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Identify and understand patient-ventilator asynchrony in patients with mechanical ventilation using electrical impedance tomography

Submission date
09/08/2021

Recruitment status
No longer recruiting

Registration date
25/08/2021

Overall study status
Completed

Last Edited
31/08/2021

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
The concept of safe mechanical ventilation continues to develop, especially for special diseases, such as acute respiratory distress syndrome (ARDS) and chronic obstructive pulmonary disease (COPD), ventilation strategy based on respiratory mechanics and lung-protective ventilation, in order to provide life support for critically ill patients and minimize iatrogenic injury. When the patient and ventilator do not match in the respiratory transmission process, patient ventilation asynchrony (PVA) will occur between the patient and ventilator. The high incidence of asynchrony is associated with prolonged hospitalization and death. Electrical impedance tomography (EIT) can evaluate the regional distribution of lung during ventilation, with time and space information, so as to provide the basis for lung protection and diaphragm protection ventilation.

Who can participate?
ICU patients over 18 years old who requiring invasive mechanical ventilation

What does the study involve?
This study is an observational study, which only collects the patients' clinical data (basic data, ventilator waveform, esophageal internal pressure, and gas distribution in the lung), and alveolar lavage fluid (this biological sample is the sample to be collected in the process of routine clinical diagnosis and treatment, which is not a special requirement of this study), does not interfere with the clinical diagnosis and treatment process.

What are the possible benefits and risks of participating?
None

Where is the study run from?
Sir Run Run Shaw Hospital Affiliated to Medical College of Zhejiang University (China)

When is the study starting and how long is it expected to run for?
July 2021 to March 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Miss Jie Ding, 2233702918@qq.com

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20210728-34

Study information

Scientific Title
Identification and mechanism of patient-ventilator asynchrony (PVA) in patients with mechanical ventilation by electrical impedance tomography (EIT)

Study objectives

The purpose of this study is to explore the identification of man-machine asynchrony and its mechanical mechanism in patients with mechanical ventilation by EIT, as well as the impact of different subtypes on the prognosis of patients, so as to provide basis for lung protection and diaphragm protection ventilation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/07/2021, Ethics committee of Shaw Hospital Affiliated to Zhejiang University (3 qingchun east road, jianggan district, hangzhou; +86 (0)571-86960497; yyc261@foxmail.com), ref: 310016

Study design
Single-centre observational cross-sectional cohort study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Patients requiring invasive mechanical ventilation

Interventions
After the eligible patients are enrolled, we will use the respcare information system continuously and automatically collect the ventilator waveform and record the respiratory mechanical parameters. We will also use the gastric tube to monitor esophageal pressure and observe the gas distribution in the lung by chest wall electrical impedance imaging every day, the identify invalid trigger (IEE), double trigger (DT) and reverse trigger (RT) in PVA through the machine . All the above will help us identify and analyse the mechanical mechanism of PVA in patients with mechanical ventilation.

1. Collection of basic data: disease diagnosis, severity score (SAPS II, sofa), presence or absence of sepsis, chest imaging, laboratory examination (ABG, cx3, CX4, CBC), treatment and outcome. Use standardized data collection tables. Identification results and clinical interpretation.
2. The Respcare information system continuously and automatically collects the ventilator waveform and records the respiratory mechanical parameters: Pvent, PMUs, paw, ers, RRs, PES, PL, Pplat, flow and volume.

3. Through gastric tube (including esophageal pressure monitoring): place the gastric tube with esophageal pressure measurement function, calibrate and measure the esophageal internal pressure (4 times a day, 1 hour each time, 10 hours in total).
4. The gas distribution in the lung was observed by chest wall electrical impedance imaging (4 times a day, 1 hour each time, a total of 10 hours): by comparing the impedance change with the reference state, the improved Newton Raphson algorithm was used to reconstruct the tidal volume distribution image. The regional and overall velocity variation process is recorded with a velocity resolution of 20Hz.The overall impedance time curve is the sum of all pixel impedance changes.
5. Identify invalid trigger (IEE), double trigger (DT) and reverse trigger (RT) in PVA through machine learning.
6. 5ml of partial alveolar lavage fluid was reserved and sent for cell analysis.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measures as of 31/08/2021:
1. Esophageal internal pressure (4 times a day, 1 hour each time) measured using the ventilator
2. To assess the accuracy of EIT in identifying PVA, the gas distribution in the lung was observed by chest wall electrical impedance imaging (4 times a day, 1 hour each time). By comparing the impedance change with the reference state, the improved Newton Raphson algorithm was used to reconstruct the tidal volume distribution image.
3. Incidence and type of PVA were recorded throughout the duration of mechanical ventilation

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Previous primary outcome measures:
1. Esophageal internal pressure (4 times a day, 1 hour each time) measured using the ventilator
2. The gas distribution in the lung was observed by chest wall electrical impedance imaging (4 times a day, 1 hour each time): by comparing the impedance change with the reference state, the improved Newton Raphson algorithm was used to reconstruct the tidal volume distribution image.
3. Incidence and type of PVA were recorded throughout the duration of mechanical ventilation

Secondary outcome measures
Current primary outcome measures as of 31/08/2021:
1. As continuous assessment of respiratory physiological aspects and mechanics of different subtypes, the Respcare information system continuously and automatically collects the ventilator waveform and records the respiratory mechanical parameters throughout the duration of mechanical ventilation: PES, Pplat, flow and volume
2. Length of stay and mortality were recorded at the end of mechanical ventilation

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Previous secondary outcome measures:
1. The Respcare information system continuously and automatically collects the ventilator waveform and records the respiratory mechanical parameters throughout the duration of mechanical ventilation: PES, Pplat, flow and volume.
2. Length of stay and mortality were recorded at the end of mechanical ventilation

Overall study start date
20/07/2021

Completion date
20/03/2023

Eligibility

Key inclusion criteria
1. Patients admitted to ICU from August 2021 to December 2022
2. Age ≥18 years old
3. Patients with mechanical ventilation
4. Voluntarily participate and sign the informed consent form (in case of incapacity, its legal representative must sign the informed consent on behalf of it)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
35

Key exclusion criteria
1. Signed the doctor's order against resuscitation (DNR)
2. Patients transferred from other intensive care units
3. No effective mechanical ventilation waveform
4. Unable to conduct EIT assessment

Date of first enrolment
01/08/2021

Date of final enrolment
30/12/2022

Locations

Countries of recruitment
China

Study participating centre

Sir Run Run Shaw Hospital affiliated to medical college of ZheJiang University
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Sponsor information

Organisation
Sir Run Run Shaw Hospital

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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
01/03/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (ding_yuejia@zju.edu.cn)

IPD sharing plan summary
Available on request