PROTOCOL OF A THESIS FOR PARTIAL FULFILMENT OF DOCTORATE DEGREE IN INTENSIVE CARE MEDICINE

Title of the Protocol:

# Evaluation of Modified Realtime ultrasound-guided bronchoscopic controlled percutaneous dilational tracheostomy using laryngeal mask airway as a novel Technique for percutaneous dilation tracheostomy: randomized controlled trial.


**Postgraduate Student: Ahmed Mohamed Reda Ali Taha**

**DIRECTOR: Prof. Dr. Mohamed Ismail Elsaidi**

Academic Position: Professor.

Department: Anesthesiology, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

**Co-DIRECTOR: Assistant Prof. Dr. Sameh Salem Hefni Taha**

Academic Position: Assistant Professor
Department: Anesthesiology, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.

**Co-DIRECTOR: Assistant Prof. Dr. Ashraf Al-Agami**

Academic Position: Assistant Professor

Department: Anesthesiology, Intensive Care and Pain Management, Faculty of Medicine, Ain Shams University.



Faculty of Medicine

Ain Shams University

2021

# Evaluation of Modified Realtime ultrasound-guided bronchoscopic controlled percutaneous dilational tracheostomy using laryngeal mask airway as a novel Technique for percutaneous dilation tracheostomy: randomized controlled trial.

## What is already known on this subject? AND

## What does this study add?

Percutaneous tracheostomy (PT) is a commonly performed bedside procedure in the Intensive Care Unit (ICU). Several studies have demonstrated that PCT is a safe and cost-effective alternative to open, surgical tracheostomy.1–3 Bronchoscopic guidance during PT may be useful in avoiding injury to surrounding structures, high placement of the tube, injury to the posterior tracheal wall and in confirming endotracheal placement.4,5 However, bronchoscopy does not identify the vascular structures or the thyroid gland in the neck region and thus does not prevent complications linked to local organ lesions (punctured vessels or a punctured thyroid) and in patients with acute brain injury, it can cause acute elevations in intracranial pressure.

Preliminary reports suggest that sonographic delineation of anatomy prior to tracheal puncture during PT may help prevent bleeding from pre-tracheal vascular structures and placement of the tracheal tube above the first tracheal ring.6,7 The use of real-time ultrasonography, with actual visualization of the needle path up to the anterior tracheal wall should further decrease the risk of puncture above the first tracheal ring as well as the risk of injury to surrounding structures and the posterior tracheal wall. Real-time guidance during PT may be particularly useful when factors that increase the technical difficulty of the procedure (morbid obesity, difficult anatomy, cervical spine precautions) are present. However, to the best of our knowledge, no published data compare the US guided and bronchoscopic guided percutaneous tracheostomy using LMA. Hence, the objectives of our study were to Compare procedure time, cost, and related complications.

## 1. INTRODUCTION / REVIEW

Previous studies demonstrate that percutaneous tracheostomy can be performed under real-time ultrasound guidance as efficacious if not with better results in comparison **bronchoscopic guided percutaneous tracheostomy which considered the standard technique** 4 and with a short completion time. Several studies have emphasized the value of pre- percutaneous tracheostomy ultrasound examination of the neck region to reduce the incidence of complications.9 Recently, Rajajee et al demonstrated the feasibility of ultrasound guidance during the implementation of percutaneous tracheostomy in a population of neuro-intensive care patients.10 ultrasound guidance has many potential advantages over other techniques of percutaneous tracheostomy. The first is the precise ability to place the tracheostomy tube below the first tracheal ring. Placement of the tracheal tube above the first tracheal ring may increase the risk of late sub-glottic cicatrization and stenosis.7,9,10 In one study of patients who underwent autopsy following percutaneous tracheostomy, 5 of 15 patients had the tracheal tube placed above the first tracheal ring when the tube was placed blindly versus zero of 11 patients when percutaneous tracheostomy was performed with ultrasound guidance.11 Real-time imaging of the needle path allows visual confirmation that the anterior wall has been passed, at which point the needle is advanced no further, and posterior wall injury is avoided.

Additional limitation to bronchoscopy guided technique is morbid obesity, that shown in previous studies to be feasible in ultrasound guided technique.8,9

The laryngeal mask airway technique is an innovative modification that showed definite advantages regarding visualization of relevant tracheal structures and the dilation process compared with an endotracheal tube either in bronchoscopy or ultrasound guidance. This may be especially relevant in the hands of inexperienced intensivists and in cases of complex patient anatomy where improved structural visualization optimizes operating conditions.15

The advantage of ultrasound guided technique is its ability to avoid vascular structures anterior to the trachea. Prior studies have demonstrated a potential role for pre-procedure ultrasound imaging in transverse section to identify vascular structures and reducing the risk of bleeding.10,13,14 In one study, bleeding from injury to vascular structures which would have likely been identified had ultrasound been used was considered significant.7 Pre-procedure ultrasound resulted in a change in the planned site of tracheal puncture in 24% of patients in another study.14 These studies did not use real-time guidance for the performance of percutaneous tracheostomy. The use of real-time imaging may be preferable for avoiding vascular structures compared to pre-procedure imaging alone, since avoidance of a vascular structure such as an inferior thyroid vein cannot be taken for granted without actual visualization of the needle path.

## 2. AIM / OBJECTIVES

The aim of this study is to compare ultrasound guided percutaneous tracheostomy Using Laryngeal mask airway with bronchoscopy guided percutaneous tracheostomy as a standard technique regarding the procedure time, cost, and procedure related complications.

Objectives

Measure and compare the time needed for both Study group A & B

Compare the complication rate for both Study group A & B

Calculate the failure rate for both Group A & B

Calculate the cost of equipment and consumables and compare for both Groups A & B

The primary outcome measure will be the procedure time defined as the time from application of bronchoscope or ultrasound probe till withdrawal of the guidewire, The secondary outcomes measure will be cost and procedure related complications, procedure difficulty and failure rate.

## 3. METHODOLOGY:

### Patients and Methods

This randomized clinical study will be carried out in the critical care department – Ain shams university –Hospital after approval of the ethics committee, written informed consent from the patient or the first-degree relative will be collected. A total of 30 patients will be enrolled in each arm of this study.
Type of Study: Randomized control clinical study.
Study Setting: will be carried out in the critical care department (Ain Shams university hospital)
Study Period: started from November 2021 till collection of required cases.
Study Population: Critically ill patients admitted to the intensive care unit and indicated for tracheostomy for any etiology.
Group B is the control arm of this study representing the standard technique for this procedure.

**Selection criteria for cases:**
**Inclusion Criteria:**
Age: > 18 years
Sex: Male or Female.
All intubated patients indicated for tracheostomy for any aetiology.

**Exclusion Criteria:**
Age: below 18 years or above 75 years.
Patient or patient's guardian refusal to give written informed consent.
Patients who have a contraindication to the procedure (coagulopathy, high FIO2 requirement, high PEEP,etc.)
**Patient with past history of COVID 19 will not be included**

**Sampling Method:**
Patients admitted to ICU and required elective tracheostomy will be randomly assigned to one of either Groups A or B; Clinical data, including characteristics, laboratory, imaging information, and medication and recorded complications and length of stay were extracted from electronic medical records and compared.

**Group A: ultrasound-guided technique**
Neck ultrasound will be performed with a 12 MHz linear probe, followed by a colour Doppler examination to evaluate the vascular anatomy of the anterior neck region, and to identify the thyroid isthmus, the cricoid cartilage, and the first three to five tracheal rings. The midline distance between

the skin and the trachea and the tracheal diameter will be measured at the second ring level. The vessels between the skin and the tracheal rings will be identified and avoided. **We will modify the technique by changing the endotracheal tube to laryngeal mask airway as innovative technique to keep the trachea empty for the procedure.** The bronchoscope will be introduced through the laryngeal mask airway to visualize the anterior and posterior tracheal walls and insure the guide wire placement inside the tracheal lumen. The puncture site will be marked between the second and third tracheal rings with the ultrasound probe in the longitudinal plane. The trachea will then be punctured under real-time ultrasound guidance with the probe in a transverse plane at the midline, with a catheter-over-the-needle device connected to a 10-mL syringe half-filled with distilled water. As soon as air aspiration will be observed in the syringe, the catheter will advance into the trachea and the needle should be out. A flexible guide wire will then gently be introduced into the catheter, which will be removed after this step. A guide wire entry at the desired tracheal ring level and an entry into the anterior quadrant will be then confirmed by using ultrasound before a skin incision and a blunt dissection. After that, the procedure will be completed as previously described by Griggs.**[10][16]**

**Group B: Bronchoscopic guided Technique**

In a bronchoscopy-guided percutaneous tracheostomy, the bronchoscopy will be performed by trained intensivists. After sedation, as previously described, the bronchoscope will be introduced and the endotracheal tube repositioned under bronchoscopy guidance, with the tip of the tube just below the vocal cords. The thyroid cartilage, the cricoid cartilage, and the first three to five tracheal rings will be identified, and the puncture site should be selected between the second and the third tracheal rings. Then, the trachea will be punctured at the chosen site with a catheter-over-the-needle device connected to a 10-mL syringe half-filled with distilled water under real-time bronchoscopy guidance. As soon as air aspiration will be observed in the syringe and the catheter detected in the trachea, the catheter will be introduced. The needle will be removed during a continuous observation using bronchoscopy. A flexible guidewire will be then gently introduced into the catheter. After that, the procedure will be completed as previously described by Griggs.**[11] [16]**

Cost estimation will be calculated as per consumables list provided from the burchasing department Ain shams university hospitals.

## Complications of tracheostomy

Immediate

- Bleeding
- Tracheal tube obstruction
- Pneumomediastinum
- Pneumothorax
- Loss of airway
- Tracheal ring fracture
- Paratracheal placement of tracheostomy tube
- Injury to thyroid
- Cardiac or respiratory decompensation

Late

- Infection
- Granulation tissue formation

- Tracheal tube displacement or malposition
- Cuff leak
- Tracheal stenosis
- Tracheoesophageal fistula
- Tracheo-vascular fistula

**Sample Size:**
Using PASS 11 program for sample size calculation, setting power at 80%, alpha error at 5%, reviewing results from previous studies and based on their findings and after 10% adjustment for dropout rate a sample size of at least 60 patients (30 per group) will be needed

Ethical Considerations:
o The study will be performed after obtaining ethical committee approval and informed written consent from the patients or their legal guardian in a private room.
o The study protocol will be explained to the patients before taking the informed consent.
o The study procedures, including the lab data, a different setting of mechanical ventilation, and protocolized treatment, will be done by the most competent experts.

We will collect, revise and tabulate Patient data, and introduce it to a PC using statistical package for social sciences. Data will be presented, and suitable analysis will be done according to the type of data obtained for each parameter.

## 4. REFERENCES


1. Sustić A. Role of ultrasound in the airway management of critically ill patients. Crit Care Med. 2007;35:S173–S177.
2. Barash M, Kurman JS. Patient selection and preoperative evaluation of percutaneous dilation tracheostomy in the intensive care unit. J Thorac Dis. 2021 Aug;13(8):5251-5260.
3. Shimizu T, Mizutani T, Hagiya K, Tanaka M. Influence of prolonged translaryngeal intubation on airway complications: a retrospective comparative analysis. Eur Arch Otorhinolaryngol. 2019 Aug;276(8):2349-2354.
4. Delaney A., Bagshaw S.M., Nalos M. Percutaneous dilatational tracheostomy versus surgical tracheostomy in critically ill patients: a systemic review and meta-analysis. Crit Care. 2006;10:R55
5. Kost K.M. Endoscopic percutaneous dilatational tracheotomy: a prospective evaluation of 500 consecutive cases. Laryngoscope. 2005;115:1–30.
6. Ghattas C, Alsunaid S, Pickering EM, Holden VK. State of the art: percutaneous tracheostomy in the intensive care unit. J Thorac Dis. 2021 Aug;13(8):5261-5276. doi: 10.21037/jtd-19-4121. PMID: 34527365; PMCID: PMC8411160.
7. Aldawood A.S., Arabi Y.M., Haddad S. Safety of percutaneous tracheostomy in obese critically ill patients: a prospective cohort study. Anaesth Intensive Care. 2008;36:69–73.
8. Guinot Pierre-Grégoire, Zogheib Elie, Petiot Sandra. Ultrasound-guided percutaneous tracheostomy in critically ill obese patients. Crit Care. 2012;16:R40.
9. Strametz R, Bergold MN, Weberschock T. Laryngeal mask airway versus endotracheal tube for percutaneous dilatational tracheostomy in critically ill adults. Cochrane Database Syst Rev. 2018 Nov 15;11(11):CD009901.

10. Rajajee V., Fletcher J.J., Rochlen L.R., Jacobs T.L. Real-time ultrasound-guided percutaneous dilatational tracheostomy: a feasibility study. Crit Care. 2011;15:R67.
11. Trouillet JL, Collange O, Belafia F, Blot F, Capellier G, Cesareo E, Constantin JM, Demoule A, Diehl JL, Guinot PG, Jegoux F, L'Her E, Luyt CE, Mahjoub Y, Mayaux J, Quintard H, Ravat F, Vergez S, Amour J, Guillot M. Tracheotomy in the intensive care unit: guidelines from a French expert panel. Ann Intensive Care. 2018 Mar 15;8(1):37.
12. Flint A.C., Midde R., Rao V.A., Lasman T.E., Ho P.T. Bedside ultrasound screening for pretracheal vascular structures may minimize the risks of percutaneous dilatational tracheostomy. Neurocrit Care. 2009;11:372–376.
13. Rees J, Haroon Y, Hogan C, Saha S, Derekshani S. The ultrasound neck imaging for tracheostomy study: A study prompting ultrasound screening prior to percutaneous tracheostomy procedures to improve patient outcomes. J Intensive Care Soc. 2018 May;19(2):107-113.
14. Singh M., Chin K.J., Chan V.W., Wong D.T., Prasad G.A., Yu E. Use of sonography for airway assessment: an observational study. J Ultrasound Med. 2010;29:79–85.
15. Marktanner, R., Shafei, A., Mostafa, M., Hon, H., Zaghloul, Y., & Taha, A. (2014). Modified technique of realtime ultrasound guided percutaneous balloon dilatational tracheostomy through laryngeal mask airway insertion. Critical Ultrasound Journal, 6(1), A5. https://doi.org/10.1186/2036-7902-6-S1-A5
16. Griggs WM, Worthley LI, Gilligan JE, Thomas PD, Myburg JA. A simple percutaneous tracheostomy technique. Surgery, gynecology & obstetrics 1990;170:543-5