suffer side effects or physical injuries caused by the research protocol, the sponsor will bear the corresponding medical expenses and economic compensation within the scope specified by relevant Chinese laws and regulations under the following conditions:

18. Your physical injury is not caused intentionally;
19. You notify your researcher immediately when the injury occurs;
20. You have followed the medical advice of the researcher.

XV. Privacy and Confidentiality

Any information and data about you obtained during the study will be strictly kept confidential. Your blood/urine samples will be identified by research numbers/digits rather than your name. Information that can identify you will not be disclosed to members outside the

research team unless with your permission. All research members and the sponsor are required to keep your identity confidential. Your files will be stored in a locked cabinet and only accessible to researchers. To ensure that the study is conducted in accordance with regulations, if necessary, government regulatory authorities, monitors authorized by the sponsor, or members of the ethics committee can review the relevant information of your participation in the study at the research institution in accordance with regulations, but they will ensure that your information is not disclosed to other parties. Although the research results may be published, your identity will not be disclosed in these publications. The research data will be stored in the Department of Anesthesiology, Subei People's Hospital.

In this study, your biological samples such as blood and tumor tissues will be coded, that is, they will have a "code" instead of being labeled with your name or any other personal information. Data collected through sample testing will also be stored and analyzed using codes. Only your research doctor or other personnel authorized by the research doctor can identify your name through the code. You should know that your blood samples will be sent to the laboratory of the Department of Anesthesiology. After the final report of this study is completed, all your biological samples and any isolates will be destroyed.

Signing this written informed consent form indicates that you agree to the research doctor collecting and processing your personal information ("research data") in this study, including: your date of birth, gender, race, personal data on physical and mental health status. Unless you withdraw your informed consent, it means that your research data will be available for use. If you withdraw your informed consent, the research doctor and the sponsor will no longer use your personal data, but the personal data shared before the withdrawal of informed consent can still be used.

The research doctor will use the research data for clinical research. The sponsor may use the data for: conducting clinical research, supporting applications for marketing authorization of research drugs, and developing new drug products, diagnostics or medical aids.

You have the right to request access to your personal data stored by the research doctor and the sponsor, and you also have the right to request correction of inaccuracies in your personal data; you have the right to withdraw your informed consent at any time. If you have the above requests, please contact the research doctor.

XVI. Treatment After the Study

After the end of the study, research drugs will no longer be provided to you. Your doctor will discuss your future treatment plan with you.

16. Contact Information

21. If a research-related injury occurs, or if you have any questions about the study and research drugs, please contact:

Doctor's name: Gao Ju

Address: Department of Anesthesiology, Subei People's Hospital

Contact number: 18051063988

22. If you have questions related to the rights and interests of subjects, please contact the Medical Ethics Committee of Subei People's Hospital, telephone: 0514-87373694

Informed Consent Form Signature Page

Subject's Informed Consent Statement:

23. I have read this informed consent form and obtained information about the background, purpose, research steps, risks and benefits of this study. I have had sufficient time and opportunity to ask questions about the clinical study and have received satisfactory answers.
24. I understand that participation in this study is voluntary.
25. I allow the use and sharing of my medical information as described in the informed consent form.
26. I know that I can withdraw from this study at any time without suffering loss of benefits or other adverse consequences.
27. I am willing to cooperate with researchers in relevant examinations or treatments.
28. I agree to the collection, storage, processing, transfer and use of my data and biological samples as described in the previous part of this informed consent form, and allow researchers, ethics committee/institutional review board, drug supervision and administration departments and representatives of the sponsor to review my data.
29. I know that my personal identity and privacy will be strictly kept confidential when participating in this study.
30. I have also been informed of whom to contact when I have questions or need further information.
31. I will receive a signed and dated copy of this informed consent form.

Name (in block letters): 庄 [illegible] Signature: [illegible] Date: 2025 year 4 month 2 day

Guardian's Signature (Applicable ☐ Not Applicable ☑):

Name (in block letters): _____ Signature: _____ Date: ____ year ____ month ____ day

Relationship with the subject (such as spouse, father, daughter, etc., please specify below):

_____

Impartial Witness [if applicable]:

I certify that all information in this informed consent form and any other written information has been accurately explained to the subject or his/her guardian, and the subject or his/her guardian has fully understood this information. I also certify that the subject (or represented by his/her guardian) voluntarily agrees to continue the treatment with the study drug and participate in this study.

Name (in block letters): _____

Signature: _____ Date: _____

ID card number: _____ Main contact information: _____

Address: _____

Statement of the Researcher Implementing the Informed Consent:

I confirm that I have explained and informed the subject in detail about the nature, purpose, requirements and possible risks of this study, answered all relevant questions of the subject, and the subject has voluntarily agreed to participate in this study. This informed consent form is in duplicate, with the researcher and the subject each retaining a signed copy. In accordance with national laws and regulations and the protocol of this study, I will accurately conduct the clinical study and take necessary measures to protect the rights and safety of the above-mentioned subjects.

Name (in block letters): _____ Signature: _____ Date: ____ year ____ month ____ day