**An-Najah National University**
**Faculty of Graduate Studies**

# EARLY VERSUS LATE TRACHEOSTOMY IN THE MECHANICALLY VENTILATED CRITICALLY ILL PATIENTS: A RETROSPECTIVE MULTICENTER COHORT STUDY IN PALESTINE

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This Thesis was defended successfully on 02/09/2025 and approved by:

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# Dedication

This thesis work is dedicated to my parents, who have supported me during my graduate studies. I am truly thankful for their unconditional love. My parents taught me the true meaning of hard work and inspired me to be what I am now.

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First, I would like to thank Dr. Mohammad Hayek for his efforts in this thesis and for his continuous guidance throughout the preparation period. You have been a major supporter of this achievement.

I would also like to express my deep gratitude to my parents and friends who supported me throughout my studies. I thank you from the bottom of my heart for your endless support. May God reward you all the best.

## Declaration

I, the undersigned, declare that I submitted the thesis entitled:

# EARLY VERSUS LATE TRACHEOSTOMY FOR THE MECHANICALLY VENTILATED CRITICALLY ILL PATIENTS: A RETROSPECTIVE MULTICENTER COHORT STUDY IN PALESTINE

I declare that the work provided in this thesis, unless otherwise referenced, is the researcher's own work, and has not been submitted elsewhere for any other degree or qualification.

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**EARLY VERSUS LATE TRACHEOSTOMY IN THE MECHANICALLY VENTILATED CRITICALLY ILL PATIENTS: A RETROSPECTIVE MULTICENTER COHORT STUDY IN PALESTINE**

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## Abstract

Background: Prolonged mechanical ventilation (PMV) is a particularly common reason for tracheostomy in patients hospitalized in the intensive care units (ICU). The operation is classified as "early" or "late" based on the date of its execution relative to the start of mechanical ventilation (MV). Although the evidence for early versus late tracheostomy varies, early tracheostomy has been linked to shorter hospital stays and lower mortality rates.

No previous studies in Palestine have compared or assessed the optimal timing of tracheostomy, although some hospitals follow an ET protocol for expected PMV patients.

Aim: To compare the clinical outcomes of early vs late tracheostomy for mechanically ventilated critically ill patients in the ICU.

Methods: This retrospective multicenter observational cohort research was carried out in Palestine from January 2023 to December 2024. Patients who had elective tracheostomies were divided into two groups: early tracheostomy (ET), which was performed during the first 10 days of intubation, and late tracheostomy (LT), which was performed beyond the tenth day. The major outcomes assessed were mortality, duration of MV, length of stay in the ICU and hospital, and incidence of ventilator-associated pneumonia (VAP). These outcomes were evaluated and compared among groups, both overall and stratified by APACHE II scores.

Results: About 66 patients were included in the study, 37 in the ET and 29 in the LT. ET was associated with significantly lower mortality ($P = 0.033$), shorter duration of MV ($P < 0.001$), and reduced length of ICU ($P < 0.001$) and total hospital stays ($P < 0.001$). VAP rates were not significantly different ($P = 0.083$). In patients with APACHE II $\leq 20$, ET significantly improved all outcomes except mortality ($P = 0.405$). In patients with

APACHE II > 20, ET significantly reduced the total duration of MV (P = 0.009), length of ICU and hospital stays (P = 0.037; P = 0.035, respectively) while having no significant impact on mortality (P = 0.238), duration of post-tracheostomy MV (P = 0.236), and VAP (P = 0.474).

Conclusion: ET appears to be associated with improved outcomes compared with LT, particularly in lower-risk patients.

**Keywords**: critically ill patients, prolonged mechanical ventilation, tracheostomy, early tracheostomy, APACHE-II score

# Chapter One

# Introduction and Theoretical Background

## 1.1 Background

The population of patients with chronic critical illness has increased in recent years as a result of declining mortality rates associated with advancements in several medical specialties (Vincent & Creteur, 2019). Globally, an estimated 30 to 45 million cases of critical illness occur annually, with a mortality rate of around 20–40% of all ICU patients (Kayambankadzanja et al., 2022; Zhang et al., 2022). The presence of various major acute organ dysfunctions and the requirement for close observation and care characterize a critically ill patient. Critically ill patients may suffer from one or more disease processes. These might vary greatly amongst patients and impact therapy and prognosis. Typically, these diseases are identified by the kinds and severity of organ dysfunctions (Vincent & Creteur, 2019).

However, there are several definitions of critically ill patients, including a patient with a condition of poor health with dysfunctional vital organs, a significant risk of death in a short period if treatment is not received, and the possibility of recovery. Another prevalent definition is an ICU stay lasting eight days or longer that is linked to at least one of the following conditions: multiple organ failure, sepsis, tracheostomy, MV for ninety-six hours or longer, and severe wounds (Kayambankadzanja et al., 2022; Núñez et al., 2021).

Mechanical ventilation is required when spontaneous ventilation is not enough to maintain life, in addition to the supportive role that MV plays in cases of surgical patients. The necessity of artificial ventilation necessitates admission to the ICU, where patients are typically kept for a brief while. However, critically ill patients may have a poor recovery process, requiring PMV (Dolinay et al., 2024). According to the National Association for Medical Direction of Respiratory Care (NAM-DRC) consensus conference, PMV is defined by the need for mechanical ventilation for at least six hours per day for at least 21 consecutive days (MacIntyre et al., 2005; Dolinay et al., 2024). Another definition of PMV is an effective extubation following at least four attempts of independent respiratory effort or ventilation duration exceeding fourteen days (Huang et al., 2022).

Long-term dependence and difficulty in weaning from MV vary greatly based on the underlying patient's condition, including persistent lung disease, disorders affecting the neuromuscular system, central nervous and spinal cord injuries, and other comorbidities, such as malnutrition, uncontrolled diabetes, excessive body weight classified as obesity, and long-term cardiac disorders (Dolinay et al., 2024). In Patients receiving PMV, prolonged bed rest related to prolonged sedation use may result in several adverse effects, such as wasting of the extremities and respiratory muscle, deficient physical condition, impaired diaphragm muscle function, which may lead to decreased lung volume, and atelectasis (Huang et al., 2022; Goligher et al., 2018). Also, invasive endotracheal PMV is correlated with a high risk of VAP incidence, tracheal complications such as tracheal stenosis, dysplasia, and even fistula (Touman & Stratakos, 2018). For a long-term outcome, patients with PMV have a higher psychiatric disorders and mortality (Ludski & Honeywill, 2023). In addition, many patients with PMV receive tracheostomies, which are frequently maintained for a long time (Kishihara et al., 2023).

Tracheostomy is a common procedure that is performed in patients with PMV, as around 10-20% of critically ill patients in the ICU may have a tracheostomy (Kishihara et al., 2023). Tracheostomy is an invasive procedure that may be performed surgically or percutaneously, by opening the anterior cervical tracheal wall and applying a small flexible tube into the airway, to relieve airway obstruction, improve pulmonary toileting, and facilitate ventilatory weaning (Whitmore et al., 2020). Many benefits come with a tracheostomy, such as reduced sedation requirements, increased patient comfort and safety, improved communication, and easier nourishment and dental care (Fouda et al., 2024). Because tracheostomy allows for less sedation, enhances patient safety and comfort, it is hypothesized that tracheostomy lowers the risk of VAP and mortality (Quinn et al., 2022). Nevertheless, tracheostomy is linked to wound infection, hemorrhage, tracheal stenosis, unintentional displacement, and in rare cases, death. However, it is still considered an effective management for patients with the difficulty of weaning, shortening the duration of MV, length of ICU and hospital stay, and decreased financial healthcare costs (Morakami et al., 2023; Quinn et al., 2022).

The optimal timing of tracheostomy and the subject of research are still controversial. There is considerable heterogeneity in the definition of tracheostomy timing in previous literature. Early tracheostomy (ET) is defined as applying tracheostomy tube within the first 7 days of translaryngeal intubation (Filice et al., 2021), while most studies defined it as performing tracheostomy at the tenth day or before (Morakami et al., 2023). Another study classified tracheostomy into ET, which is performed in the first 5 days, intermediate tracheostomy from the 6th day to 10th day of intubation, and late tracheostomy (LT) after 10 days (Zhao et al., 2024).

However, it is still considered an effective procedure in improving patients' outcomes by decreasing the duration of MV, length of ICU and hospital stay, and lower VAP rates, while showing no improvement in mortality rates in compared with LT (Fouda et al., 2024; Marra et al., 2021). These benefits allow for improved patient rehabilitation, earlier discharge, and decreased health costs (de Franca et al., 2020).

### 1.2 Problem Statement

Patients in critical condition frequently need PMV, which is linked to a greater risk of complications including VAP, bed sores, pulmonary problems, and increased hospital stays, which directly correlated with increased hospitalization and higher economic burdens, and a negative impact on the patient's overall quality of life (Huang et al., 2022; Goligher et al., 2018).

Tracheostomy is the golden solution for PMV, but the optimal timing of tracheostomy is still controversial. ET (within 10 days of intubation) has shown benefits such as shorter MV duration, less VAP incidence, and decreased length of ICU and hospital stay, which promote earlier rehabilitation and discharge (de Franca et al., 2020; Morakami et al., 2023; Fouda et al., 2024). However, there is no unanimous agreement on which ET or LT (after 10 days of intubation) is preferable to ensure safety, effectiveness, and cost efficiency.

To our knowledge, no previous studies in Palestine have compared or assessed the optimal timing of tracheostomy, although some hospitals in Palestine follow an ET protocol for expected PMV patients. So, we aimed to fill the notable gap in knowledge and research by conducting a study to compare clinical outcomes between ET and late LT in critically ill patients in the ICU.

## 1.3 Research Aim

To compare the clinical outcomes of early vs late tracheostomy for the mechanically ventilated critically ill patients in the ICU.

## 1.4 Research objectives

The objectives of this study to:

- Assess the mortality rate associated with ET compared to LT.
- Assess the effect of ET compared to LT on mechanical ventilation duration.
- Determine the effect of ET compared to LT on the length of ICU and total hospital stay.
- Evaluate the effect of tracheostomy timing on the incidence of VAP in critically ill patients.

## 1.5 Research Question

- What is the rate of mortality associated with ET compared to LT in critically ill patients?
- What is the effect of tracheostomy timing on mechanical ventilation duration?
- Does ET, compared to LT, influence the ICU length of stay and total hospital length of stay?
- What is the incidence of VAP associated with ET compared to LT in critically ill patients?

## 1.6 Hypothesis

- H1: ET is associated with lower mortality than LT in mechanically ventilated critically ill patients.
- H2: ET is associated with shorter MV duration than LT in mechanically ventilated critically ill patients.
- H3: ET is associated with shorter length of ICU and total hospital stay than LT in mechanically ventilated critically ill patients.

- H4: ET is associated with lower VAP incidence than LT in mechanically ventilated critically ill patients.

### 1.7 Significance of the Study

The lack of clear guidelines in Palestine for the optimal timing of tracheostomy has resulted in delayed or premature use of tracheostomy without a solid scientific foundation based on Evidence-Based Practice. This has contributed to PMV, delayed weaning, recovery, and prolonged ICU and hospital stay.

So, this study is significant as:

- This research will be beneficial in establishing a foundation for the enhancement and improvement of overall well-being and outcomes for expected prolonged intubated critically ill patients, leading to better weaning and recovery strategies.
- The findings have the potential to influence intensivists, decision makers, and planners of care delivery in reconsidering the currently accepted tracheostomy timing practices for critically ill patients. This, in turn, could enhance the overall quality of care provided and help prevent associated complications.
- The results may provide a base for further studies in Palestine in the future regarding tracheostomy timing practices for critically ill patients, aiming to fill the existing gap in research and knowledge about this topic.

### 1.8 Conceptual and Operational Definition

#### 1.8.1 Conceptual Definition

**Intensive Care Unit**: It is a structured approach to caring for critically ill patients that offers specialized and intensive medical and nursing care, improved monitoring capabilities, and various forms of physiologic organ support to maintain the patient life during a life-threatening organ system insufficiency (Marshall et al., 2017).

**Critically Ill Patient**: a patient with a condition of poor health that requires ICU stay lasting eight days or longer with multiple organ failure, sepsis, tracheostomy, MV for ninety-six hours or longer, and severe wounds, in which a significant risk of death in a short period if treatment is not received, and the possibility of recovery (Kayambankadzanja et al., 2022; Núñez et al., 2021).

**Mechanical Ventilation**: It is a critical intervention for maintaining life in emergency situations, especially when patients have hypoxemic respiratory failure, limited airways, or poor ventilation. Positive pressure breathing is used during this process, which depends on the resistance and compliance of the airway system (Hickey et al., 2024).

**Prolonged Mechanical Ventilation**: the demand for invasive ventilatory supports for a minimum duration of 6 hours per day for no less than 21 uninterrupted days, or an effective extubation following at least four attempts of independent respiratory effort or ventilation duration exceeding fourteen days (MacIntyre et al., 2005; Huang et al., 2022; Dolinay et al., 2024).

**Tracheostomy**: It is an invasive surgical procedure in which a small flexible tube is inserted through the trachea by opening a small orifice into the anterior wall of the cervical trachea to support patients' respiration. Tracheostomy may be performed surgically or percutaneously (Whitmore et al., 2020).

**Early tracheostomy**: Tracheostomy that is performed within the first 10 days of initial endotracheal intubation (Morakami et al., 2023). (This definition was used in our study)

**Late Tracheostomy**: Tracheostomy that is performed after the $10^{th}$ day of initial endotracheal intubation (Morakami et al., 2023). (This definition was used in our study).

**Ventilator-associated Pneumonia**: Pneumonia that develops 48 hours following invasive tracheal or endotracheal intubation (invasive MV) or if the initial pneumonia worsens 48 hours following MV, and is characterized by the presence of signs of systemic infection (body temperature and white blood count), a new or progressive pulmonary infiltrate, change in sputum characteristics (color, amount), and detection of the causative agent (Sanketh et al., 2023).

**Acute Physiology and Chronic Health Evaluation II (APACHE II) score**: It is defined as a scoring system used to assess the severity of a patient's health condition, and predict mortality risk, showing patients who have high susceptibility for death and require intensive care, which helps in determining the level of care (Knaus et al., 1985; Mumtaz et al., 2023).

### 1.8.2 Operational Definitions

Duration of MV, length of ICU stays, length of hospital stays, mortality, and ventilator-VAP: These measures were extracted using a data collection sheet from the patient's medical and clinical report.

**VAP incidence**: It is measured and recorded from the patient's medical records according to the intensivist and physician diagnosis by follow-up body temperature, leukocyte count, tracheal secretion volume and characteristics, arterial oxygenation status, chest radiographic (X-ray), and tracheal aspirate culture.

**Mortality**: After reviewing relevant data from patients' medical records, the occurrence of death during the predefined study period (during hospitalization) was recorded.

**Duration of Mechanical Ventilation**

Measurement Criteria: The initiation and termination times of MV supports were recorded in days by reviewing the patient's medical record.

Criteria for Extubation: It was measured by the anesthesiologist according to hospital policy criteria, which include three major criteria: when the patient demonstrates adequate spontaneous breathing, sufficient oxygenation, and hemodynamic stability.

**Intensive Care Unit length of stay**

Measurement Criteria: The number of days from admission to the ICU until the patient's transfer out of the ICU was recorded.

**Hospital length of stay**

Measurement Criteria: The number of days from admission to the ICU until the patient is discharged from the hospital to home or rehabilitation centers was recorded.

Criteria for Discharge: The discharge process from the ICU and hospital was followed up by a specialist, intensivist, and anesthesiologist according to policy criteria. It was considered when the patient meets predefined recovery criteria, including stable hemodynamics, respiratory function, and consciousness.

**APACHE II score**: calculated at ICU admission, these data extracted from patient's and hospital medical files and documentations: include the 12 physiological variables (temperature, mean arterial blood pressure, heart rate, respiratory rate, oxygenation (A-a $PO_2$ ($Fio_2$ > 50%) or $PaO_2$ ($Fio_2$ <50%)), arterial pH, , serum HCO3-, sodium, potassium, creatinine, hematocrit, white blood cell count, and the Glasgow Coma Scale (GCS)) each variable weight from 0-4 points, age (0 point for age < 44, 2 points 45-54, 3 points55-64, 5 points 65-74, and 6 points for age of 75 or more), and chronic health evaluation (5 points for the patient who has severe chronic organ insufficiency or is immunocompromised and the reason for ICU admission is non-operative, 2 points for post-operative patients) (Knaus et al., 1985; Mumtaz et al., 2023).

## 1.9 Literature Review

### 1.9.1 Critically Ill Patients

Recently, an increasing number of patients are presenting with critical illness to healthcare facilities globally, due to advancements in medicine and new technology, making the life span longer for those patients (Vincent & Creteur, 2019). However, it is difficult to diagnose and classify critically ill patients precisely because of the large variation in their definition. Kayambankadzanja et al. (2022) conducted a concept analysis to define critical illness; four basic themes were identified: significant risk of near-term mortality, failure of vital organs, dependence on intensive interventions to prevent death, and the possibility of clinical recovery (Kayambankadzanja et al., 2022; Zhang et al., 2022).

Acute organ dysfunction, either present or at imminent risk, is the primary characteristic that defines a patient as critically ill. Crucially, even while the phrase "life-threatening" is frequently used concerning critical illness, it is not a necessary part of its definition, even though many critically ill individuals have a "life-threatening" condition. For instance, because it is possible to survive without renal function with the right support, people who are at risk of developing acute renal failure may be critically ill but not necessarily have a life-threatening illness (Vincent & Creteur, 2019).

Critically ill patients may complain of one or several disease processes that pose challenges in defining the critical illness state. For instance, some complex patients with septic shock from peritonitis associated with acute respiratory distress syndrome (ARDS) also have many comorbidities, such as complicated diabetes and chronic obstructive pulmonary disease (COPD), as well as secondary renal failure. Therefore, the types and severity of organ dysfunctions, which vary from patient to patient and affect treatment processes and outcomes, are typically what define critically ill individuals. However, these patients require intensive monitoring and management and may last in the ICU for more than eight days, with a possible need for tracheostomy and MV support for no less than 96 hours (Vincent & Creteur, 2019).

### 1.9.2 Mechanical Ventilation (MV)

MV is an essential therapeutic intervention used to maintain and provide life-sustaining support, and ensure sufficient oxygen delivery during emergencies, primarily in cases of poor oxygenation status, airway obstruction, and inadequate pulmonary function (Hickey et al., 2024). This method is also employed during and following major surgery, as well as to treat different types of respiratory failure (Tran et al., 2021). This process involves the delivery of airflow under positive pressure, and its effectiveness and efficiency are influenced by key mechanical factors of the respiratory system, namely airway resistance and lung compliance (Hickey et al., 2024).

According to estimates, ventilatory assistance is used in 2–6% of all hospitalizations worldwide (Jivraj et al., 2023). Epidemiological data from the United States recently revealed that more than 4 million patients are admitted to an ICU annually, with approximately 40% of those patients receiving invasive MV for nonsurgical reasons, and invasive ventilation is performed on 310 adults per 100,000 (Zisk-Rony et al., 2019; Rackley, 2020).

Mechanical ventilation is not a treatment that targets a particular disease. Moreover, individual patients with distinct characteristics and co-morbidities may not always be reflected in population-based data (Pelosi et al., 2021). MV indications are classified into four main indications. The first indication includes airway compromise, that associated with the need for securing and maintaining airway patency, such as facial trauma or infection of the oropharyngeal area. Patients with either upper airway occlusion, as in cases of angioedema, or lower airway occlusions as obstructive airway disorders, such as severe asthma or acute COPD deterioration (Hickey et al., 2024). The second indication is hypoventilation can cause hypercapnic respiratory failure due to gas exchange issues, pump failure, or poor driving, as occurred in cases of central drive impairment (drug overdose, for example, weakening of the respiratory muscles (such as myositis and muscular dystrophy), defects of the peripheral nerve system (such myasthenic crisis or Guillain-Barré syndrome), restrictive ventilatory deficits (e.g., major pneumothorax or effusion, disease or damage to the chest wall) (Hickey et al., 2024; Farkas et al., 2020; Jablonski et al., 2020). The third indication includes hypoxemic respiratory failure that arises from impaired oxygen exchange as a result of pulmonary congestion or edema, ARDS, pneumonia, other alveolar filling abnormalities, diffusion abnormalities (like advanced pulmonary fibrosis), and pulmonary vascular anomalies that result in V/Q mismatches (such as large pulmonary artery air or thromboembolism) (Hickey et al., 2024; Jablonski et al., 2020). Finally, conditions that lead to increased metabolic and ventilatory demands, such as sepsis, shock status, and severe metabolic acidosis (Hickey et al., 2024; Jung et al., 2019).

A positive pressure breath is applied by MV, which is affected by the mechanical properties of the airway, including resistance and compliance (Hickey et al., 2024). During spontaneous inhalation, the respiratory muscles of the diaphragm and intercostal muscles contract, which leads to an increase in the thoracic cavity, which drives transpulmonary pressure, allowing air to flow from positive atmospheric pressure to negative pressure inside the lungs. On the other hand, controlled breaths by MV force the airflow through ventilator circuits and the airway tree to the lungs by applying positive ventilatory pressure (Pleil et al., 2021). During assisted mode, MV delivers breath after being triggered by when patient-initiated inspiratory attempt. The pressure simultaneously results from the product of interaction between positive pressure in the alveoli and the negative pressure within the pleural space (Cronin et al., 2022).

The most commonly used modes of MV include volume-assist control (VAC), pressure-assist control (PAC), and synchronized intermittent mandatory ventilation (SIMV), often used in conjunction with pressure support ventilation (PSV) (Hickey et al., 2024). PSV mode is frequently utilized throughout the weaning process from MV rather than as a primary mode. Additional ventilation modalities that deliver air until a set pressure is reached, regardless of the volume of air given called pressure controlled, or delivers a preset volume of air, regardless of the pressure it takes to deliver it called volume control, including controlled mechanical ventilation, and intermittent mandatory ventilation modes (Hickey et al., 2024). The amount of air exchanged during each complete inspiration and expiration process is known as the tidal volume (VT), which is based on the patient's calculated ideal body weight that is considered in terms of both weight and height of patients, instead of weight alone (Hallett et al., 2024). Standard MV settings often target a VT range of 8 to 10 mL/kg, while new models recommend delivering VT at a range of 6-8 mg/kg to minimize the risk of lung injury and are physiologically influenced by the height and sex of the individual (Hallett et al., 2024; Hickey et al., 2024).

There are two main types of breath delivery in MV: volume-control and pressure-control. Airway resistance, respiratory compliance, and the chosen ventilatory strategy all affect VT and airway pressure. For example, in VAC mode, VT is fixed at a certain level, and lung compliance affects the pressure measured during an inspiratory pause, known as plateau pressure, while in contrast, the inspiratory pressure gradient is applied at a constant value in PAC mode, which causes variable ventilation according to lung compliance (i.e., lower lung compliance results in lower VT, whereas higher lung compliance results in higher VT) (Hickey et al., 2024).

The four phases of MV are the trigger, Inspiratory, cycling, and expiratory phases. Inhalation initiates during the trigger phase, during which activation may occur in response to the patient's inspiratory effort or through automatic initiation based on ventilator settings. During the inspiratory phase, VT is delivered into the patient's lungs. The cycling phase occurs after inspiration, marking the end of inhalation but before exhalation begins. Finally, the patient's passive exhalation of air from their lungs occurs during the expiratory phase (Hickey et al., 2024).

As with any medical intervention, MV may cause many consequences that affect multiple body systems. Increased intrathoracic pressure may cause hemodynamic alterations, as it implies compression during positive MV pressure on the heart and great mediastinum vessels, subsequently leading to depressed myocardial performance accompanied by low blood pressure. As a result of decreased cardiac output, renal hemodynamics and glomerular function are impaired (Pham et al., 2017; Silva et al., 2022). Although increased intrathoracic pressure may increase intracranial pressure, it results in an alteration in cerebrovascular circulation and intracranial dynamics, as well as increasing the risk for developing abdominal compartment syndrome, especially in patients with abdominal surgery, critical injury, gastric distension, and acute pancreatitis (Silva et al., 2022).

When ventilator settings are not modified following ideal body weight, ventilator-associated lung injury frequently results, particularly in diseases such as acute respiratory distress syndrome that are characterized by stiff lungs (Hickey et al., 2024). It encompasses atelectrauma, volutrauma, barotrauma, and biotrauma. The opening and closing of recruitable atelectatic lung units by high-shear forces results in atelectrauma. High lung inflation pressure causes barotrauma in patients on MV, which can lead to subcutaneous emphysema, alveolar rupture, pneumothorax, and pneumomediastinum. Alveolar overdistension causes volutrauma, which can result in interstitial and alveolar edema. Biotrauma is the term for the harmful effects of an unfavorable inflammatory response that can result from mechanical injury to the lungs. Other complications may occur, accompanied by MV, such as gastric stress ulcer, deep venous thrombosis, bed sores, and VAP (Haribhai & Mahboobi, 2022).

### 1.9.3 Prolonged Mechanical Ventilation (PMV)

Patients with life-threatening conditions who require intensive care in the ICU department frequently require PMV, with an incidence rate between 6.3% to 9.9% of patients receiving invasive ventilatory support (Núñez et al., 2021). Approximately 30% of critically ill patients require PMV. Accurate evaluation of these individuals is impossible as PMV lacks a defined criterion. However, a prior study estimated that 7.4 out of 100,000 people had long-term MV (Vali et al., 2023), with approximately 15% of patients having MV for more than 7 days, and 4.6% requiring it at 60 days (Dolinay et al., 2024). Among individuals experiencing critical respiratory dysfunction, 5% to 13% require the use of MV supports for an extended period, as global data indicate a steadily increasing pattern of its usage (Huang et al., 2022).

There is a heterogeneity in the definition of PMV, with definitions ranging from seven to twenty-one days of continuous MV (Vali et al., 2023). The NAM-DRC consensus conference defined the PMV as the demand for invasive ventilatory supports for a minimum duration of 6 hours per day for no less than 21 uninterrupted days (MacIntyre et al., 2005; Dolinay et al., 2024). Another definition of PMV is an effective extubation following at least four attempts of independent respiratory effort or ventilation duration exceeding fourteen days (Huang et al., 2022).

Comorbidities worsen illnesses and significantly affect how well patients who need PMV fare. Patients with PMV commonly have comorbidities such as end-stage renal illness, cancer, neurological disorders (including neuromuscular or cerebrovascular), heart disorders, COPD, and additional risk factors for PMV include infection, including sepsis, infections resistant to multiple drugs, malnourishment, diaphragmatic impairment related to MV, combined neuropathic and myopathic dysfunction related to critical illness, and encephalopathy (Huang et al., 2022). Furthermore, determined by the lung condition and the reason for respiratory impairment, patients with PMV may have different basal respiratory drive levels (Sato et al., 2021).

A high APACHE II score, pneumonia, prior ICU hospitalizations, and underlying respiratory conditions are known as factors that lead to weaning failure. Additional factors related to failed weaning are low serum albumin, increased blood urea nitrogen levels, low maximal inspiratory pressure, and low GCS scores (Huang et al., 2022).

While MV is often a life-saving intervention, PMV may lead to numerous complications related to immobility and long-term ventilator use, which increase the burden of disease and management, such as limb and respiratory muscle atrophy, impaired functional status, diaphragm dysfunction, decreased lung volume, and atelectasis. (Huang et al., 2022; Goligher et al., 2018). In addition to tracheal complications such as tracheal stenosis, dysplasia, and even fistula, VAP, ventilator-associated lung damage, prolonged hospitalization, higher psychiatric disorders, and increasing mortality (Vali et al., 2023; Ludski & Honeywill, 2023; Touman & Stratakos, 2018).

The challenges in weaning PMV patients may contribute to prolonged hospitalization and increase both morbidity and mortality. PMV patients usually have a poor prognosis. Jubran et al. (2019) reported that in the United States, 66.9% of patients who needed PMV were still alive at year one, and upon hospital discharge, 53.7% were effectively and successfully extubated without the need of reinstitution of ventilatory supports. However, in one year following hospital discharge, the survivorship percentage for patients with MV reliance was only 16.4% (Jubran et al., 2019). According to international data, patients who use PMV for more than 21 days are typically associated with an unfavorable outcome, and diminished long-term survival, with mortality occurring by year two rate of about 25% (Dolinay et al., 2024).

### 1.9.4 Ventilator-Associated Pneumonia (VAP)

VAP is a hospital-acquired (nosocomial) infection that affects lung tissues following forty-eight hours (two calendar days) of initiating invasive MV via endotracheal tube, which is considered early if it occurs within the first ninety-six hours, and late if it occurs after ninety-six hours most commonly by microorganisms resistant to multiple classes of antimicrobial agents (Mergulhão et al., 2024).

VAP is a form of acquired pneumonia in the ICU that affects 20% to 36% of ventilated patients and is recognized as the most frequent nosocomial infection (Swain & Jena, 2021). Data from the European Centre for Disease Prevention and Control's 2017 surveillance of ICU-acquired infections indicated that endotracheal intubation was associated with 97.3% of the 8,983 pneumonia cases reported in ICUs (Mergulhão et al., 2024). There was a great variation in the percentage of VAP incidence in the patients supported by MV, with a range of 5% to 40% (Papazian et al., 2020). The percentage variations related to the different ICU settings, diagnostic methods, and regional health care differences, as developed countries with rich resources, such as the United States, have lower VAP than limited resources countries, with an incidence rate of 9 versus 18.5 per 1000 days of ventilatory support, respectively (Bonell et al., 2019: Papazian et al., 2020). Significantly, VAP prevalence is significantly influenced by the ICU case mix, with greater rates seen in cancer patients (24.5%) and trauma patients (17.8%) (Mergulhão et al., 2024).

VAP is basically associated with the presence of an invasive endotracheal tube for a long time through two mechanisms, including aspiration of secretions containing pathogenic microorganisms and biofilm (Swain & Jena, 2021). After intubation, the endotracheal tube penetrates the glottis and larynx's anatomical barriers, impairs the natural closure of the glottis and establishes a direct pathway to the lower respiratory tract, which facilitates the microaspiration of secretions originating from the oropharynx and nasal sinuses; moreover, the endotracheal tube cuff may experience deflation, displacement, or the formation of minor folds, all of which can permit accumulated secretions to seep past the cuff into the lungs (Howroyd et al., 2024). Sedation, which further impairs natural reflexes, is typically the cause of cough reflex suppression (Xu et al., 2020). It has been suggested that the stomach, oropharynx, nasal cavities, and paranasal sinuses are sources of infectious materials. Lower airway colonization and subsequent lung infection are caused by aspirating infected secretions. Patients on MV in the ICU frequently had microbial biofilm on the luminal surface of their endotracheal tubes. This biofilm developed within hours of tracheal insertion and became abundant by 96 hours. Microbial biofilm may serve as a pathogen reservoir, leading to recurring infections (Swain & Jena, 2021). According to Soares et al. (2020), the same bacteria were recovered from the endotracheal tube and deeper airway sputum specimens in 70% of patients with VAP. Additionally, the development of microbial bacterial resistance is frequently linked to biofilms (Soares et al., 2020).

There are several risk factors for VAP incidence. Intubation is considered the main risk factor for VAP, as it is associated with more than 95% of pneumonias in the ICU (Swain & Jena, 2021). Male sex, advanced age, history of trauma, and the overall severity of a patient's underlying medical condition are some of the independent risk factors that contribute to the occurrence of VAP. Diabetes, chronic renal failure, and coronary heart disease are among the chronic diseases that have been identified as risk factors for VAP. Currently, the internationally recognized factors include prolonged ICU stays, prior antibiotic medication, invasive procedures, burns, comorbidities, disorders of consciousness (Glasgow Coma Scale less than 9), and gene polymorphisms. The risk of VAP is also linked to the duration of MV; the progressive-cumulative risk is 3% per day during the first week of supported MV and 2% per day during the second week. Between eight and ten days, the risk of infection is at its peak. Additional factors include hyperoxemia, intra-abdominal hypertension, and smoking (Mergulhão et al., 2024; Wu et al., 2019).

The diagnosis of VAP typically involves three key components: clinical suspicion, radiographic evidence of new or progressive and persistent infiltrates, and microbiological confirmation from lower respiratory tract samples (Papazian et al., 2020). Suspicion based on clinical findings is typically the first step in identifying VAP, common signs include elevated temperature, increased white blood cell count, impaired oxygen levels, purulent heavy tracheal secretions, abnormal chest imaging, and microbiological analysis of tracheal aspirates using Gram stain and culture techniques (Papazian et al., 2020; Howroyd et al., 2024). Although most definitions of VAP include radiographic findings as a diagnostic criterion, chest X-rays are widely acknowledged to have limited sensitivity and specificity in accurately identifying VAP, while computed tomography scans are more sensitive; they might be a good substitute (Papazian et al., 2020). Recently, lung ultrasonography has been suggested as a diagnostic tool for VAP; however, there is a paucity of information about its sensitivity and specificity (Bouhemad et al., 2018). In conclusion, there is currently no single clinical indicator, scoring tool, or biological that can reliably and accurately diagnose ventilator-associated pneumonia (VAP). The condition may present with or without newly developed or worsening infiltrates in the lungs, though VAP should be taken into consideration whenever there are new indications of respiratory deterioration that may be caused by an infection (such as fever, purulent sputum, leukocytosis, worsening oxygenation, unexplained hypotension, or increasing vasopressor requirements) (Papazian et al., 2020; Howroyd et al., 2024).

VAP is associated with increased lengths of stay in the ICU and hospital, as well as difficulties weaning off the ventilator. These factors result in a significant demand for medical resources and increased healthcare-related costs for individuals and hospitals (Mergulhão et al., 2024). As a result, VAP patients frequently spend more time on invasive MV and consume more antibiotics, which account for 50% of all antibiotics used in the ICU. This leads to significant hospital and ICU admission expenses (Mergulhão et al., 2024; Swain & Jena, 2021). There is a two-fold increase in mortality related to VAP, with a wide range of mortality rates from 24 to 76%. However, determining the direct impact of VAP on patient mortality remains a challenging issue. This difficulty arises from the complexity and severity of patients' underlying medical conditions in addition to the variability in diagnostic criteria and practices across different ICU populations (Swain & Jena, 2021). According to the 2016 clinical guidelines published by the American Thoracic Society (ATS) and the Infectious Diseases Society of America (IDSA), the death rate from VAP in the United States might be as high as 13%. However, multicenter prospective studies in Europe found that the death rate for early VAP was 19.2 % while the mortality rate for late VAP was 31.4% (Wu et al., 2019). Early recognition and prompt, appropriate intervention are crucial to preventing these life-threatening sequelae such as ARDS and septic shock (Swain & Jena, 2021). As a result, prevention is crucial and includes minimizing needless sedation, limiting ICU length of stay, invasive MV duration, and maintaining strict hygiene standards (Mergulhão et al., 2024).

Prevention of VAP is one of the challenging issues that face critical care nurses. However, many practices may be followed to prevent VAP in different clinical settings, in which these interventions may have a vague effect on VAP (Papazian et al., 2020). Current practices for VAP prevention may classified to practices that may lower VAP including head of bed elevation (Wang et al., 2016), automated endotracheal tube cuff pressure monitoring (Papazian et al., 2020), subglottic secretion drainage (Caroff et al., 2016), selective oral and digestive decontamination (Wittekamp et al., 2018; Plantinga et al., 2018), VAP prevention bundles (Pileggi et al., 2018). Another category is practices with unclear effects on VAP, including oral care with chlorhexidine (Deschepper et al., 2018; Papazian et al., 2020), and probiotics (Weng et al., 2017). Taper-con shaped endotracheal tube cuffs and ultrathin polyurethane showed no impact (Jaillette et al., 2017; Maertens et al., 2018), while stress ulcer prophylaxis may increase VAP rates (Huang et al., 2018; Alhazzani et al., 2018; Krag et al., 2018).

### 1.9.5 Tracheostomy

Tracheostomy is an invasive surgical technique in which a small, flexible tube is inserted through the trachea by opening a small orifice into the anterior wall of the cervical trachea to support patients' respiration, and can be performed through two techniques, surgically or percutaneously (Whitmore et al., 2020).

Tracheostomies are performed on 20–24% of intubated patients in the ICU. Patients who are intubated following neurological situations may have a tracheostomy rate of approximately 35%, whereas the rate in general intensive care units is between 10% and 15% (McMahon et al., 2023; Tekin & Bulut, 2024).

Surgical, also called open tracheostomy, is the process of inserting a tracheostomy cannula under direct view following tracheal wall incision and dissection of pretracheal tissues, and it is performed in the operation room. In the percutaneous tracheostomy technique, the pretracheal tissues are separated using blunt dissection, followed by dilation of the trachea open over a guidewire and insertion of a tracheal cannula through the Seldinger method; this minimally invasive procedure is often performed at the ICU bedside without the need for an operating room (Mehta & Mehta, 2017).

Although percutaneous tracheostomy provides a reliable way for respiratory support, some situations indicate the use of surgical tracheostomy, such as short neck patients, cervical instability, emergency airway, pediatric patients less than 15 years old, and cartilage destruction (Khaja et al., 2022).

Historically, tracheostomy was the only airway management for upper airway obstruction, and it still remains one of the most urgent indications of tracheostomy (Raimonde et al., 2020). However, tracheostomy has many indications that are classified as emergent and elective tracheostomy. Emergent tracheostomy included failed endotracheal intubation related to acute upper airway obstruction, resulting from cases such as foreign body, angioedema, and anaphylaxis. Other emergent situations include post-cricothyrotomy, severe facial and neck injuries associated with fractures, traumatic laryngeal injuries, and burns. For elective tracheostomy indications, PMV was the most common indication as tracheostomy provides long-term ventilation and promotes the weaning process (Khaja et al., 2022).  Also, tracheostomy is used electively in patients with refractory obstructive sleep apnea, neuromuscular disorders, congenital anomalies such as subglottic stenosis, and in patients who are unable to manage secretions effectively (Raimonde et al., 2020).

Except for symptomatic cellulitis of the anterior cervical region, there are no medical reasons that prevent tracheostomy placement; however, there are special conditions that needs special consideration regarding tracheostomy, which included sever hypoxemia, poorly controlled bleeding (INR > 2; platelet less than 50000 x $10^9$/L), and hemodynamic instability (Khaja et al., 2022; Raimonde et al., 2020).

Tracheostomy has many advantages compared to oral endotracheal intubation as it provides a more secure airway, which increases patient comfort, improves communication, patient mobility, promotes pulmonary toileting and bronchial suctioning, decreases direct laryngeal injury and oral ulcers, and enhances oral feeding (Khaja et al., 2022). Also, it provides airway protection for patients with a high risk of aspiration, who have a poor or absent cough reflex, and impaired swallowing function. However, tracheostomy allows for less sedation requirements, improved and decreased airway resistance, promotes weaning from MV, and allows for early transfer and discharge from ICU, resulting in a decrease in risk for nosocomial infection and VAP incidence (Quinn et al., 2022).

As with any surgical procedure, tracheostomy is associated with complications, which are classified according to timing into immediate complications such as bleeding, loss of airway combined with hypoxemia and hypercapnia, damage of surrounding structures (posterior tracheal wall tears), and aspiration. Another category is early complications that occur within the first seven days of tracheostomy placement, including bleeding that may be complicated by airway obstruction, tube displacement, stomal infection and ulcer, subcutaneous emphysema, and pneumothorax or pneumomediastinum, which have a higher incidence in pediatric patients. However, late complications occur after the seventh day of tracheostomy placement, and they include tracheal stenosis (most commonly serious), tracheomalacia, tracheoesophageal fistula (very rare, life-threatening), and, in rare cases, death (Lee & Wilson, 2021).

### 1.9.6 Acute Physiology and Chronic Health Evaluation II (APACHE II) Score

In critically ill patients, especially those requiring PMV, the decision to pursue a tracheostomy is influenced by diverse clinical considerations, reflecting the severity of the underlying health condition (Chen et al., 2024). The APACHE II score is a prevalent scoring system utilized in the ICU for the objective assessment of illness severity and outcome prediction (Mumtaz et al., 2023).

The APACHE II score was developed in 1985 by Knaus et al. (1985). It is composed of three main components, which include the 12 physiological variables (temperature, mean arterial blood pressure, heart rate, respiratory rate, oxygenation (A-a $PO_2$ ($Fio_2$ > 50%) or $PaO_2$ ($Fio_2$<50%)), arterial pH, serum HCO3-, sodium, potassium, creatinine, hematocrit, white blood cell count, and the GCS) each variable weight from 0-4 points, age (0 point for age < 44, 2 points 45-54, 3 points 55-64, 5 points 65-74, and 6 points for age of 75 or more), and chronic health evaluation (5 points for the patient who has severe chronic organ insufficiency or is immunocompromised and the reason for ICU admission is non-operative, 2 points for post-operative patients), with score ranging from 0 to 71, as scoring increases, the illness severity and risk of mortality increase (Knaus et al., 1985; Mumtaz et al., 2023).

Many Studies have ensured the validity of the APACHE II score usage in assessing the severity of illness, predicting ICU and hospital mortality, length of ICU and hospital stay, and VAP incidence in critically ill patients (Czajka et al., 2020; Marget et al., 2023; Sutiono et al., 2022; Fernandes et al., 2023). Clinical professionals are prompted to improve their treatment protocols by APACHE II scoring, which acts as an early warning indicator of death. Because of this, it is a valuable tool for clinically predicting ICU mortality (Mumtaz et al., 2023).

APACHE II score at first 24 hours of ICU admission was identified as a significant risk factor for intubation, and the risk of intubation increases with a higher APACHE II score (Kozak et al., 2024). For expected PMV patients, Moussa et al. (2020) and Gupta et al. (2023) recommended that the APACHE II score is valuable to be calculated at ICU admission according to scientific criteria to make a timely, accurate ET decision, and facilitate physician/family agreement on tracheostomy procedure (Moussa et al., 2020; Gupta et al., 2023).

According to Farajzadeh et al. (2021) showed that a cut-off point of APCHE II score of equal or greater than 19 can be used as a highly sensitive and specific reference point for patient ICU admission (Farajzadeh et al., 2021). While Tian et al. (2023) revealed that the optimal time to obtain the APACHE II score is day 3 of ICU admission, with a best cut-off point of 17, for defining patients at high risk of mortality, showing high sensitivity and specificity in non-survivor cases (Tian et al., 2023). Another study showed that for critically ill patients with acute kidney injury, an APACHE II score above 34 has a 100% mortality, with a cut-off value of more than 23 predicting mortality with 79% accuracy (Kumar et al. 2023). In the context of VAP, the APACHE II Scoring system is a good predictor of VAP in ICU settings, with a greater chance of developing VAP in patients with an APACHE II score higher than 20 compared to APACHE II score lower than 20 (Rehman et al., 2025).

Mumtaz et al. (2023) regrouped patients into four main groups according to APACHE II score stratification: group 1 with an APACHE II score of 31-40, group 2 with an APACHE II score of 21-30, group 3 with an APACHE II score of 11-20, group 4 with an APACHE II score of 3-10. The mortality in group 1 and group 2 was 100%, while group 3 was 28.45%, and group 4 was 0% (Mumtaz et al., 2023). However, Situ et al. (2024)

restratified surgical patients with acute peritonitis into three strata: 0-10, 11-20, and > 20, and the results showed that the corresponding mortality was 7.1%, 27.3%, and 100%, respectively, which supports that the APACHE II > 20 is associated with higher ICU and hospital mortality (Situ et al., 2024).

### 1.9.7 Tracheostomy vs. Prolonged Intubation

In a study conducted by Villemure-Poliquin et al. (2023) in Canada assessed the advantages of tracheostomy compared to extended endotracheal intubation and whether the timing of the intervention affects outcomes in traumatic brain injury patients. The main outcome was the 30-day death rate. Additional outcomes were death in the ICU, death after 6 months, ventilator duration, period of ICU residency, period of hospital residency, VAP, and post-discharge care setting (home, rehabilitation center, post-acute care center, and Chronic care center). The tracheostomy was associated with a marked decline in 30-day, ICU, and six-month death rates compared to prolonged endotracheal intubation ($P<0.001$). No significant variation regarding VAP, ICU, and hospital residency duration period, and number of MV days. According to subgroup analysis, ET compared to LT had a reduced duration of MV and length of ICU residency period, but not length of hospital residency. In addition, VAP incidence and discharge orientation did not significantly differ. In conclusion, tracheostomy improved overall clinical outcomes, with better health conditions at discharge, making it a recommended medical procedure for patients who have an expectation for invasive ventilation for a prolonged period (Villemure-Poliquin et al., 2023).

Prospective randomized comparative research in Egypt between February 2018 to February 2021 assessed the effect of ET procedure within the early days of admission ($4^{th}$ -$5^{th}$ day) versus extended endotracheal intubation in severe traumatic head injury patients. The main outcome was the duration of invasive MV. Other studied variables were nosocomial pneumonia and mortality rates. The study enrolled 200 patients, randomly categorized into two equal groups: ET one (n=100), extended endotracheal group (n=100). The findings showed that the ET group had significantly less time spent on MV as opposed to the extended group ($p = 0.02$), while there was no marked variation in the occurrence of nosocomial pneumonia between the two groups ($p=0.62$). The mortality rates neither significantly decrease in ET patients nor with extended intubation. In conclusion, despite previous concerns regarding high mortality rates in the patient population, ET on the fourth day of hospitalization is advantageous and greatly reduces the duration of artificial ventilatory support. Hence, decreasing the residency duration of ICU and hospitalization (Abdelkader et al., 2021).

### 1.9.8 Tracheostomy Timing

There remains ongoing debate regarding the most appropriate timing for performing a tracheostomy, which guarantees the maximum benefits and minimum risks (Fouda et al., 2024). Considerations like how severe the illness is, clinical judgement, the views of the patient and their family, hospital resources, and the anticipated survival rate (Tekin & Bulut, 2024). Historically, doctors have considered the advantages and disadvantages while determining the timing of tracheostomy. However, a growing body of literature indicates that involving multiple disciplines in both the preparation and follow-up phases of tracheostomy can contribute to fewer complications and better clinical recovery prospects (McGrath et al., 2020; Brenner et al., 2020; Zhao et al., 2024).

There is a significant variation between the literature and hospitals regarding when tracheostomy is performed. The definition of ET ranged from the 4th day of initial intubation to the $10^{th}$ day. ET was defined as it performed less than 4 days of post-intubation (Anand et al., 2020), within 6th days of initial intubation (Rifki et al., 2024), 7th day of intubation (Shen et al., 2022; Fokin et al., 2020), $10^{th}$ day of intubation (Fouda et al., 2024; Sarwar et al., 2024; Morakami et al., 2023), and $14^{th}$ day of intubation (Miyake et al., 2024). However, according to a last considerable retrospective cohort study by Zhao et al. (2024), tracheostomy timing is categorized into two criteria: criteria I, ET that is inserted throughout 5 days of initial endotracheal intubation, intermediate tracheostomy that is inserted between the $5^{th}$ and 10th day, and LT after the $10^{th}$ day. Criteria II defined ET as performed within 7 days of initial endotracheal intubation, intermediate tracheostomy between the $7^{th}$ and $14^{th}$ day, and LT after the $14^{th}$ day (Zhao et al., 2024).

According to the Eastern Association of Surgical Trauma (EAST) guidelines, patients who need prolonged ventilatory support or who have serious closed-head injuries should have their tracheostomies performed 3–7 days following intubation. Similarly, many professional organizations have suggested tracheostomy during post-intubation days 5-7 for non-trauma patients who have failed ventilator weaning (Adly et al., 2018; Raimonde et al., 2020). While over half of tracheostomies were done within seven days of intubating trauma patients on MV, the majority of ARDS patients have their tracheostomies more than seven days following the beginning of symptoms (Zhao et al., 2024).

A study conducted by Fouda et al. (2024) investigated the impact of tracheostomy timing for patients requiring intensive care and showed that ET reduced the time spent on MV, length of ICU and hospital stay, and VAP incidence, while the results were not significant for mortality (Fouda et al., 2024). In other studies, that targeted neurotraumatic injury patients, the results were in agreement with the last research, but the researches indicated that the main cause of death is related to severe central nervous system insult (Mubashir et al., 2021; Marra et al., 2021; de Franca et al., 2020; Anand et al., 2020).

### 1.9.9 Early Vs Late Tracheostomy (Clinical Outcomes)

Marra et al. (2021) conducted a study to compare the impact of ET versus LT on mortality and VAP incidence in traumatic brain injury patients. A systematic review and meta-analysis of 9 studies with a fair quality score, with a total of 5106 patients, divided into 2509 patients in the ET, and 2597 in the LT group. The results showed that ET was associated with a significant decline in the occurrence of VAP, shorter time spent on MV, and length of ICU and hospital stay.  Despite the clinical benefits, the mortality rates are still high in the ET group, and even higher than LT one. In summary, ET may be associated with benefits for acute traumatic brain injury patients, and increase the possibility of early patient recovery and discharge by reducing the risk of nosocomial adverse events and secondary injuries, but the results are still not conclusive (Marra et al., 2021).

Another systematic review and meta-analysis carried out by de Franca et al. (2020) aimed to compare the hospitalization outcomes of ET versus LT in patients with severe traumatic brain injury. A total of eight studies were reviewed systematically, seven of which were deemed suitable for meta-analytic evaluation. While mortality rates were similar between the ET and LT cohorts, the study demonstrated that ET contributed to shorter ventilation periods, diminished ICU and hospital stays, and fewer cases of VAP. The results of this meta-analysis indicate that ET increases the possibility of early rehabilitation and discharge for patients with severe traumatic brain injury by reducing their exposure to nosocomial adverse events and secondary insults (de Franca et al., 2020).

The prognostic markers for hemorrhagic and ischemic stroke patients with MV were compared using a retrospective cohort and meta-analysis study. LT was carried out after the seventh day, while ET was placed within seven days of endotracheal intubation. The retrospective analysis comprised 29 patients with LT and 32 patients with ET, for a total of 61 patients. The results revealed no discernible difference between ET and LT in terms of mortality and VAP incidence for prognostic markers. However, the ET group experienced MV for a median of 5.5 days, which was a shorter length. ET was significantly lower than LT for both the ICU and the overall hospital length of stay. Eight studies totaling 16,772 people were included in the meta-analysis. Three to ten days following endotracheal intubation was the definition of ET. The results demonstrated that while the mortality and duration of MV did not differ significantly between the two groups, ET significantly lowered the incidence of VAP, length of ICU stay, and overall hospital stay (Shen et al., 2022).

A systematic review and meta-analysis, conducted to assess the optimal timing of tracheostomy in spinal cord injury patients and evaluate the potential benefits of ET versus LT. The analysis incorporated 8 retrospective studies with a total of 1220 adult patients, 441 of whom received an ET, while 779 received a LT. In-hospital mortality and length of ICU stay were the primary outcomes. Pneumonia rates and the duration of MV were secondary outcomes. Although pooled risk for in-hospital mortality rates was lower in the ET group, but statistically not significant.  Also, the ET and LT groups did not differ in terms of pneumonia incidence. In contrast, ET reduced the duration of MV and length of ICU stay by 18.30 days, 13 days, respectively. However, it is difficult to draw firm conclusions because of the low quality of the studies and the paucity of clinical data available (Mubashir et al., 2021).

Another retrospective cohort study characterized the in-hospital clinical outcomes associated with tracheostomy timing following traumatic cervical spinal cord injury. 4 days was used as a cutoff point to identify two groups, the ET group (within 4 days of initial endotracheal intubation) and the LT group (after 4 days of initial endotracheal intubation). The Primary outcomes included respiratory complications, MV duration, and in-hospital mortality. Secondary outcome measures included length of ICU and hospital stays. A total of 5,980 cervical spinal cord injury patients were included in this study, stratified into ET, 1,010 (17%) patients, and LT, 4,970 (83%) patients. According to findings, compared to LT, in the ET group, respiratory complications were less frequent, and the duration of ICU and hospital admission was reduced. However, tracheostomy timing wasn't correlated with in-hospital mortality. On sub-analysis, the sample was restratified using a 7-day or a 10-day cutoff point, and similar results were observed. In addition, traumatic brain injury was a concomitant injury that may affect the duration of MV, thus the timing of tracheostomy. In conclusion, ET may improve clinical outcomes in patients with cervical spinal cord injury (Anand et al., 2020).

In a recent meta-analysis aimed at assessing the effect of ET versus LT on adult patients receiving MV, 21 RCTs, with a total of 3621 patients, were enrolled for this meta-analysis. In the ET group, there were 1796, and in the LT group, there were 1825. The primary outcomes were the mortality and incidence of VAP, while secondary outcomes were the duration of MV, and the length of ICU and hospital stay. Mortality and VAP were reported in 20, 18 trials, respectively, and findings showed that overall mortality and VAP incidence were lower in the ET group than the LT group, but it was not significant ($p = 0.06$). However, ET in comparison to LT significantly shortened the duration of MV ($p = 0.02$), and length of ICU stays ($p = 0.0003$), but not significant for length of hospital stay ($p = 0.18$). However, the prognosis of tracheotomy is dependent on several variables, including the disease's severity and the course of treatment (Han et al., 2024).

Sarwar et al. (2024) conducted a retrospective study from January 2022 to December 2023 at the Bahria International Hospital in Pakistan to compare clinical outcomes between ET (performed within 10 days of endotracheal intubation) and LT (performed after 10 days) in ICU adult patients who required MV. Clinical outcomes included in this study were duration of MV, length of ICU and hospital stays, and mortality rates. A total of 50 patients participated in the study and were assigned to either the ET group or the LT group, each group containing 25 patients. After statistical analysis, the results showed that the ET group has significantly shorter ICU (mean of days: 20 Vs 33 days; $P = 0.03$) and hospital stay (mean of days: 43 Vs 53 days; $P = 0.01$), decreased duration of MV ($P < 0.0001$), with longer durations without MV ($P = 0.04$). Although ET shows a trend in decreasing mortality and improving ICU survival ($P = 0.05$), these differences were not statistically significant for hospital mortality ($P = 0.08$) (Sarwar et al., 2024).

Another recent retrospective cohort study was conducted by Rifki et al. (2024) to assess the relationship between tracheostomy timing and patient outcomes who require MV in the ICU. The clinical outcome was the duration of MV and VAP scoring. According to the timing of tracheostomy, the participants were divided into two groups, ET (≤ 6) and LT (> 6 days). 62 patients from 143 met the eligible criteria, 37 in the ET group, 25 in the LT group. After data analysis, post-tracheostomy mean duration of MV was not significant between the two groups; however, total mean duration of MV was significantly shorter in the ET compared to the LT group. On the other hand, both pre-tracheostomy and post-tracheostomy showed significantly lower VAP scores, which means that the relationship between tracheostomy timing and VAP score was significant. In conclusion, the implementation of ET contributed to lowering the incidence of VAP and reducing the overall time patients remained on MV (Rifki et al., 2024).

In a prospective cohort observational study conducted in Egypt, the appropriate timing of tracheostomy and its effect on different clinical outcomes were evaluated in 43 critically ill adult patients expected to receive PMV in ICUs. The patients were assigned into two groups, the ET group (n=20) who received tracheostomy within 10 days post-intubation, and the LT group who received tracheostomy between 11 to 21 days post-intubation. Complications (such as localized surgical emphysema, minor bleeding, pneumothorax) and VAP were statistically significantly higher in LT than in ET. Weaning success was statistically significant in ET compared to LT, with shorter periods of sedation, MV, and ICU stay. However, ET had no significant impact on mortality (Fouda et al., 2024).

A retrospective study comparing the clinical outcomes between ET (≤ 10 days) and LT (> 10 days) in intensive care patients, positive effects of ET on overall outcomes were observed. A total sample of 1075 tracheostomized patients, admitted to the intensive care settings, and over a decade period of the study were included. It was divided into two groups: 552 patients in the ET group and 523 in the LT group. Patients with ET showed shorter ICU and hospital occupancy and reduced periods of ventilatory support. Although overall survival at hospital discharge was similar between early and late groups, there was a larger proportion of survivors at ICU discharge among patients in the ET group (Morakami et al., 2023).

The outcomes of ET versus LT among 25 critically ill Individuals who received a planned tracheostomy procedure for PMV were examined in a retrospective study carried out in a multicenter mixed ICU in Lebanon by Moussa et al. (2020). The patients were assigned to either the ET group (n = 12) or the LT group (n = 13). Based on the APACHE II score, which was assessed on their first day in the ICU, these two groups were subdivided: Individuals were stratified using APACHE II scores into two strata: those scoring above 25 (6 ET and 7 LT) and those scoring under 25 25 (6 ET and 6 LT). In both subgroups, the findings showed that ET was not significant for short-term mortality but was significant for long-term mortality compared to LT; however, it was associated with a significant decrease in duration of MV and length of ICU stay. In conclusion, the findings support and favor ET as a strategy to enhance patient outcomes and possibly reduce complications related to prolonged intubation and ICU exposure (Moussa et al., 2020).

A retrospective cohort study conducted by Fokin et al. (2020) compared the clinical outcome of ET (within 7 days of intubation) versus LT (after 7 days of intubation) in adult patients with rib fractures. Findings revealed that patients who had tracheostomy earlier than the $7^{th}$ day spent less time on invasive ventilatory supports and in intensive care settings, while mortality was significantly higher in the ET group. Despite showing benefits for intensive care duration, the recovery effect of early intervention remained limited to intensive care settings rather than total hospitalization. Further analysis was performed to compare between prompt tracheostomy group (within 3 days of intubation, n=20) and the rest tracheostomy patients (after 3rd day of intubation, n=104), and the results showed as same as the comparison between the ET and LT group (significant reduction in length of intensive care settings, and duration of MV, with higher mortality rates). Traumatic brain injury was the dominant cause of mortality. In conclusion, for traumatic chest patients, ET was associated with more beneficial clinical outcomes than the LT group regarding period of intensive care hospitalization and the length of time on ventilatory support, with no effect of tracheostomy timing on mortality (Fokin et al., 2020).

Miyake et al. (2024) conducted a recent retrospective cohort study to compare the effectiveness of ET and LT in post-cardiac surgery adult patients. ET was defined as applying tracheostomy 1-14 days after surgery, and LT as applying tracheostomy 15-30 days after surgery. This study enrolled 784 patients; after excluding patients with missing values, patients were divided into two groups, the ET and LT groups comprising 284 and 326 patients, respectively. Findings showed that in-hospital mortality was significantly lower in the ET group compared to the LT ($p = 0.01$). Significant increase in ventilator-free days in the ET group compared with the LT group ($p < .001$). At the same time, there is no significant difference regarding the incidence of deep sternal wound infection between the two groups ($P = 0.27$). In conclusion, ET was not inferior to LT for cardiac surgery patients, and may be considered for patients requiring PMV, but careful decision is required for tracheostomy at early periods of treatment (Miyake et al., 2024).

# Chapter Two

# Methodology

## 2.1 Study Design

A retrospective multicenter observational cohort study was used to compare ET and LT for mechanically ventilated critically ill patients in the ICU.

## 2.2 Study Site and Setting

The research was multicentered, carried out at Ibn Sina Specialized Hospital (ISH), and Specialized Arab Hospital (SAH), prominent referral hospitals located in Genin and Nablus City, respectively, in the north of the West Bank of Palestine. It holds the distinction of accreditation from the Joint Commission International (JCI). This accreditation signifies the hospital's adherence to international procedures in providing patient care.

ISH contains several main departments with a total capacity of 120 beds. The ICUs contain 22 beds, divided as follows: 12 beds in the mixed ICU and 10 beds in the mixed Cardiac Care Units (CCU). The occupancy rate of the ICU over the duration of the study was approximately 113%.

While SAH has a total capacity of 115 beds, divided as follows: 8 beds in mixed ICU, 6 beds in medical CCU, and 6 beds in surgical CCU, with an occupancy rate of the ICU during the study period of approximately 110%.

Both hospitals are highly and well-equipped with advanced medical equipment, and well prepared to deal with complex, critical, and emergency cases, different surgeries, and advanced procedures.

## 2.3 Study Population

The participants in this study were all mechanically ventilated patients admitted to the ICU and CCU at ISH and SAH, who underwent elective tracheostomy after endotracheal intubation.

## 2.4 Sample Size

As this study utilized a retrospective design. All eligible patients who underwent tracheostomy during the two-year study period were included. A total of 66 patients were recruited from ISH and SAH.

## 2.5 Sample and Sampling

The convenience sampling technique was used to recruit the sample, which is a sampling approach that explains the procedure for gathering data from a research population that the researcher can easily contact, is readily available, and has access to.

Convenience sampling has several advantages. First, the researchers can choose the subjects with minimal effort. Second, it is really affordable. Third, less time is spent by the researchers. Lastly, they are not required to prepare a list of every component of the population (Golzar et al., 2022).

All eligible patients who met the inclusion criteria during the study period were conveniently included. Both the early tracheostomy group and the late tracheostomy group will have the same clinical characteristics and presentations.

## 2.6 Study Period

All patients who underwent an elective tracheostomy during the last two years, in the period between 1$^{st}$ January 2023 to 31$^{st}$ December 2024, were included in the study, and the patients were selected according to inclusion and exclusion criteria.

## 2.7 Eligibility Criteria

Inclusion:

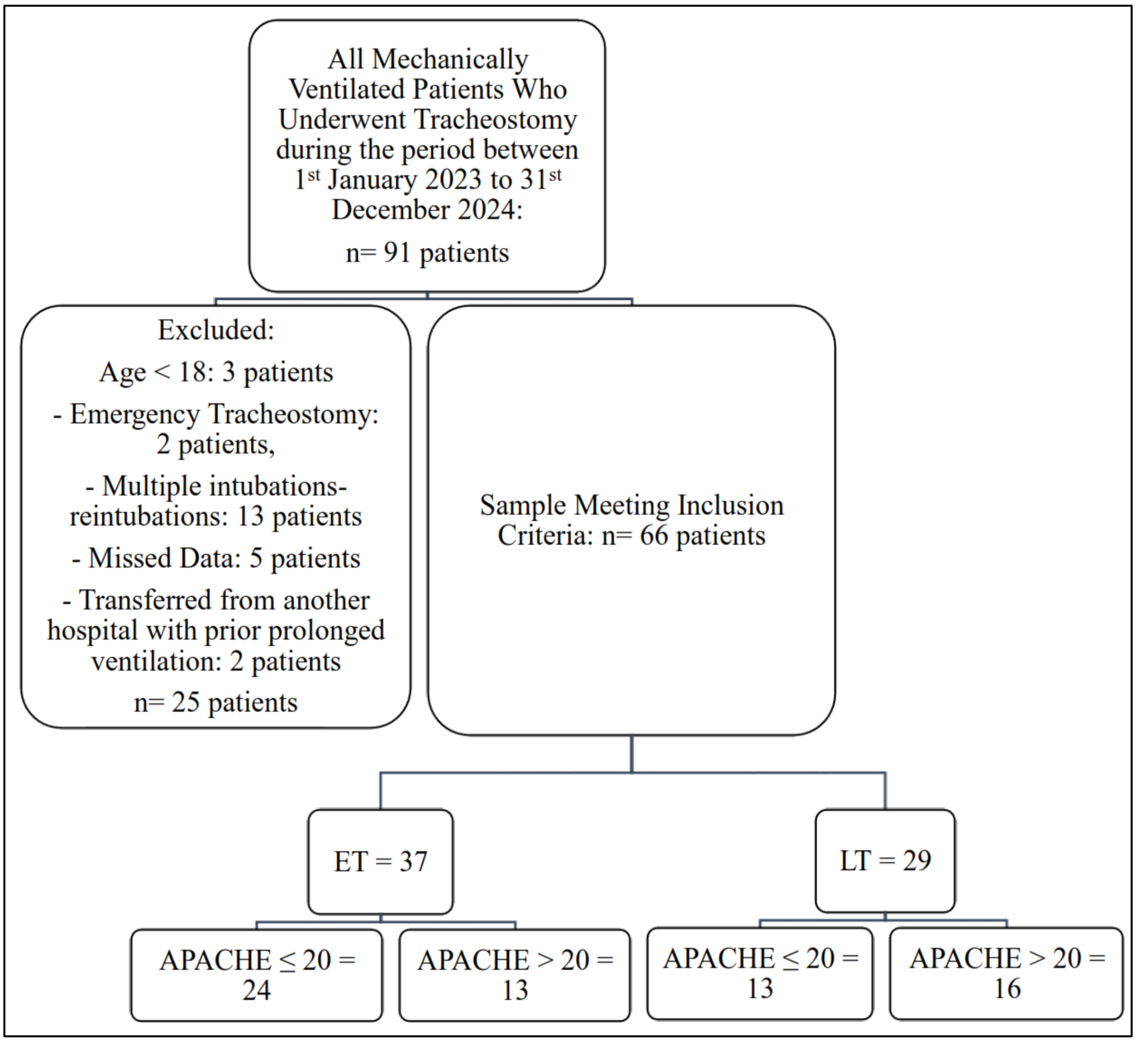
- Male and female patients 18 years old or older
- Mechanically ventilated patients with endotracheal intubation.
- Mechanically ventilated ≥48 hours who received tracheostomy during ICU admission for acute critical illness.
- Elective tracheostomy

Exclusion:

- Emergency tracheostomy.
- Tracheostomy for chronic conditions, for permanent or long-term use, such as in patients with neuromuscular diseases or chronic respiratory disorders.
- Multiple intubations-reintubations during the same ICU stay, which may interrupt the MV period.
- Multiple separated ICU admissions during the same hospital stay, which may interrupt the stay in the ICU.
- Insufficient or missing data from medical records
- Transfer from another hospital with prior prolonged ventilation.

**Figure 2.1**

*Flow diagram of mechanically ventilated patients who underwent tracheostomy*



### 2.8 Ethical Considerations

Approval from the Institutional Review Board (IRB) of An-Najah National University (ANNU) (Fgs/Med. Feb. 2025/74) and the director and Research Ethics Committee of ISH and SAH was obtained, ensuring full institutional support and transparency. All procedures adhered to the university's ethical guidelines. This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Anonymity was strictly maintained through the use of codes instead of names for data analysis, and confidentiality was ensured to prevent unauthorized access to the data. The goal of this study's data collection was scientific research. Nothing was gathered that could reveal the patient's identity. Before analysis, the gathered data were coded and made anonymous. Throughout the study, the completed data-collecting forms were stored in a secure place.

### 2.9 Study Variables

#### 2.9.1 Independent Variables

- Tracheostomy Timing
- Demographic Data
  - Age
  - Sex
  - Comorbidities
  - Primary ICU diagnosis
  - GCS at ICU admission
  - APACHE II score at ICU admission
  - Procedure type

#### 2.9.2 Dependent Variables

- Mortality
- Duration of MV
- Length of ICU stay
- Length of total hospital stay

- VAP incidence

### 2.10 Data Collection Procedure

After ethical approval for the study from the Institutional Review Board (IRB) of An-Najah National University (ANNU) was obtained. The IRB form was sent to ISH and SAH and reviewed by their Research Ethics Committee. Approval was obtained from the two hospitals to use the database and revise the medical profiles of patients for data collection. A special electronic system was used, limited only to patients who had a tracheostomy during the last two years, with a limitation to observe data only; no interaction with medical records can be done, and the patients were coded to ensure confidentiality.

Data was collected using a specific, well-designed data extraction sheet to collect required data from patients' medical records and files in the ISH and SAH at the North West Bank.

After data collection, patients were divided into two groups: the ET group, who underwent elective tracheostomy during the first 10 days of endotracheal intubation in the ICU, and the LT group, who underwent elective tracheostomy after the $10^{th}$ day of endotracheal intubation.

Patients were further divided according APACHE II score calculated at ICU admission, using a score of 20 as a cut-off point, as patients were divided into patients with APACHE II $\leq 20$ who considered as low-moderate risk strata, and APACHE II $> 20$, who considered as high-risk strata (Knaus et al., 1985; Mumtaz et al., 2023; Situ et al., 2024; Rehman et al., 2025).

### 2.11 Data Collection Sheet

After examining pertinent literature, the data collection form was designed. The content validity of the data collection form was established following a review by a panel of experts. The experts were two intensivists, two anesthesiologists, three critical care nurses, and two academic professors in critical care specialty. All items in the data collection form were reviewed for relevance and suitability of inclusion. The panelists commented on the contents of the data collection form. All comments of the panelists were taken into consideration when the final data collection form was revised. The panelists approved the final data collection form that has been used in this study. The form consists of 4 parts. Part I includes the patient's demographic data (age, sex, hospital, and ICU Admission Source). Part II includes clinical characteristics and severity scores (Primary ICU Diagnosis, comorbidities, GCS, and APACHE II scores calculated at ICU admission, reason for intubation). Part III includes tracheostomy details (tracheostomy timing and tracheostomy procedure). Part IV includes clinical outcomes (mortality, duration of mechanical ventilation, length of ICU and total hospital stay, and VAP incidence). The data collection form is provided in Appendix A.

### 2.12 Research Process

The research process began by designing a well-designed data extraction sheet to collect required data from patients' medical records and files. The data extraction sheet was then tested for its content validity with a panel of experts in healthcare and patient safety, with subsequent changes made to better tailor it according to the specific medical databases and patient profiles in the targeted hospitals. Thereafter, ethical approval from the respective IRBs and hospital administrations concerned was sought to guarantee the application of appropriate ethics on issues of consent by participants and data confidentiality.

Targeted hospitals in the north of the West Bank, ISH, and SAH, were coordinated after securing approvals. The visits to hospital administrators included arranged meetings to ensure their cooperation and enable access to the hospital's medical database. The study began with reviewing patients' medical profiles in the selected hospitals, and ensured the anonymity and confidentiality of participants in responding honestly and without bias.

### 2.13 Statistical Analysis

The collected data in this study were entered into an Excel spreadsheet and then coded and entered into SPSS. Data were analyzed using SPSS version 25.0.

Normality of distribution was assessed using the Shapiro-Wilk test. The data were not normally distributed, so medians and interquartile range (IQR) were used.

Categorical data (mortality and VAP) were compared using the Chi-square test of independence, and for continuous data (duration of MV, length of ICU stay, and total hospital stay), the Mann-Whitney U test was used. A p-value of $< 0.05$ indicated statistical significance.

# Chapter Three

# Results

## 3.1 Demographic and Clinical Characteristics

About 66 patients were included in the current study. The mean age of included patients was 54.06 ± 19.89 years (Table 1). About 74.2% were males. The patients' ICU admission source was mostly from the emergency department (89.4%), while 10.6% were from the hospital ward. Among 66 patients, 37 patients (56.1%) had an ET procedure, while 29 patients (43.9%) had an LT procedure.

Descriptive information related to ET versus LT is shown in Table 1. The comparison between ET and LT groups revealed that the only statistically significant difference was gender as revealed by the chi-square test, with males being more prevalent in the ET (83.8%) compared to the LT group (62.1%), $X^2$ $(1, N = 66) = 4.009$, $p = .045$. Age was slightly higher in the LT group (56.97 ± 19.95 years) than in the ET group (51.78 ± 19.81 years), though not significantly different (p = .402).

Clinical severity at ICU admission, assessed by GCS and APACHE II scores, showed marginal differences favoring the LT group (higher GCS and APACHE II), but these were not statistically significant ($p > .05$).

Primary ICU diagnoses, including cardiac disorders and traumatic brain injuries, were similarly common in both groups. Traumatic brain injury cases were notably higher in the ET group (37.8%) compared to the LT group (13.8%). GI and pulmonary disorders were more prevalent in the LT group. Differences across primary diagnosis categories were not statistically significant ($p > 0.05$). Comorbidities, including cardiovascular comorbidity (e.g., hypertension), were equally common in both groups (~60%). Pulmonary and neurological diseases showed small differences (e.g., more neurological diseases in the LT group: 20.7% vs. 13.5%), but none reached statistical significance ($p > 0.05$).

Both groups predominantly underwent surgical tracheostomy, with no significant difference in procedure type. Risk stratification using APACHE II scores showed more low-moderate risk patients (64.9%) in the ET group and more high-risk in the LT group

(55.2%), without statistical significance ($p > 0.05$). Discharge outcomes were identical, with 38.5% of patients from both groups going home and 61.5% transferred to rehabilitation, indicating similar recovery trajectories regardless of tracheostomy timing, without statistical significance ($p > 0.05$).

**Table 1**

*Demographic characteristics of the included patients (n = 66)*

| Variable | n | % | Early Tracheostomy (n=37) | | Late Tracheostomy (n=29) | | P-value |
|---|---|---|---|---|---|---|---|
| | | | n | % | N | % | |
| Gender | | | | | | | |
| Male | 49 | 74.2 | 31 | 83.8 | 18 | 62.1 | 0.045 |
| Female | 17 | 25.8 | 6 | 16.2 | 11 | 37.9 | |
| Primary ICU Diagnosis | | | | | | | |
| Stroke/neurological disorder | 15 | 22.7 | 9 | 24.3 | 6 | 20.7 | 0.122 |
| Cardiac disorder | 19 | 28.8 | 9 | 24.3 | 10 | 34.5 | |
| GI disorder | 3 | 4.5 | - | - | 3 | 10.3 | |
| Pulmonary disorder | 3 | 4.5 | 1 | 2.7 | 2 | 6.9 | |
| Trauma | 8 | 12.1 | 4 | 10.8 | 4 | 13.8 | |
| Traumatic Brain Injury | 18 | 27.3 | 14 | 37.8 | 4 | 13.8 | |
| Comorbidities | | | | | | | |
| Preexisting Pulmonary Disease (COPD, Asthma, IPF) | 7 | 10.6 | 4 | 10.8 | 3 | 10.3 | 0.500 |
| Preexisting Neurological Disease (CVA, Alzheimer, Dementia, Parkinson) | 11 | 16.7 | 5 | 13.5 | 6 | 20.7 | |
| Preexisting Cardiovascular Disease (HTN) | 40 | 60.6 | 22 | 59.5 | 18 | 62.1 | |
| Others | 32 | 48.5 | 20 | 54.1 | 12 | 41.4 | |
| Free | 20 | 30.3 | 11 | 29.7 | 9 | 31 | |
| Procedure Type | | | | | | | |
| Surgical | 54 | 81.8 | 29 | 78.4 | 25 | 86.2 | 0.413 |
| Percutaneous | 12 | 18.2 | 8 | 21.6 | 4 | 13.8 | |
| APACHE II Score at Presentation to the ICU | | | | | | | |
| Low-moderate Risk | 37 | 56.1 | 24 | 64.9 | 13 | 44.8 | 0.513 |
| High Risk | 29 | 43.9 | 13 | 35.1 | 16 | 55.2 | |
| Discharge Destination | | | | | | | |
| Home | 15 | 38.5 | 10 | 38.5 | 5 | 38.5 | 0.633 |
| Rehabilitation Center | 24 | 61.5 | 16 | 61.5 | 8 | 61.5 | |
| Variable | M | SD | M | SD | M | SD | |
| Age | 54.06 | 19.89 | 51.78 | 19.81 | 56.97 | 19.95 | 0.402 |
| GCS at ICU Admission | 7.68 | 3.79 | 7.03 | 3.42 | 8.52 | 4.12 | 0.244 |
| APACHE II Score at ICU Admission | 21.17 | 7.77 | 20.38 | 7.99 | 22.17 | 7.48 | 0.215 |

### 3.2 Intubation Related Information

In ET, the primary reason for intubation was noted to be a decreased level of consciousness in 78.4% of cases. In LT, the primary reason for intubation was noted to be a decreased level of consciousness, accounting for 44.8% (Table 2).

A chi-square test of independence indicated a significant relationship between the reason for intubation and the tracheostomy groups, $X^2$ (4, N = 66) = 11.799, $p$ = .019. The finding suggests that the decreased level of consciousness was the main indication for ET.

**Table 2**

*Intubation Related Information*

| Variable | n | % | Early Tracheostomy (n=37) | | Late Tracheostomy (n=29) | | P-value |
|---|---|---|---|---|---|---|---|
| | | | n | % | N | % | |
| Reason for Intubation | | | | | | | |
| Decreased Level of Consciousness | 42 | 63.6 | 29 | 78.4 | 13 | 44.8 | 0.019 |
| Acute Respiratory Distress | 8 | 12.1 | 1 | 2.7 | 7 | 24.1 | |
| Cardiac arrest | 10 | 15.2 | 5 | 13.5 | 5 | 17.2 | |
| Respiratory Failure | 4 | 6.1 | 2 | 5.4 | 2 | 6.9 | |
| Surgical Operation | 2 | 3.0 | - | - | 2 | 6.9 | |

### 3.3 Mortality

A notable difference was observed between mortality and the tracheostomy groups, independent of the APACHE II score, $X^2$ (1, N = 66) = 4.354, $p$ = .033, in which mortality was lower in the ET group compared to the LT group (29.7%, 55.2%, respectively).

In the population with an APACHE II score ≤ 20, the ET group exhibited a mortality rate of 12.5%, while the LT group had a rate of 23.1% (Table 3). A chi-square test of independence indicated no significant difference between mortality and the tracheostomy groups, $X^2$ (1, N = 37) = .694, $p$ = .405.

In the population with an APACHE II score > 20, the ET group exhibited a mortality rate of 61.5%, while the LT group had a rate of 81.3%. A chi-square test of independence indicated no significant difference between mortality and the tracheostomy groups, $X^2$ (1, N = 29) = 1.395, $p$ = .238.

**Table 3**

*Mortality Among Tracheostomy Groups*

| Mortality | n | % | Early Tracheostomy (n=37) | | Late Tracheostomy (n=29) | | P-value |
|---|---|---|---|---|---|---|---|
| | | | n | % | n | % | |
| APACHE II score ≤ 20 | | | | | | | |
| Alive | 31 | 83.8 | 21 | 87.5 | 10 | 76.9 | 0.405 |
| Dead | 6 | 16.2 | 3 | 12.5 | 3 | 23.1 | |
| APACHE II score > 20 | | | | | | | |
| Alive | 8 | 27.6 | 5 | 38.5 | 3 | 18.8 | |
| Dead | 21 | 72.4 | 8 | 61.5 | 13 | 81.3 | 0.238 |

### 3.4 Duration of Mechanical Ventilation (MV)

The Mann-Whitney U test was employed to compare outcomes between ET and late LT groups within each APACHE II category, given the non-parametric nature of the data as revealed by the Shapiro-Wilk test of normality (p = 0.000).

When analyzing the data without considering APACHE II scores, the Mann-Whitney U test results showed a statistically significant difference between the duration of post-tracheostomy MV of ET group and LT group (median: 12.0 days, IQR: 12.0, median: 21.0 days, IQR: 17.5, respectively), $U = 359.500$, $p = 0.022$. The results revealed that the ET group had a significantly lower duration of post-tracheostomy MV compared to the LT group. Similarly, the Mann-Whitney U test results showed a statistically significant difference between the total duration of MV of ET group and LT group (median: 20.0 days, IQR: 11.5, median: 34.0 days, IQR: 16.5, respectively), $U = 171.000$, $p < 0.001$. The results revealed that ET group had significantly lower duration of MV compared to LT group.

In the APACHE II ≤ 20, the median duration of MV post-tracheostomy was significantly shorter in the ET group (11.5 days, IQR: 8.5) compared to the LT group (21.0 days, IQR: 17.5), $U = 93.000$, p = 0.016 (Table 4). For total MV duration, it was significantly reduced in the ET group (median: 18.5 days, IQR: 8.75) compared to the LT group (median: 34.0 days, IQR: 18.0), $U = 39.500$, p <0.001.

In the APACHE II > 20, there was no significant difference between the duration of post-tracheostomy MV of the ET group (median: 16 days, IQR: 23.5) and the LT group (median: 19 days, IQR: 19.25), p = 0.236. However, the total duration of MV remained significantly shorter in the ET group (median: 21.0 days, IQR: 22.0) compared to the LT group (median: 34.0 days, IQR: 17.25), *U* = 45.500, p = 0.009.

**Table 4**

*Duration of mechanical ventilation among tracheostomy groups*

| Variable | M | IQR | Early Tracheostomy (n=37) | | Late Tracheostomy (n=29) | | P-value |
|---|---|---|---|---|---|---|---|
| | | | M | IQR | M | IQR | |
| APACHE II score ≤ 20 | | | | | | | |
| Duration of MV (Days) Post-tracheostomy | 14.00 | 11.50 | 11.50 | 8.50 | 21.00 | 17.50 | 0.016 |
| Total Duration of MV (Days) | 23.00 | 16.50 | 18.50 | 8.75 | 34.00 | 18.00 | <0.001 |
| APACHE II score > 20 | | | | | | | |
| Duration of MV (Days) Post-tracheostomy | 16.00 | 19.50 | 16.00 | 23.50 | 19.00 | 19.25 | 0.236 |
| Total Duration of MV (Days) | 27.00 | 21.00 | 21.00 | 22.00 | 34.00 | 17.25 | 0.009 |

M: Median, IQR: Interquartile Range.

### 3.5 Length of ICU and Hospital Stay

When analyzing the data without considering APACHE II scores, ET group had significantly lower length of ICU stay than LT group (median: 25.0 days, IQR: 13.0 versus median: 40.0 days, IQR: 22.5), *U* = 202.000, *p* = .000. Additionally, the ET group had significantly lower hospital stay than the LT group (median: 34.0 days, IQR: 17.0 versus median: 45.0 days, IQR: 25.5), *U* = 269.500, *p* < 0.001.

In the APACHE II score ≤ 20 (Table 5), the duration of ICU stay for the ET group was shorter than that of the LT group (median: 24.0 days, IQR: 9.75 versus median: 42.0 days, IQR: 24.50). A Mann-Whitney U test was conducted to compare ET group and LT group. The results indicated a significant difference (U = 41.000, p <0.001). Similarly, the overall length of hospital stay for the ET group was also reduced compared to the LT group (median: 34.0 days, IQR: 16.50 versus median: 52.0 days, IQR: 21.50). A Mann-Whitney U test indicated a significant difference (U = 61.000, p = 0.002).

In the APACHE II score > 20, the duration of ICU stay for the ET group was shorter than that of the LT group (median: 27.0 days, IQR: 19.0 versus median: 38.50 days, IQR: 20.25). A Mann-Whitney U test indicated a significant difference (U = 56.500, p = 0.037). Additionally, the ET group also had a significantly shorter hospital stay than LT (U = 56.000, p = 0.035); median: 31.0 days, IQR: 16.5 versus median: 42.50 days, IQR: 27.75, respectively.

**Table 5**

*Length of stay among tracheostomy groups*

| Variable | M | IQR | Early Tracheostomy (n=37) | | Late Tracheostomy (n=29) | | P-value |
|---|---|---|---|---|---|---|---|
| | | | M | IQR | M | IQR | |
| APACHE II score ≤ 20 | | | | | | | |
| Length of ICU Stay (Days) | 27.00 | 20.50 | 24.00 | 9.75 | 42.00 | 24.50 | <0.001 |
| Total Length of Hospital Stay (Days) | 40.00 | 19.00 | 34.00 | 16.50 | 52.00 | 21.50 | 0.002 |
| APACHE II score > 20 | | | | | | | |
| Length of ICU Stay (Days) | 31.00 | 19.50 | 27.00 | 19.00 | 38.50 | 20.25 | 0.037 |
| Total Length of Hospital Stay (Days) | 36.00 | 20.00 | 31.00 | 16.50 | 42.50 | 27.75 | 0.035 |

M: Median, IQR: Interquartile Range.

### 3.6 Ventilator-associated Pneumonia (VAP)

There was no significant relationship between VAP and the tracheostomy groups, without considering the APACHE II score, $X^2$ (1, N = 66) = 3.005, $p$ = 0.083, in which VAP was lower in the ET group compared to the LT group (21.6%, 41.4%, respectively).

In the population with an APACHE II score ≤ 20, the ET group showed a VAP rate of 20.8%, while the LT group had a rate of 53.8% (Table 6). A chi-square test of independence was performed to evaluate the relationship between tracheostomy groups and VAP. The relationship between these variables was significant, $\chi^2$ (1, $N$ = 37) = 4.192, $p$ = 0.041. The ET group had a lower VAP occurrence than were LT group.

When considering APACHE II score > 20. The ET group showed a VAP rate of 23.1%, while the LT group had a rate of 31.3%. A chi-square test of independence indicated no significant association between VAP and the tracheostomy groups, $X^2$ (1, N = 29) = .240, $p$ = 0.474.

**Table 6**

*Ventilator-associated pneumonia among tracheostomy groups*

| Ventilator-associated pneumonia (VAP) | n | % | Early Tracheostomy (n=37) | | Late Tracheostomy (n=29) | | P-value |
|---|---|---|---|---|---|---|---|
| APACHE II score ≤ 20 | | | | | | | |
| Yes | 12 | 32.4 | 5 | 20.8 | 7 | 53.8 | 0.041 |
| No | 25 | 67.6 | 19 | 79.2 | 6 | 46.2 | |
| APACHE II score > 20 | | | | | | | 0.474 |
| Yes | 8 | 27.6 | 3 | 23.1 | 5 | 31.3 | |
| No | 21 | 72.4 | 10 | 76.9 | 11 | 68.8 | |

# Chapter Four

# Discussion and Conclusion

## 4.1 Summary of the Key Findings

The population of critically ill patients has increased recently, leading to a growing need for MV. However, due to the nature of critical illness, these patients may require MV for a prolonged period, resulting in an increased number of tracheostomized patients (Kishihara et al., 2023). ET is one of the treatment strategies used for PMV patients. This study aimed to assess the clinical outcomes of early versus late tracheostomy for mechanically ventilated critically ill patients in the ICU.

10 days was used as a cut-off day for defining ET, as patients who underwent tracheostomy during the first 10 days of intubation were classified in the ET group, while after 10 days of endotracheal intubation were in the LT group.

A total of 66 patients were included, among them 37 (56.1%) underwent ET and 29 (43.9%) underwent LT. In the ET, the total number of patients with an APACHE II score ≤ 20 was 24, and with an APACHE II score > 20 was 13. In the LT, the total number of patients with an APACHE II score ≤ 20 was 13, and with an APACHE II score > 20 was 16.

Patients undergoing ET had a considerably improved survival, shorter total and post-tracheostomy MV duration, decreased length of ICU, and total hospital stay. However, ET had no significant effect on VAP incidence. In the APACHE II ≤ 20, ET had no significant impact on mortality, while it significantly shortened the total and post-tracheostomy MV duration, decreased the length of ICU and total hospitalization stay, and lowered VAP incidence. In the APACHE II > 20, ET had no significant impact on mortality, VAP incidence, and post-tracheostomy duration of MV. In contrast, ET had a significantly shorter total duration of MV, length of ICU, and total hospital stay.

## 4.2 APACHE II Score Cut-off Point

According to the APACHE II score, we used a point of 20 as a cut-off point, and were stratified into two strata: group with APACHE II ≤ 20 (low-moderate risk), and group with APACHE II > 20 (high risk). While in a study conducted by Moussa et al. (2020), a score of 25 was used as a cut-off point. However, the previous cut-off point may be less significant, as APACHE II scores from 21 to 24 may have a high mortality risk, as supported by Farajzadeh et al. (2021), who recommended the use of a cut-off point of 19. Mumtaz et al. (2023) and Situ et al. (2024) supported that strata of APACHE II > 20 were associated with high mortality (Mumtaz et al., 2023; Situ et al., 2024). Regarding VAP, a higher incidence of VAP was observed among patients on invasive MV supports with APACHE II scores greater than 20 (Rehman et al., 2025).

## 4.3 Mortality

### 4.3.1 Mortality without Considering APACHE II Score

The primary findings of the study are that the mortality rate was lower in the ET group than the LT group, and the difference was statistically significant. These findings are consistent with what was reported in Japan (Miyake et al., 2024), who reported similar outcomes in cardiac surgery patients, though their findings may have limited generalizability to broader critically ill populations. Another study conducted by Sarwar et al. (2024) further supported the mortality benefit of ET, as it significantly decreased ICU mortality, not hospital mortality, which may be related to comorbidities, differences in consistency and quality of provided post-ICU care, and poor rehabilitation care.

In a prospective observational study conducted by Robba et al. (2020) on traumatic brain injury patients, discovered that a one-day delay in performing a tracheostomy was linked to a 6% increase in the probability of dying and a 4% increase in the risk of an adverse result. Although this link might imply that an ET would be beneficial, patients with more severe injuries might require more time to stabilize their state and manage the progression of intracranial damage, which would delay tracheostomy, or they might have a worse predicted result, which would limit the decision to undergo a tracheostomy (Robba et al., 2020).

The reduction in mortality in the ET group could be theoretically explained, as ET improves and promotes early weaning off the MV, which reduces the chance of ventilator-associated trauma (barotrauma, volutrauma, pneumothorax, and alveolar injuries), VAP, and other nosocomial infections.

However, our findings regarding mortality contradicted prior findings of previous retrospective studies that showed no significant mortality differences between ET and LT groups (Anand et al., 2020; Shen et al., 2022), and in contrast, ET was associated with higher mortality (Fokin et al., 2020). These discrepancies in results are possible due to differences in the sample demographics, sample size, and definition of ET. As Anand et al. (2020) targeting traumatic cervical spinal cord injury patients, with large sample size (n= 5980), 4 days was used as a cutoff point to identify the ET and LT groups (Anand et al., 2020), while Shen et al. (2022) conducted a study on hemorrhagic and ischemic stroke patients, with almost similar sample size of our study, but different ET criteria (within 7 days of endotracheal intubation). However, Fokin et al. (2020) conducted a study of 124 traumatic chest injury patients with rib fractures, using 7 days as a cutoff point between ET and LT groups.

### 4.3.2 Mortality Considering APACHE II Score

Our study showed that ET has lower mortality rates, but it has no significant difference in mortality rate between patients undergoing ET versus LT, in both APACHE II ≤ 20 and APACHE II > 20. These findings were not consistent with the findings of a study conducted by Moussa et al. (2020), who reported the same findings regarding short-term mortality, but contrasted findings regarding long-term mortality, as ET was significantly reducing the long-term mortality in both APACHE < 25 and APACHE II > 25.

The use of different APACHE II cut-off points in comparison between the ET and LT groups may help interpret the differences in mortality between the current study and Moussa et al (2020). Other factors may explain the differences in findings, including differences in mortality endpoints, sample size (66 in our study, 25 in Moussa et al. (2020)), as a smaller sample size is correlated with decreased ability to make conclusive generalizable findings, follow-up duration, and contextual healthcare factors.

## 4.4 Duration of Mechanical Ventilation (MV)

### 4.4.1 Total Duration of MV without Considering APACHE II Score

In our study, there was a significantly shorter total duration of MV in the ET group compared to the LT group. These findings were consistent with a recent study conducted by Sarwar et al (2024), using the same ET criteria (within the first 10 days of orotracheal intubation), which showed a significant difference between ET and LT. Also, current study findings are consistent with a recent meta-analysis aimed at assessing the effect of ET versus LT on adult patients receiving invasive ventilation; 21 randomized control trials, with a total of 3621 patients, were enrolled for this meta-analysis. Results showed that ET, compared to LT, significantly shortened the duration of MV (Han et al., 2024). Another prospective cohort study in Egypt by Fouda et al. (2024), conducted on 43 critically ill patients, aimed to compare the clinical outcomes between ET and LT, and showed that ET has a benefit in minimizing sedation time, which improves the weaning, and thus decreases the duration of MV (Fouda et al., 2024), which is aligned with our study findings. This could be due to prolonged trans-laryngeal endotracheal intubation, and late tracheostomy may require long-term opioids and sedatives. Thus, delayed weaning off from MV and a higher risk of ventilator-associated injuries could result from LT, which further prolongs the duration of MV. Also, as a result of ET being linked to improved secretion clearance, decreased respiratory labor, decreased dead space, decreased airway resistance, and the ability of respiratory muscles to exercise and recover (Deng et al., 2021).

In a meta-analysis by Shen et al. (2022), a study was conducted on severe hemorrhagic and ischemic stroke patients, including 5 studies that enumerated the results of MV time, and a total of 762 patients were included. The result revealed similar ventilator times in both ET and LT groups that did not reach a statistically significant level. The previous results are opposite to our results. These discrepancies can be explained as in the previous meta-analysis, there was a great variation in the ET definitions and weaning protocols, and neurological patients usually have difficulties in the weaning process related to their nature of disease; however, the study doesn't completely deny that ET has a benefit in shortening the duration of MV (Shen et al., 2022).

### 4.4.2 Post-tracheostomy Duration of MV without Considering the APACHE II Score

In our study, the duration of MV was measured after insertion of tracheostomy, and the results showed that the ET group had significantly lower duration of post-tracheostomy MV compared to the LT group. These findings were inconsistent with Rifki et al. (2024), who conducted a retrospective study to assess the relationship between tracheostomy procedure timing and patient health-related outcomes who require MV in the ICU, including a total of 62 intensive care patients. The results revealed that ET has a lower post-tracheostomy duration than ET, but this difference was not statistically significant. These differences in findings can be related to differences in tracheostomy criteria between our study (within the first 10 days of intubation) and the previous study (within the first 6 days of intubation). In the previous study, most patients were neurological patients and had comorbidities of respiratory disorders such as COPD, asthma, and bronchitis, which led to an increase in the time the patient needed to be on a ventilator. (Rifki et al., 2024).

#### 4.4.3 Total & Post-tracheostomy Duration of MV Considering the APACHE II Score

This study showed that ET patients had a significantly lower total duration of MV in both APACHE II ≤ 20 (low-moderate risk strata) and APACHE II > 20 (high risk strata). Moussa et al. (2020) showed consistent results with our study, in both APACHE II < 25 and APACHE II > 25.

For the duration of post-tracheostomy MV, the results showed that ET compared to LT significantly decreased the mean days of MV in patients with APACHE II ≤ 20, while no significant difference for patients with APACHE II > 20.

The previous findings could be explained as patients with APACHE II ≤ 20, considered in low-moderate strata (Mumtaz et al., 2023; Situ et al., 2024), who have less critical illness and better prognostic conditions, which led to the use of less sedation and opioids, which promote the early weaning process, and shorten the time supported by MV. In contrast, patients with APACHE II > 20 are located in high-risk strata (Mumtaz et al., 2023; Situ et al., 2024), having severe critical illness, hemodynamic instability, multiple organ dysfunction, and poor prognostic conditions, in which delayed weaning off from MV and preventing early extubation lead to increased ventilation time.

### 4.5 Length of ICU and Hospital Stay

#### 4.5.1 Length of ICU and Total Hospital Stay without Considering APACHE II Score

A significant decrease in the length of ICU and hospital stays was observed in patients who underwent ET compared to patients with LT. Similar trends have been reported in earlier studies, even though the length of ICU and hospitalization periods differed across these studies (Sarwar et al., 2024; Anand et al., 2020; Morakami et al., 2023). The discrepancies in lengths could be attributed to differences in definitions of ET, demographics of populations, and contextual healthcare differences. In another study by Marra et al. (2021), who conducted a Systematic review and meta-analysis of 9 studies, with a total of 5106 traumatic brain injury patients, showed consistent results with the current study, as ET significantly reduced the length of ICU and hospital stay. And the same results were reported in another systematic review and meta-analysis, which can potentially reflect how tracheostomy contributes to improved hemodynamic balance and accelerated liberation from ventilatory support (de France et al., 2020). ICU and hospital occupancy duration increased by approximately 1 and 2 days for every 2 days of tracheostomy delay, respectively, in patients who received LT (Robba et al., 2020).

Han et al. (2024) conducted a meta-analysis of 21 randomized controlled trials to assess the health-related outcomes between ET and LT in intensive care individuals, and showed that ET patients have spent significantly less time in intensive care, which is consistent with the current study, but not significant for length of total hospital stay, which is in contrast with our findings. The discrepancies regarding the total length of stay could be attributed to the methodological differences between the previous study and the current study, as well as high-level variability and heterogeneity in the meta-analysis trials.

The previous findings could be explained theoretically, as ET reduced the need for sedation, thus reducing the period of supported invasive MV, which contributes to a higher chance of avoiding ventilator-associated injuries and nosocomial infections, including VAP. As a result of previous benefits, ET patients have shorter lengths of ICU and hospital stay, hence decreasing the burden of healthcare costs on families and hospitals.

### 4.5.2 Length of ICU and Total Hospital Stay Considering APACHE II Score

In both APACHE II score ≤ 20 and APACHE > 20, the duration of ICU stay and total length of hospital stay for the ET group were significantly shorter than those of the LT group. These findings were consistent with what was reported by Moussa et al. (2020), in the population with APACHE II < 25 and APACHE > 25. The differences in mean duration could be attributed to that the previous study used a different APACHE score cut-off point for risk stratification. Moreover, Moussa et al. (2020) assessed only the post-tracheostomy length of ICU stay, while in current study assessed the total length of ICU stay, and total hospital stay.

### 4.6 Ventilator-associated Pneumonia (VAP)

#### 4.6.1 VAP without Considering APACHE II Score

In this study, the VAP incidence was lower in the ET group than in the LT group. This difference was not statistically significant. These findings were consistent with a meta-analysis conducted by Han et al. (2024), who reported that VAP is a common complication in ventilatory supported patients, with an overall VAP incidence of 31.46% in the ET and 37.91% in the LT group, and no statistically significant difference between the two groups. The incidence of pneumonia in traumatic and neurology individuals, including traumatic brain injury patients, was not decreased by ET. The tracheostomy itself and its timing have no clear role or influence on the risk of pneumonia, which was consistent with our study, as the neurology patients and trauma patients were the most predominant cases in our sample, which explains the findings regarding VAP, as neurology patients had diminished cough reflexes, poor weaning abilities related to their nature of illness. Another meta-analysis reported that the ET has no clear advantage over late procedures in reducing VAP occurrence in spinal cord injury patients (Mubashir et al., 2021).

In contrast, previous studies still emphasize the benefits of ET, as it revealed that ET had a significant reduction in VAP incidence compared to LT in mechanically ventilated critically ill patients (Marr et al., 2021; de France et al., 2020; Rifki et al., 2024). Fouda et al. (2024) reported that VAP was significantly lower in the ET group, that related to ET reducing the sedation duration and promoting weaning off MV, which decreases the potential exposure to nosocomial infection, especially VAP.

#### 4.6.2 VAP Considering APACHE II Score

In APACHE II ≤ 20, the ET group showed a VAP rate of 20.8%, while LT had a rate of 53.8%. The ET group had a significantly lower VAP incidence than the LT group (P = 0.041). While in APACHE II > 20, VAP occurred less frequently in patients receiving ET than in those with LT (23.1% versus 31,3%). However, these variations in VAP rates between the two groups lacked statistical significance, which could be interpreted as patients with APACHE II > 20 (high-risk strata) were more critically ill, and poorly prognostic condition, which contributed to the difficulty in the weaning process and increasing MV duration. Though increasing the chance of VAP was related to the severity of illness rather than the effect of tracheostomy timing itself.

### 4.7 Limitations

- Retrospective design of the study makes it less reliable and more prone to bias compared to a prospective design.
- The study period was relatively short. Even though the study period was two years, a longer duration of study period might have made it possible to include a larger sample size. A larger sample size was enrolled in previous studies, which were thought to have more statistical power and reliable findings.
- Heterogeneity of the included sample in our study. Variation in underlying conditions, such as surgical versus medical ICU patients, may act as a confounding variable.
- Heterogeneity in clinical practices among clinicians, such as differences in weaning practices and sedation approaches.
- The follow-up period was limited to in-hospital observations, in which long-term outcomes may be lost.

### 4.8 Conclusion

Findings of this study indicated that performing tracheostomy within ten days of endotracheal intubation (ET) in mechanically ventilated patients has been associated with improved clinical outcomes, including lower mortality, shorter duration of MV, decreased length of ICU and hospital stay. While ET had no significant effect on the incidence of VAP. Subgroup analysis showed that patients with lower disease severity (APACHE $\leq 20$) benefited more from ET in terms of decreased MV duration, ICU and hospital stays, and VAP incidence. For patients with higher disease severity (APACHE II $> 20$), ET still has more advantages in terms of shortening the duration of MV, and length of ICU and hospital stays, though it has no benefits regarding mortality and VAP incidence.

## 4.9 Recommendations

1. For research

- More research is still needed to determine the proper tracheostomy timing for mechanically ventilated patients in the ICU. Future studies should involve larger, more homogenous samples, considering complications of both ET and LT.
- Conduct a prospective study with long-term follow-up, to assess many outcomes such as: quality of life, speech and swallowing functions, and long-term mortality.
- Include cost-effectiveness studies to evaluate the economic impact of tracheostomy timing on healthcare systems.

2. For Patients

- Educate patients' families about the purpose and benefits of tracheostomy to reduce anxiety and misconceptions.
- Encourage early involvement of patients and families in decision-making when prolonged mechanical ventilation is anticipated.
- Provide rehabilitation and psychosocial support programs for patients with tracheostomy to improve quality of life and facilitate recovery.

3. For clinical practice

- Create a uniform protocol and guideline in Palestinian ICUs for early detection of the need for ET.
- APACHE II score should be taken into consideration at ICU admission, as it is valuable to be calculated according to scientific criteria during the first 24 hours of ICU admission for mechanically ventilated patients, to make a timely, accurate ET decision.
- Promote multidisciplinary collaboration (intensivists, surgeons, nurses, respiratory therapists) when deciding on tracheostomy timing.
- Provide training programs for ICU nurses and staff on tracheostomy care, including airway management, infection prevention, and patient communication.
- Establish monitoring and documentation systems to track outcomes and complications, ensuring continuous quality improvement.

## List of Abbreviations

| Abbreviation | Meaning |
|---|---|
| APACHE II | Acute Physiology and Chronic Health Assessment II |
| ARDS | Acute Respiratory Distress Syndrome |
| ATS | American Thoracic Society |
| CCU | Cardiac Care Unit |
| COPD | Chronic Obstructive Pulmonary Disease |
| EAST | Eastern Association of Surgical Trauma |
| ET | Early Tracheostomy |
| GCS | Glasgow Coma Scale |
| ICU | Intensive Care Unit |
| IDSA | Infectious Disease Society of America |
| IRB | Institutional Review Board |
| ISH | Ibn Sina Specialized Hospital |
| JCI | Joint Commission International |
| LT | Late Tracheostomy |
| MDR | Multidrug Resistant |
| MV | Mechanical Ventilation |
| NAM-DRC | National Association for Medical Direction of Respiratory Care |
| PAC | Pressure-limited Assist Control |
| PMV | Prolonged Mechanical Ventilation |
| PSV | Pressure Support Ventilation |
| SAH | Specialized Arab Hospital |
| SIMV | Synchronized Intermittent Mandatory Ventilator |
| VAC | Volume-limited Assist Control |
| VAP | Ventilator-associated Pneumonia |
| VT | Tidal Volume |

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# Appendices

## Appendix A

## Data Extraction Sheet

### Part One: Demographic Data

| Variable | Option | Notes |
|---|---|---|
| Patient Code | | |
| Hospital | | |
| Age (Years) | | |
| Sex | Male/Female | |
| Admission Date | | |
| ICU Admission Source | ER/OR/Ward/Other ICU | |

### Part Two: Clinical Characteristics & Severity Scores

| Variable | | Options | Notes |
|---|---|---|---|
| Primary ICU Diagnosis | | | |
| Comorbidities | | | |
| GCS at ICU Admission | | | |
| Vital Signs at ICU Admission | Blood Pressure | | |
| | Heart Rate | | |
| | Respiratory Rate | | |
| | Body Temperature | | |
| Lab Test at ICU Admission | WBC | | |
| | CRP | | |
| | Na+ | | |
| | K+ | | |
| | Creatinine | | |
| | Hematocrit | | |
| Arterial Blood Gases at ICU Admission | pH | | |
| | PaO2 | | |
| | PCO2 | | |
| | HCO3- | | |
| FiO2 | | | |
| APACHE II Score at ICU Admission | | | |
| Reason for Intubation | | | |
| Intubation Date | | | |

### Part Three: Tracheostomy Details

| Variable | Format/Options | Notes |
|---|---|---|
| Tracheostomy Date | | Days From Intubation |
| Timing Group | Early Tracheostomy (≤10 days)<br>Late Tracheostomy (>10 days) | |
| Procedure Type | Surgical/Percutaneous | |

**Part Four: Clinical Outcomes**

| Variable | Option | Note |
|---|---|---|
| Mortality | | |
| Date of Death | | |
| Mechanical Ventilation Duration (Days) | Pre-tracheostomy: | |
| | Post-tracheostomy: | |
| | Total: | |
| ICU Length of Stay (Days) | | |
| Hospital Length of Stay (Days) | | |
| VAP Incidence | Yes/No | |

## Appendix B

## IRB



جـــامـــعـة النجـــاح الـوطـنـيـة
An-Najah National University

مكتب مجلس المراجعة المؤسسية
Office of Institutional Review Board (IRB)

**Dear Dr.Mohammed F. Hayek,**

We are pleased to inform you that your research proposal titled "***Early Versus Late Tracheostomy in the Mechanically Ventilated Critically Ill Patients: A Retrospective Multicenter Cohort Study in Palestine***" has been approved by the Institutional Review Board (IRB) at **An-Najah National University**.

Here are the approval details:

| | |
|---|---|
| Submitted by: | Mohammed F. Hayek, Abdelrauof Yousef Khader abu Tammam |
| Approval Date: | 25th February. 2025 |
| IRB Protocol Number: | Fgs/Med. Feb. 2025/74 |

Please report any changes to the study protocol to the IRB for review. If you have any questions, contact us at irb@najah.edu. Thank you for your commitment to ethical research.

Best regards,

Naim Kittana, Dr.

IRB, Chairperson

IRB Institutional Review Board

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جامعة النجاح الوطنية

كلية الدارسات العليا


# عملية فتح القصبة الهوائية المبكرة مقابل المتأخرة لدى مرضى الحالات الحرجة على أجهزة التنفس الصناعي: دراسة استعادية متعددة المراكز في فلسطين


إعداد

عبدالرؤوف يوسف خضر أبو تمام

إشراف

د. محمد الحايك



قدمت هذه الرسالة استكمالا لمتطلبات الحصول على درجه الماجستير في تمريض العناية المكثفة، من كلية الدارسات العليا، في جامعة النجاح الوطنية، نابلس– فلسطين.

2025

# عملية فتح القصبة الهوائية المبكرة مقابل المتأخرة
# لدى مرضى الحالات الحرجة على أجهزة التنفس الصناعي:
# دراسة استعادية متعددة المراكز في فلسطين

**إعداد**

**عبد الرؤوف يوسف خضر أبو تمام**

**إشراف**

**د. محمد الحايك**

## الملخص

خلفية الدراسة: يُعدّ إطالة مدة التهوية الميكانيكية سببًا شائعًا بشكل خاص لإجراء فتح القصبة الهوائية لدى المرضى المُعالجين في وحدات العناية المركزة. تُصنّف العملية على أنها "مبكرة" أو "متأخرة" بناءً على تاريخ إجرائها نسبةً إلى بدء التهوية الميكانيكية. على الرغم من تباين الأدلة على فتح القصبة الهوائية المبكر مقابل المتأخر، إلا أن فتح القصبة الهوائية المبكر يرتبط بقصر مدة الإقامة في المستشفى وانخفاض معدلات الوفيات.

هدف الدراسة: تقييم النتائج السريرية لفتح القصبة الهوائية المبكر مقابل المتأخر للمرضى ذوي الحالات الحرجة الذين يستخدمون التهوية الميكانيكية في وحدة العناية المركزة.

منهجية الدراسة: أُجريت هذه الدراسة الاستعادية في فلسطين من يناير 2023 إلى ديسمبر 2024. قُسّم المرضى الذين خضعوا لفتح القصبة الهوائية الاختياري إلى مجموعتين: فتح القصبة الهوائية المبكر، الذي أُجري خلال الأيام العشرة الأولى من التنبيب، وفتح القصبة الهوائية المتأخر، الذي أُجري بعد اليوم العاشر. النتائج الرئيسية التي تم تقييمها هي معدل الوفاة، ومدة التهوية الميكانيكية، ومدة الإقامة في وحدة العناية المركزة والمستشفى، ومعدل الإصابة بالالتهاب الرئوي المرتبط بجهاز التنفس الصناعي. تم تقييم هذه النتائج ومقارنتها بين المجموعات، سواءً بشكل عام أو طبقي حسب مقياس APACHE II.

نتائج الدراسة: شملت الدراسة 66 مريضًا، 37 منهم في مجموعة فتح القصبة الهوائية المبكرو29 في مجموعة فتح القصبة الهوائية المتأخر. ارتبط فتح القصبة الهوائية المبكر بانخفاض ملحوظ في معدل الوفيات (29.7% مقابل 55.2%)، وقصر مدة التهوية الميكانيكية، وتقليل مدة الإقامة في وحدة العناية المركزة وإجمالي مدة الإقامة في المستشفى. لم تختلف معدلات الإصابة بالالتهاب الرئوي المرتبط بجهاز التنفس الصناعي بشكل كبير. المرضى الذين حصلوا على مقياس (APACHE II ≤ 20) أدى فتح القصبة الهوائية المبكر إلى تحسين جميع النتائج بشكل ملحوظ باستثناء معدل الوفيات. أما في المرضى الذين حصلوا على مقياس (APACHE II > 20) فقد قلل فتح القصبة الهوائية المبكر من إجمالي مدة التهوية الميكانيكية، ومدة الإقامة في وحدة العناية المركزة وإجمالي الإقامة في المستشفى، دون أن يؤثر على معدل الوفيات، أو مدة التهوية الميكانيكية بعد فتح القصبة الهوائية، أو الالتهاب الرئوي المرتبط بجهاز التنفس الصناعي.

الاستنتاجات: يتفوق فتح القصبة الهوائية المبكر على فتح القصبة الهوائية المتأخر في خفض معدل الوفيات، ومدة التهوية الميكانيكية، ومدة الإقامة في وحدة العناية المركزة، وإجمالي مدة الإقامة في المستشفى. ومع ذلك، في المرضى المعرضين لخطركبير، لا يرتبط توقيت فتح القصبة الهوائية بمعدلات الوفيات أو الالتهاب الرئوي المرتبط بجهاز التنفس الصناعي.

**الكلمات المفتاحية:** المرضى في حالة حرجة، التهوية الميكانيكية المطولة، القصبة الهوائية، فتح القصبة الهوائية المبكرة، مقياس APACHE-II