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A new way to perform tracheostomy: study comparing two techniques using ultrasound and a special airway mask

Submission date
29/06/2024

Recruitment status
No longer recruiting

Registration date
02/07/2024

Overall study status
Completed

Last Edited
28/04/2025

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
A percutaneous tracheostomy (PT) is a procedure often performed at the bedside in the Intensive Care Unit (ICU). This procedure involves creating an opening in the neck to insert a tube into the windpipe (trachea) to help a patient breathe. Studies have shown that PT is a safe and cost-effective alternative to the traditional open surgical method.

During PT, different guidance techniques can be used to enhance safety and accuracy. One common method is bronchoscopic guidance, which uses a bronchoscope (a thin tube with a camera) to guide the procedure. This technique helps avoid injuries to nearby structures and ensures the tube is placed correctly. However, it has its limitations; for instance, it cannot detect blood vessels or the thyroid gland, which can lead to complications like puncturing these areas. Additionally, in patients with brain injuries, it can increase brain pressure.

Ultrasound guidance has emerged as another effective technique. Preliminary reports suggest that using ultrasound, an imaging technique that uses sound waves, before and during PT can help prevent bleeding and ensure the tube is placed correctly. Real-time imaging with ultrasound allows for precise visualization of the needle's path, reducing the risks of puncture and injury. This method provides better visualization, especially in patients with complex anatomy or obesity, and helps avoid blood vessels, making it advantageous over bronchoscopy in certain scenarios.

The aim of this study is to compare ultrasound-guided PT using a laryngeal mask airway (a device that keeps the airway open) with bronchoscopy-guided PT. The study focuses on three main aspects: the time each procedure takes, the associated costs, and any complications that arise during or after the procedure.

Real-time ultrasound guidance has shown promise in improving the safety and effectiveness of PT. Studies indicate that it can help avoid placing the tube too high, which can cause long-term complications. Pre-procedure ultrasound can identify blood vessels beforehand, potentially reducing the risk of bleeding. Additionally, using a laryngeal mask airway offers better

visualization of the trachea, which is especially useful for less experienced doctors or patients with difficult anatomy.

In summary, the study aims to determine whether ultrasound guidance with a laryngeal mask airway is more efficient and safer compared to the standard bronchoscopy-guided PT. By investigating procedure time, cost, and complications, the study seeks to improve patient outcomes in the ICU.

Who can participate?
The study included adult patients in the Intensive Care Unit (ICU) who were critically ill, intubated, and on mechanical ventilation. These patients needed an elective percutaneous tracheostomy (PT), a procedure to create an opening in the neck to help them breathe.

What does the study involve?
In a study conducted in the ICU, patients who needed a planned tracheostomy (a procedure to create an opening in the neck to place a tube into the windpipe) were divided into two groups to compare two different methods of performing the procedure.

One group had the procedure done using ultrasound and a device called a laryngeal mask airway (LMA), while the other group had it done using a bronchoscope (a thin, flexible tube with a camera to see inside the airways).

Patients were randomly assigned to each group in equal numbers (1:1 ratio) using a method called blocked randomization, which ensures that each group has a balanced number of participants. The randomization process was managed by a computer program and overseen by a biostatistician who did not take part in the rest of the study. This was done to keep the assignments hidden from the researchers to prevent any bias in selecting participants for either group.

What are the possible benefits and risks of participating?
For participants, there are no additional risks or benefits beyond those of conventional procedures

Where is the study run from?
Ain Shams University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
May 2021 to December 2022

Who is funding the study?
Ain Shams University Hospital (Egypt)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FMASU MD 164/2021

Study information

Scientific Title
A novel technique for percutaneous dilatational tracheostomy: randomized controlled trial evaluating modified real-time ultrasound-guided bronchoscopy controlled tracheostomy using laryngeal mask airway

Study objectives

The utilization of ultrasound guidance during tracheostomy procedures has become increasingly prevalent across diverse clinical contexts owing to its capacity to provide dynamic imaging of anatomical structures in real-time, potentially minimizing procedural complications. Ultrasound guidance offers enhanced visualization of the trachea, adjacent vasculature, and pertinent anatomical landmarks, facilitating precise needle insertion and identification of potential impediments. Furthermore, it obviates the necessity for radiation exposure inherent in fluoroscopy and obviates the expenses linked to bronchoscopy equipment.
Several studies have explored the efficacy and safety of ultrasound-guided percutaneous dilatational tracheostomy (PDT) in comparison to the standard technique using bronchoscopy guidance PDT with controversial results. Laryngeal mask airways (LMAs) have been successfully used instead of ETTs during PDT, with better visualization of relevant tracheal structures. No studies have explored the efficacy and safety of the ultrasound-guided PDT approach using an LMA compared to the bronchoscopy-guided PDT technique.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/12/2021, Research Ethics Committee of Ain Shams University Faculty of Medicine (Ramsis Street Square, El Weili, Cairo, -, Egypt; +202 26857539 ; viced.research@med.asu.edu.eg), ref: FMASU MD 164/2021

Study design
Open-label parallel randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Other, Safety, Efficacy

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Procedure for patients with prolonged respiratory failure

Interventions
Bedside percutaneous dilatation tracheostomy using ultrasound-guided and LMA and compared with conventional technique using bronchoscopy.
Patients admitted to the ICU requiring elective PDT were randomized in a 1:1 ratio to either ultrasound-guided technique using LMA (US-guided LMA) or bronchoscopy-guided technique arm in random permuted blocks of 4 to ensure balanced allocation across intervention arms. Randomization sequences within each block were generated using SAS code to conduct blocked

randomization, and an independent biostatistician conducted the randomization. Allocation concealment was maintained to minimize selection bias.

Intervention Type
Procedure/Surgery

Primary outcome measure
Procedure time, defined by the time (in minutes) between the trachea puncture and the patient's ventilation in US LMA and bronchoscopy-guided PDT measured using patient records

Secondary outcome measures
Measured using patient/hospital records at the end of the study:
1. Cost of the procedures (including the perioperative drugs used, the tracheostomy set, and fiberoptic bronchoscope sterilization)
2. Complications related to the procedures

Overall study start date
01/05/2021

Completion date
03/12/2022

Eligibility

Key inclusion criteria
1. Age: >18 years
2. Sex: Male or Female.
3. All intubated patients indicated for tracheostomy for any etiology

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
65

Total final enrolment
60

Key exclusion criteria
1. Age: below 18 years or above 75 years.
2. The patient or the patient's guardian refuses to give written informed consent.
3. Patients who have a contraindication to the procedure (coagulopathy, high FIO2 requirement, high PEEP, etc.)
4. Patients with a history of COVID-19 will not be included.

Date of first enrolment
04/12/2021

Date of final enrolment
03/12/2022

Locations

Countries of recruitment
Egypt

Study participating centre
Faculty of medicine - Ain shams university hospitals
Abbassyia, Faculty of Medicine
Cairo
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11566

Sponsor information

Organisation
Ain Shams University Hospital

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Sponsor type
University/education

Website
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ROR

https://ror.org/00p59qs14

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Ain shams University hospital

Results and Publications

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

Intention to publish date
01/08/2024

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
ahmed_reda43@yahoo.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			02/07/2024	No	No
Results article		25/04/2025	28/04/2025	Yes	No