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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

Registration date
17/04/2024

Overall study status
Completed

Last Edited
15/04/2024

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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, ΔPes, 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 parametersThe 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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Quality of life, Safety, Efficacy

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(s)

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 (Vte/kg of PBW), in order to target a Vte/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 cmH2Obecause 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 ΔPes, PEEPi,dyn, PEEPtot, 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 PEEPtot 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, ΔPes, 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 Vte/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 ΔPes, trigger delay, and asynchrony index measured by esophageal pressure during PEEP titration were recorded offline.
3.2. EIT measurements: ΔEELI, GI.
We compare the trigger delay, ΔPes, asynchrony index, GI under the optimal PEEP obtained by these three methods.

Key secondary outcome(s))

There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
85 years

Sex
All

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
Sir Run Run Shaw Hospital, Zhejiang University School of Medicine
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Sponsor information

Organisation
Sir Run Run Shaw Hospital

ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes