

The investigation of various titration techniques aimed at determining the most effective positive end expiratory pressure (PEEP) for individuals suffering from acute exacerbations of chronic obstructive pulmonary disease (AECOPD)

Submission date 09/04/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/04/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 15/04/2024	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Incorrectly adjusting the positive end expiratory pressure (PEEP) in patients experiencing acute exacerbations of chronic obstructive pulmonary disease (AECOPD) can result in two outcomes: either inadequate PEEP (known as intrinsic PEEP or iPEEP) when set too low, or an increase in lung volume when set above iPEEP. Thus, adjusting PEEP is akin to personalized medicine, aiming to recruit the small airways, alleviate iPEEP, reduce the work of breathing (WOB), and enhance patient-ventilator interaction (PVA), such as addressing ineffective triggering and trigger delay.

This research seeks to investigate the best method for titrating PEEP in patients with AECOPD to decrease iPEEP, lower respiratory effort, minimize trigger delay, and enhance synchronization between the patient and the ventilator.

Who can participate?

AECOPD patients aged 18-85 years.

What does the study involve?

A total of 30 AECOPD patients were enrolled and optimal PEEP titration was performed using different methods (EIT, esophageal pressure, end-expiratory obstruction, etc.) We compare the PEEPtot, PEEPi, trigger delay, ΔP_{es} , asynchrony index under the optimal PEEP obtained by different methods.

What are the possible benefits and risks of participating?

This study is free of charge, and patients can obtain accurate respiratory mechanical parameters to help guide the Settings of ventilator parameters The placement of esophageal pressure may

cause a small amount of bleeding and discomfort in the nasal mucosa of the subjects, which is an additional risk for this study. However, because the esophageal pressure tube is only placed for a short time in this study, other related complications (such as gastritis, gastric bleeding, perforation, etc.) are generally not encountered.

Where is the study run from?

Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (China)

When is the study starting and how long is it expected to run for?

June 2022 to December 2024

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

2022091055651336

Study information

Scientific Title

Study on optimal PEEP titration in patients with acute exacerbation of chronic obstructive pulmonary disease

Study objectives

There are many methods for titration of optimal PEEP in patients with AECOPD, and we wanted to compare the advantages and disadvantages of different titration methods to obtain optimal PEEP and the clinical manifestations

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 12/09/2022, Medical Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (Sir Run Run Shaw Hospital, 3 Qingchun Dong Lu, Shangcheng District, Hangzhou, 310016, China; +86 86006811; 594961420@qq.com), ref: 2022, No. 0332

Study design

Observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Quality of life, Safety, Efficacy

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

The reasonable setting of PEEP in AECOPD patients can prevent the poor effect caused by setting too low, and the excessive lung inflation caused by setting too high

Interventions

A cohort study was used in this study. Patients were divided into an invasive ventilation group and a non-invasive ventilation group according to clinical treatment. This study did not interfere with this treatment regimen.

Invasive ventilation group: A total of 10 patients were included to verify the significance and accuracy of PEEPi measured by electrical impedance technique (EIT), esophageal pressure monitoring and end-expiratory obstruction in guiding optimal PEEP setting.

Non-invasive ventilation (NIV) group: A total of 20 patients were included to verify the significance of EIT, esophageal titration and setting optimal PEEP for automatic PEEPi monitoring of Mindray SV70 respirator in improving human-machine synchronization.

The patients were ventilated at a supine position with mechanical ventilation, then a multifunctional nasogastric tube was placed, and then EIT was connected. Once the patient was used to the experimental setting and appeared to be relaxed, measurements were performed: PEEP titration was started, subsequently increased 1 cmH₂O every 10 minutes, until EIT showed that EELI was significantly elevated. Then we obtained the respiratory mechanical parameters of optimal PEEP under different titrations and compared them clinically

Intervention Type

Other

Primary outcome measure

In NIV group

1. The patients were ventilated at supine position with mechanical ventilation settings as follows: S/T mode, RR12 bpm, Pressure support (PS) was set at 6 cmH₂O, and then progressively modified, according to tidal volume (V_{te}/kg of PBW), in order to target a V_{te}/kg of 6 ~8 mL/kg PBW and a spontaneous RR lower than 24 breaths/min, FiO₂ was increased to target a SpO₂ ≥90%; The oronasal facemask was finely adjusted to target a leak flow lower than 20 L/min. The inspiratory trigger was set at medium and respiratory cycling was set at medium of the inspiratory peak flow.

2. A multifunctional nasogastric tube was placed, and then EIT was connected. Once the patient was used to the experimental setting and appeared to be relaxed, measurements were performed: PEEP titration was initially set at 4 cmH₂O (because that the lowest PEEP of NIV is currently 4 cmH₂O), and subsequently increased by 1 cm H₂O every 10 minutes, until to EIT showed that EELI was significantly elevated. All measurements were performed during a relatively stable spontaneous breathing pattern of 10 minutes and results were averaged for each assessment step.

3. Data recording

3.1. Esophageal pressure measurements: The ΔP_{es}, PEEPi_{dyn}, PEEPt_{tot}, trigger delay, asynchrony index measured by esophageal pressure during PEEP titration were recorded offline.

3.2. EIT measurements: ΔEELI. The value of ΔEELI was the average of the change in EELI for any 10 breaths per PEEP (compared with PEEP 4cmH₂O).

We defined the optimal PEEP as "The PEEPt_{tot} curves traced during PEEP titration were recorded offline, and the inflection point before the steep rise of the curve was selected as the best PEEP point; if not, 4cmH₂O was selected as the optimal PEEP." We observed the performance of PEEPi_{dyn}, ΔP_{es}, trigger delay, asynchrony index, and ΔEELI at optimal PEEP.

Invasive mechanical ventilation group:

1. Spontaneous breathing phase

the patients were ventilated at supine position with mechanical ventilation settings as follows: PCV mode, RR12 bpm, Pressure support (PS) was set to target a V_{te}/kg of 6 ~8 mL/kg PBW and a spontaneous RR lower than 24 reaths/min, FiO₂ was increased to target a SpO₂ ≥90%. A multifunctional nasogastric tube was placed, and then EIT was connected.

Then measurements were performed: PEEP titration was initially set at 0 cmH₂O, and subsequently increased 2 cmH₂O every 10 minutes, until to EIT showed that EELI was significantly elevated.

All measurements were performed during a relatively stable spontaneous breathing pattern of 10 minutes and results were averaged for each assessment step. We chose 80% of PEEPi_{dyn} as

the optimal PEEP based on esophageal pressure (measured at PEEP0). We chose PEEP at the lowest RVD as the optimal PEEP.

2. Deep sedation phase

Then placed the patient under deep sedation, we performed three end-expiratory occlusions and take the average as PEEPi.

3. Data recording

3.1. Esophageal pressure measurements: The ΔP_{es} , trigger delay, and asynchrony index measured by esophageal pressure during PEEP titration were recorded offline.

3.2. EIT measurements: $\Delta EELI$, GI.

We compare the trigger delay, ΔP_{es} , asynchrony index, GI under the optimal PEEP obtained by these three methods.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/06/2022

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. Diagnostic criteria for AECOPD met according to The 2018 GOLD definition needing noninvasive ventilation within 3 days
2. Age older than 18 years and younger than 85 years
3. Signed informed consent able to be obtained.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

85 Years

Sex

Both

Target number of participants

30

Key exclusion criteria

1. Hemodynamically unstable
2. Gastrointestinal bleedings

3. Severe neurological disease
4. End-stage malignant disease
5. Interstitial lung disease
6. Chest wall deformities
7. Suffering from other organ failure
8. Cancer
9. Contraindication to use of EIT
10. Inability to cooperate with noninvasive ventilation.

Date of first enrolment

01/06/2022

Date of final enrolment

31/12/2024

Locations

Countries of recruitment

China

Study participating centre

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Sponsor information

Organisation

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Sponsor type

Hospital/treatment centre

Website

<http://www.srrsh.com/html/main/gb2312/>

ROR

<https://ror.org/00ka6rp58>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date