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A comparison of two devices to measure the endotracheal tube (ETT) cuff pressure in intubated patients

Submission date 06/12/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 09/12/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 09/12/2020	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
An endotracheal tube (ETT) is a flexible plastic tube that is placed through the mouth into the trachea (windpipe) to help a patient breathe. The endotracheal tube is then connected to a ventilator, which delivers oxygen to the lungs. The process of inserting the tube is called endotracheal intubation. The cuff is designed to provide a seal with the airway, allowing airflow through the ETT but preventing passage of air or fluids around the ETT.
Monitoring and maintaining ETT cuff pressure in a reasonable range is of great significance in clinical practice force as well as a challenge.
This study compared the effect of a manual cuff pressure gauge and disposable pressure transducer in the monitoring of ETT cuff pressure

Who can participate?
Patients requiring intubation for mechanical ventilation (assisted breathing) for over 48 hours.

What does the study involve?
Patients were randomly divided into the control group and the test group. In the control group, ETT cuff pressure was measured using the ETT manual cuff pressure gauge; while in the test group the disposable pressure transducer was used. Measurements were taken every 4 hours.

What are the possible benefits and risks of participating?
None

Where is the study run from?
The Third the People's Hospital of Bengbu (China)

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

Who is funding the study?
The Third the People's Hospital of Bengbu (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of manual cuff pressure gauge and disposable pressure transducer in the monitoring of endotracheal tube (ETT) cuff pressure in artificial airway patients and the compliance of nurses to measure ETT cuff pressure

Study objectives
Compared with intermittent Endotracheal tube (ETT) cuff pressure monitoring with manual cuff pressure gauge, continuous ETT cuff pressure monitoring with a disposable pressure transducer can dynamically monitor pressure changes on the basis of ensuring good monitoring effect to reduce the workload of nurses, improve the compliance of nurses, and better improve the qualified rate of ETT cuff pressure monitoring in artificial airway patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 22/10/2018, Ethics Committee of The Third People's Hospital of Bengbu (38 Shengli Street, Bengbu, Anhui, China; +86 (0)552-2051760; hulibu123456@163.com), ref: BBSY-2018.44

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Endotracheal tube (ETT) cuff pressure in intubated patients

Interventions
Patients were divided into the control group and test group, using a computerized random number generator by a trial statistician who had no clinical involvement in the project.

In the control group ETT cuff pressure was measured using the ETT manual cuff pressure gauge; while in the test group the disposable pressure transducer was used.

Measurements included the ETT cuff pressure level, the average air leakage of the cuff, the number of patients of ventilator leakage alarm, the number of patients with Ventilator-Associated Pneumonia (VAP) and the compliance of bedside nurses to monitor and adjust the ETT cuff pressure.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
German VBM ETT manual cuff pressure gauge, USA OHMEDA ECG monitor, disposable pressure transducer and its accessories

Primary outcome measure

ETT cuff pressure measured by nursing staff in the ICU every four hours using the devices under investigation

Secondary outcome measures
1. Air leakage of cuff (the difference between the pressure after the last cuff recharge and the next) measured every four hours
2.The number of ventilator leakage alarms measured by checking the alarm records on the ventilators every four hours
3. The number of patients with Ventilator-Associated Pneumonia (VAP) whilst in hospital measured using data from the hospital infection management department
4. The compliance of bedside nurses to monitor and adjust ETT cuff pressure measured by analysis of daily bedside video

Overall study start date
15/10/2018

Completion date
30/12/2019

Eligibility

Key inclusion criteria
1. Mechanical ventilation in patients with tracheal intubation
2. Age of patients ≥18 years
3. Mechanical ventilation time >48 hours
4. ETT from the same manufacturer, model 8,7.5, or 7, and using high volume low-pressure cuff (HVLP)
5. informed consent of patients or family members , and willing to participate in this study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
104

Total final enrolment
104

Key exclusion criteria

1. Patients with airway malformation, airway stenosis
2. Patients with trachea and esophagus leak or cuff leak
3. Patients with pulmonary infection before trachea cannula
4. Patients with tracheotomy
5. Patients being involved with other researchers

Date of first enrolment
01/07/2019

Date of final enrolment
30/11/2019

Locations

Countries of recruitment
China

Study participating centre
The Third People's Hospital of Bengbu
Shengli 38
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Sponsor information

Organisation
The Third People's Hospital of Bengbu

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name
The Third People's Hospital of Bengbu

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/02/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available