

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

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<b>Last Edited</b> 09/12/2020	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Xin Lin, 798431769@qq.com

## 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**  
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

## **Study type(s)**

Other

## **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(s)**

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

## **Key secondary outcome(s)**

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

**Completion date**

30/12/2019

## Eligibility

**Key inclusion criteria**

1. Mechanical ventilation in patients with tracheal intubation
2. Age of patients  $\geq 18$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

## **Funder(s)**

**Funder type**  
Hospital/treatment centre

**Funder Name**  
The Third People's Hospital of Bengbu

## **Results and Publications**

**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