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The effect of airway pressure release ventilation on respiration and circulation in post-operative heart surgery patients

Submission date
01/02/2020

Recruitment status
No longer recruiting

Registration date
10/02/2020

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Postoperative lung (pulmonary) complications and heart (cardiovascular) complications are major causes of morbidity, mortality and resource utilization in cardiac surgery patients. Patients undergoing cardiopulmonary bypass (CPB) frequently experience hypoxemia and pulmonary complications after surgery and may develop acute respiratory distress syndrome. In addition, improper postoperative ventilator settings are associated with an increased risk for lung infection, a longer duration of intubation and a longer hospital stay.

Airway pressure release ventilation (APRV) is a lung protective strategy that has been proposed to treat refractory hypoxemic respiratory failure while preventing ventilator-induced lung injury . However, APRV introduces a higher mean airway pressure (Pmean) compared to conventional ventilation mode, which may increase intrathoracic pressure, and subsequently right atrial pressure. Hence, APRV might lead to a decrease in systemic venous return compared to conventional mechanical ventilation. A randomized controlled trial was designed to compare APRV with conventional PCV.

Who can participate?
Patients aged over 18 years who receive cardiothoracic surgery and need invasive mechanical ventilation after admission to the ICU.

What does the study involve?
Patients are randomly divided into routine ventilation group (PCV group) and APRV group and treated accordingly.

What are the possible benefits and risks of participating?
The use of APRV mode during postoperative respiratory support may promote pulmonary retention after general anesthesia, reduce postoperative complications, and shorten mechanical ventilation and ICU stay.And during the study, we continued to monitor the patient's ventilation

indicators and vital signs. The electrical impedance imaging test used in the study was non-invasive in vitro, requiring only chest straps placed before and after the roll, without frequent movement. Therefore, this study is relatively safe.

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?
December 2018 to December 2021

Who is funding the study?
Sir Run Run Shaw Hospital Affiliated to Medical College of Zhejiang University (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
20181225-6

Study information

Scientific Title
The effect of airway pressure release ventilation (APRV) on the incidence of postoperative pulmonary complications in patients with cardiothoracic surgery

Study objectives
The use of APRV mode in post-operative cardiac surgery patients can promote pulmonary retention after general anesthesia, reduce postoperative complications and shorten mechanical ventilation and ICU stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/12/2018, Ethics committee of Sir Run Run Shaw Hospital of Zhejiang University (3 Qingchun East Road, Jianggan District, Hangzhou, 310016, China; +86 571 8600681; 594961420@qq.com), ref: 20181225-6

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Postoperative pulmonary complications and cardiovascular complications

Interventions
Patients who receive cardiothoracic surgery and need invasive mechanical ventilation after admission to the ICU are randomly divided into routine ventilation group (PCV group) and APRV group. The random scheme is generated by referring to the random comparison table without any restriction, intervention or adjustment in advance or in the process of implementation.

All patients are supported by Evita4 ventilator, and the initial parameters of a ventilator in the PCV group are set as follows: respiratory frequency 12 times/min, tidal volume 6-8ml/ ideal kg body weight, inhalation oxygen concentration and positive end-expiratory pressure (PEEP) are set according to the needs of patients.
The initial respiratory rate, tidal volume, and inhaled oxygen concentration of the APRV group are set the same as that of the conventional ventilator group, with the low pressure set to 0, and the low pressure time (Tlow) is set at the time required to reduce the flow rate at pressure release to 50%-75% of the peak flow rate. The distribution of functional residual gas and tidal gas is measured by EIT equipment at the time of enrollment, 30min and 1h after enrollment. Vital signs and respiratory physiological indicators are also recorded as well as the incidence of ventilator-associated pneumonia, atelectasis, mechanical ventilation duration, length of ICU stay, and final prognosis.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Evita4 ventilator

Primary outcome(s)
Electrical impedance imaging (EIT) was used to determine the difference in pulmonary gas distribution in patients undergoing cardiothoracic surgery before and after admission to the ICU after APRV

Key secondary outcome(s))
From patient records:
1. Incidence of ventilator-associated pneumonia
2. Incidence of atelectasis
3. Duration of mechanical ventilation
4. Length of ICU stay
5. Final outcome (death/survival)

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Age above 18
2.Received cardiothoracic surgery and needed invasive mechanical ventilation after admission to the ICU

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Chronic obstructive pulmonary disease
2. Asthma
3. Mechanical ventilation pre-operation
4. Mechanical device to maintain hemodynamics

Date of first enrolment
26/12/2018

Date of final enrolment
26/12/2021

Locations

Countries of recruitment
China

Study participating centre
Sir Run Run Shaw Hospital Affiliated to Medical College of Zhejiang University
3 Qingchun East Road
Jianggan District
Hangzhou
China
310016

Sponsor information

Organisation
Sir Run Run Shaw Hospital

ROR
https://ror.org/00ka6rp58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Sir Run Run Shaw Hospital Affiliated to Medical College of Zhejiang University

Results and Publications

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 beginning 9 months and ending 36 months following article publication.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/06/2021	28/03/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes