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Association Between Early Tracheostomy and Patient Outcomes in Critically Ill Patients on Mechanical Ventilator: A Retrospective Cohort Study

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Thesis Approval

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Declaration

I certify that this thesis submitted to the degree of Master is the result of my own research, except where otherwise acknowledged, and that this thesis or any of its parts have not been submitted for a higher degree to any other university or institution.

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continued success and fulfillment.

Abstract

Background: Tracheostomy is a common intervention for critically ill patients, often recommended to avoid the complications associated with prolonged intubation, such as longer ventilation periods and extended hospital stays. Despite these benefits, its effect on mortality rates is not well established. This study investigates the relationship between the timing of tracheostomy and patient outcomes, specifically focusing on mortality in a cohort of ventilated ICU patients.

Methods: the researcher performed a retrospective cohort study using data from the Japan Intensive Care Patient Database, encompassing adult ICU patients who underwent tracheostomy between January 2021 and July 2023. Patients were excluded if their tracheostomy occurred within 29 days of ICU admission to focus on those with more prolonged intubation. The primary outcomes of interest were hospital and ICU mortality rates. The patients were stratified into quartiles based on the timing of their tracheostomy: Q1 (≤6 days), Q2 (7-14 days), Q3 (15-22 days), and Q4 (>22 days). Regression analyses were conducted to evaluate the association between tracheostomy timing and mortality, adjusting for potential confounders.

Results: Our analysis included 60 ICU patients. The data revealed that hospital mortality rates increased with the delay in tracheostomy. Specifically, mortality rates were 5.9% in Q1, 12.5% in Q2, 28.6% in Q3, and 30.77% in Q4, with a significant trend (P=0.001). The adjusted odds ratio for mortality in Q4 compared to Q1 was 3.04 (95% CI: 0.22–40.82), indicating a significantly higher risk in later tracheostomy quartiles. Subgroup analyses focusing on patients with respiratory failure and reduced awareness upon ICU admission revealed similar trends. However, no significant differences were observed in other parameters of interest (P>0.05).

Conclusion: This study provides evidence of a significant independent association between the timing of tracheostomy and both hospital and ICU mortality rates. Early tracheostomy appears to be linked with improved outcomes, suggesting a potential benefit in reducing mortality. The results highlight a gradient effect, with varying levels of mortality risk associated with different timings of the procedure. These findings underscore the importance of considering timing in the management of critically ill patients and may inform clinical decision-making to optimize patient outcomes.

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List of Abbreviations

APACHE	Acute Physiology and Chronic Health Evaluation
GCS	Glasco Coma Scale
BMI	Body Mass Index
CI	Confidence interval
ICU	Intensive Care Unit
ECMO	Extracorporeal membrane oxygenation
JIPAD	Japanese Intensive Care Patient Database
VAP	Ventilator -associated pneumonia
MV	Mechanical Ventilator
TT	Tracheostomy Tube
IMV	Invasive Mechanical Ventilator
LT	Late Tracheostomy
ET	Early Tracheostomy
RF	Respiratory Failure
TBI	Traumatic Brain Injury
ETT	Endotracheal tube
PI	Prolonged Intubation
LOS	Length Of Stay
OR	Odds Ratio
PaO2	Partial Pressure Of Oxygen in the arterial blood
FIO2	Fraction Of Inspired Oxygen
RCTs	Randomized Controlled Trials
WMD	Weighted Mean Difference
ARDs	Acute respiratory distress syndrome
VFDs	Ventilator Free Days
PDT	Percutaneous Dilatational Tracheostomy

IQR	International Quartile Range
PEEP	Positive end-expiratory pressure
NP	Nosocomial Pneumonia
CCI	Charlson comorbidity index
VV- ECMO	Venovenous - extracorporeal membrane oxygenation
VA- ECMO	Venoarterial -extracorporeal membrane oxygenation
PMV	Prolonged mechanical ventilation
IPTW	Inverse probability of treatment weighting
DRG	Disease related group

Chapter One

Introduction

1.1 Background

In severely ill patients, tracheostomy is frequently performed due to its clinical benefits over prolonged trans laryngeal endotracheal intubation (Tanaka, 2022). Early tracheostomy has been shown to reduce both the length of stay and the need for artificial ventilation. However, its connection to mortality is currently unknown (Tanaka, 2022). The primary aim of this research was to examine how the timing of tracheostomy correlates with mortality rates among patients undergoing mechanical ventilation (Tanaka, 2022).

The experiences of critically ill patients constitute a crucial component of the quality of treatment in the intensive care unit (ICU), findings from studies conducted between 1970 and 2007 consistently highlight this topic (Johnson, 1972; Asbury, 1985; Burfitt et al., 1993; Russell, 1999; McCabe, 2004; Magnus and Turkington, 2006). In addition to saving lives, the primary objective of intensive care is to provide assistance to patients and their families throughout a critical illness (Pattison, 2005; Hofhuis et al., 2008).

A re-intubation may be necessary in about 10–20% of patients who ultimately fail to be liberated from mechanical ventilation due to extubating failure (Griffiths et al., 2005). Such patients are at an increased risk of death, patients who cannot be extubated endure prolonged mechanical ventilation and often require tracheostomy (Fernando et al., 2019). In 1989, the National Association of Medical Directors of Respiratory Care recommended that trans laryngeal (endotracheal) intubation be reserved for patients needing less than 10 days of artificial ventilation, and a tracheostomy should be considered for patients still requiring artificial ventilation 21 days after admission (Griffiths et al., 2005).

Two main types of patients requiring tracheostomy during extended weaning are those lacking airway protection due to neurological impairment and those with persistent respiratory impairment (Cabrio et al., 2022). Tracheostomy facilitates airway protection, reduces the duration of mechanical ventilation, expedites the transition to long-term care institutions, but does not decrease mortality in patients with neurological sequelae ,for patients with persistent respiratory impairment, tracheostomy is preferable to orotracheal intubation as it reduces the work of breathing, sedation needs, allows for greater movement, and enhances patient comfort (Cabrio et al., 2022). Additionally, it improves contact with healthcare professionals and simplifies tracheobronchial toilet, oral feeding can often be resumed when mechanical ventilation is discontinued, even if the tracheostomy cannula is still in place (Cabrio et al., 2022).

The optimal timing for tracheostomy placement remains a subject of controversy despite several trials (Chorath et al., 2021b). Meta-analyses from previous studies have shown different clinical outcomes between early and late tracheotomy, for example, in studies by (Szakmany et al.,2015) and (Hosokowa et al.,2015). there was no significant difference between early and late tracheotomies in terms of the duration of mechanical ventilation, the incidence of ventilator-associated pneumonia (VAP), or short-term mortality (Chorath et al., 2021b).However, a study by (Siempos and colleagues et al., 2015) reported a reduction in the incidence of VAP with early tracheotomy, although there was no change in short-term mortality , consistent with these findings, a Cochrane review indicated that mortality at 28 days was comparable for early and late tracheotomies, but long-term follow-up data revealed increased survival in the early intervention group (Chorath et al., 2021b).

This study explored the optimal timing and advantages of early adoption to establish appropriate indications for tracheostomy in critically ill patients receiving mechanical ventilation (Gupta et al., 2023). Recent systematic reviews of randomized controlled trials consistently show beneficial outcomes with early tracheostomy, leading to a shorter duration of mechanical ventilation (Gupta et al., 2023). The retrospective analysis, conducted at the Government Medical College in Jammu between April 2021 and November 2022, focused on 111 tracheotomized patients in the critical care unit (Gupta et al., 2023).'Early tracheostomy' (ET) was defined as tracheostomies performed within 10 days following intubation, while 'late tracheostomy' (LT) referred to procedures performed beyond 10 days(Gupta et al., 2023). APACHE II scores at the time of critical care unit admission were recorded for all included patients, mortality rates, the duration of mechanical ventilation, and the length of stay in the intensive care unit (ICU) were examined (Gupta et al., 2023). The findings suggest that, in terms of mortality, the number of days spent on mechanical ventilation, and the length of stay in the critical care unit, early tracheostomy is preferable to late tracheostomy (Gupta et al., 2023).

Over 90% of patients in need of (ICU) treatments present with respiratory failure (RF), often requiring invasive mechanical ventilation (IMV) (Abril et al., 2021). This makes RF with IMV one of the most prevalent diagnoses for individuals admitted to the ICU(Abril et al., 2021). To mitigate the discomfort and potential side effects associated with prolonged endotracheal tube use, such as ventilator-associated pneumonia, reduced mobility, prolonged sedation, pressure ulcers, direct damage to oropharyngeal structures, delirium, and muscle weakness, patients with RF requiring prolonged IMV with an endotracheal tube may be offered tracheostomy , tracheostomy is one of the most frequent operations performed on ICU patients experiencing prolonged RF with IMV(Abril et al., 2021). A study by (Mehta et al.,2021). revealed that from 1993 to 2012, the age-adjusted prevalence of tracheostomies among all patients with mechanical ventilation increased from 16.7 to 34.3 instances per 100,000 people (Abril et al., 2021).

While closely monitoring the rate at which the Glasgow Coma Scale is rising and paying specific attention to the best motor response, some researchers recommend early tracheostomy for patients with severe Traumatic Brain Injury (TBI) who have a potential for survival (Kumar et al., 2019). Despite this, published literature does not consistently demonstrate the benefits of tracheostomy across various illnesses (Kumar et al., 2019). A literature search reveals a lack of information, even though tracheostomy is a common surgical procedure used in the treatment of neurotrauma cases , the primary goals and objectives of the current retrospective data analysis were to evaluate the relationship between tracheostomy and post-operative complications and the survival outcomes in neurosurgical cases receiving ICU treatment at a tertiary care teaching hospital (Kumar et al., 2019).

Ideally, individuals in critical condition should receive high-quality care continuously (Kuijsten et al., 2010). Unfortunately, this is not always the case, staffing levels often decrease during off-peak hours, leading to delays or rescheduling of therapeutic and diagnostic procedures for regular office hours (Kuijsten et al., 2010). Admission during non-office hours may be associated with an increased mortality rate, as the early hours following admission to the intensive care unit (ICU) significantly influence the overall outcome of treatment (Kuijsten et al., 2010).

Although literature is all around us, do nurses read it? Or do they actually put it into practice?

Even though the timing of this treatment is still open to considerable practice variation, the start of the Tracheostomy plays an important role in the care of these patients' airways.

There is still a lack of recent literature on this subject in Palestine that demonstrates how advantages and risks of prolonged ventilation in critically ill patients are related to compliance to stay in the hospital and high mortality rates.

To understand the scope of this issue and create a successful strategic plan, clinical and educational institutions in Palestine will benefit from knowing the compliance and factors of early tracheostomy use before 14 days.

1.2 Statement of the problem

Prolonged ventilation in critically ill patients is associated with extended stays in the intensive care unit (ICU) and hospital, along with high mortality rates (Tanaka, 2022). Tracheostomy offers more potential benefits than trans laryngeal endotracheal intubation for patients on mechanical ventilation (Tanaka, 2022). These advantages include reduced sedative use, improved patient comfort, easier mobilization, less invasive attachment to and disconnection from the ventilator, and a decreased risk of ventilator-associated pneumonia (VAP), according to international consensus, tracheostomy is typically recommended for individuals anticipated to require extended mechanical ventilation (Tanaka, 2022).

Even after replacing an endotracheal tube (ETT) with a tracheostomy tube (TT), persistent laryngeal consequences remain. The TT frees the upper airway from tubing, allowing it to regain capacity, akin to removing a plaster cast to initiate mobilization (Sutt & Fraser, 2023). The upper airway, often stented open with an ETT and potentially damaged, requires evaluation and rehabilitation (Sutt & Fraser, 2023). Airflow plays a crucial role in providing sensory information; without it, patients may struggle to detect saliva presence and volume, impacting swallowing (Sutt & Fraser, 2023). A TT without techniques to restore airflow and with an inflated cuff can desensitize and decondition the upper airway further (Sutt & Fraser, 2023). This is especially crucial for patients with neurological damage, complicating communication and swallowing (Sutt & Fraser, 2023; Premraj et al., 2023).

Early tracheostomy has been associated with shorter durations of mechanical ventilation and ICU stays compared to late tracheostomy (Tanaka et al., 2022). However, identifying associations with mortality remains challenging, direct two-arm comparisons are difficult because different studies use varying definitions for considering a tracheostomy early (between 2 and 10 days) or late (between 6 and 29 days or more) (Tanaka et al., 2022). Consequently, there is currently no evidence establishing a clear relationship between tracheostomy timing and mortality (Tanaka et al., 2022).

Tracheostomy plays a crucial role in managing the airways of patients, although the timing of this procedure remains subject to significant practice variance (Arabi, 2004). Unfortunately, no recent literature on this topic has been found in Palestine, prolonged ventilation in critically ill patients is associated with long stays in the intensive care unit (ICU) and hospital, along with high mortality rates (Arabi, 2004). Tracheostomy offers numerous potential benefits for patients on mechanical ventilation, including lower airflow resistance and breathing effort, reduced sedative administration, improved patient comfort and mobilization, weaning with less invasive attachment to and disconnection from the ventilator, and a lower incidence of ventilator-associated pneumonia (Arabi, 2004). However, tracheostomy operations come with risks of complications, including bleeding, stomal infection, and tube problems (Arabi, 2004).

1.3 Significant of the study

The association between early tracheostomy and patient outcomes in critically ill patients on mechanical ventilation has been a topic of interest in medical research. Tracheostomy is a surgical procedure that involves creating an opening in the neck to provide direct access to the trachea. Here are some significant aspects related to this association:

1. Ventilator-Associated Complications:

Reduction in Ventilator-Associated Pneumonia (VAP): Early tracheostomy has been associated with a potential decrease in the incidence of ventilator-associated pneumonia, a common complication in mechanically ventilated patients (Tanaka et al., 2022).

2. Duration of Mechanical Ventilation:

Shortened Ventilation Duration: early tracheostomy may be linked to a shorter duration of mechanical ventilation, this can have implications for reducing the risk of complications associated with prolonged intubation (Tanaka et al., 2022).

3. ICU Length of Stay:

Reduced ICU Length of Stay: Early tracheostomy may contribute to a shorter overall length of stay in the intensive care unit (ICU) This could have implications for resource utilization and healthcare costs (Tanaka et al., 2022).

4. Weaning from Mechanical Ventilation:

Facilitation of Weaning: Tracheostomy may facilitate the weaning process, potentially allowing for an earlier transition to spontaneous breathing and eventual liberation from mechanical ventilation (Tanaka et al., 2022).

5. Communication and Patient Comfort:

Improved Communication and Comfort: Patients with tracheostomies may find it easier to communicate, and healthcare providers may find it more convenient to manage respiratory care. This can contribute to improved patient experience and care (Tanaka et al., 2022).

6. Timing of Tracheostomy:

On Optimal Timing: There is ongoing debate regarding the optimal timing of tracheostomy. Early tracheostomy is generally considered within the first 7–10 days of mechanical ventilation, but the ideal timing may vary based on individual patient characteristics and clinical circumstances (Tanaka et al., 2022).

7. Risk of Complications:

Consideration of Risks: While early tracheostomy may have benefits, it is essential to consider the potential risks and complications associated with the procedure, including bleeding, infection, and issues related to the surgical site (Tanaka et al., 2022).

8. Patient Selection Criteria:

Importance of Patient Selection: The decision to perform early tracheostomy should consider patient-specific factors, such as the underlying medical condition, severity of illness, and likelihood of prolonged mechanical ventilation (Tanaka et al., 2022).

9. Guidelines and Practice Variation:

Variability in Practice: Practices regarding the timing of tracheostomy may vary across different healthcare settings, and guidelines may provide recommendations based on available evidence (Tanaka et al., 2022).

1.4 Purpose of study

This study aimed to assess the relationship between early tracheostomy and patient outcomes in critically ill patients on mechanical ventilation.

1.5 Specific objectives

1. To determine the relationship between timing of tracheostomy and demographic characteristics.

2. To assess the relationship between timing of tracheostomy and ICU treatment.

3. To assess the relationship between timing of tracheostomy and duration of length on mechanical ventilation.

4. To assess the relationship between timing of tracheostomy and duration of length of stay.

5. To assess the relationship between timing of tracheostomy and clinical outcomes.

1.6 Research questions

1. Is there a significant difference between timing of tracheostomy and demographic characteristics?

2. Is there a significant difference between timing of tracheostomy and ICU treatment?

3. Is there a significant difference between timing of tracheostomy and duration of length on mechanical ventilation?

4. Is there a significant difference between timing of tracheostomy and duration of length of stay?

5. Is there a significant difference between the timing of tracheostomy and clinical outcomes?

1.7 Conceptual definitions and operational definitions

A) Conceptual definitions

- **Mechanical ventilator (MV)**

Positive-pressure ventilation in the form of mechanical ventilation is a life-saving intervention for patients experiencing acute severe hypoxemia or worsening respiratory acidosis that is refractory to conservative measures (Tobin, 1994). In individuals with severe cardiac distress, where the effort of breathing becomes intolerable, mechanical ventilation replaces the function of respiratory muscles (Tobin, 1994). In certain cases, as much as 50% of the total oxygen used comes through the respiratory muscles , mechanical ventilation under such conditions allows the redistribution of valuable oxygen reserves to other susceptible tissue beds (Tobin, 1994).Additionally, providing sufficient rest for respiratory muscles is essential for reversing respiratory muscle fatigue, a factor contributing to the development of acute ventilatory failure , positive-pressure ventilation helps reduce the effort required to breathe by enabling inspiration at a more compliant part of the pulmonary pressure-volume curve and can reverse and prevent atelectasis(Tobin, 1994). Improvement in pulmonary gas exchange, pressure-volume relations, and relief from excessive respiratory effort can contribute to the recovery of the lungs and airways (Tobin, 1994). It's important to note that while positive-pressure ventilation has significant benefits, it also carries the potential to cause or worsen alveolar injury and lower cardiac output (Tobin, 1994). As a result, the goals of mechanical ventilation have been reevaluated in consideration of the risks associated with ventilator-induced lung damage (Tobin, 1994).

- **Endotracheal tube (ETT)**

Inserting the tube into the trachea involves ensuring its proper depth within the trachea. Various methods confirm tracheal intubation, such as observing the tube passing between the vocal cords during direct laryngoscopy or using a fiberscope to visualize the tracheal rings and carina after intubation (Salem, 2001).The primary purposes of the endotracheal tube (ETT) cuff are to pressurize the respiratory system and prevent aspiration , maintaining sufficient pressure inside the cuff is crucial for achieving these goals, thereby reducing the patient's risks (González et al., 2023).

- **Ventilator-associated pneumonia (VAP) :**

Hospital-acquired pneumonia is associated with a significant risk of morbidity and death and stands as one of the most common infections acquired in intensive care units, gram-negative bacteria are particularly implicated, contributing to higher death rates, and accounting for 55–85% of cases of hospital-acquired pneumonia (Lodise et al., 2021).

- **Tracheostomy tube (TT)**

Endotracheal tubes are employed to facilitate access to the lower respiratory tract for airway clearing, maintain a patent airway, and deliver positive-pressure ventilation (Meng et al., 2015) These tubes are produced by various manufacturers and come in a range of sizes and designs, including those with cuffs and those without (Hess & Altobelli, 2014).

When patients in the intensive care unit (ICU) require prolonged intubation (PI) with mechanical ventilation (MV) and are not able to successfully wean off the ventilator soon , tracheostomy is a commonly employed treatment to replace trans laryngeal intubation (Meng et al., 2015).

- **Critically Ill Patients**

Signs of respiratory failure, the need for mechanical ventilation, and the occurrence of other organ dysfunction and shock may necessitate admission to the intensive care unit (WHO, 2020a).

In order to preserve life during a period of acute organ system insufficiency, critically ill patients receive various modalities of physiologic organ support, expanded monitoring capabilities, and extensive and specialized medical and nursing care (Marshall et al., 2017).

In another definition, it is characterized by an increased risk of impending mortality, malfunctioning essential organs, the need for medical attention to prevent death, and possible reversibility (Kayambankadzanja et al., 2022).

- **Hospital mortality**

An in-hospital death is defined by an encounter with a discharge status of 'died' or 'died in a medical facility' (NHCS - About the National Hospital Care Survey, n.d. 2022).

One important measure of the standard of treatment is in-hospital mortality, research has indicated that factors related to both patients and hospitals have an impact on death rates within the hospital (Pórcel-Gálvez et al., 2020).

- **ICU mortality**

The intensive care unit (ICU) is a hospital unit that provides highly specialized care and round-the-clock monitoring for severely ill patients, both surgical and medical , stablished approximately 50 years ago, the ICU has become an indispensable component of hospital treatment, particularly for patients facing life-threatening diseases that necessitate extensive care (Timmers, 2014).The ICU serves as a repository of knowledge aimed at assisting individuals in need of heightened medical attention and organ support (Timmers, 2014).

Gaining a comprehensive understanding of the prolonged effects on severely ill patients is crucial for the intensive care unit (ICU) to make collaborative decisions (Detsky et al., 2017). Hospitalized patients facing acute conditions are at risk of enduring diminished physical and cognitive function post-discharge—an outcome of great significance to the patients, individuals requiring life-sustaining therapy in ICU settings appear to be notably more susceptible to impairment and mortality (Detsky et al., 2017). studies on ICU patients with conditions like acute respiratory distress syndrome, necessitating prolonged mechanical ventilation, have indicated substantial declines in health-related quality of life and increased healthcare utilization, these effects may persist for months or even years after leaving the ICU (Detsky et al., 2017).

Several studies suggest that tracheostomy may reduce the length of an ICU stay, the duration of mechanical ventilation (MV), and the incidence of ventilator-associated pneumonia (VAP) (Meng et al., 2015).

In trauma ICU patients, early tracheostomy is associated with shorter periods of mechanical ventilation without influencing ICU or hospital outcomes, implementing a consistent approach to early tracheostomy in well-selected patients may potentially aid in reducing unnecessary resource use (Arabi et al., 2004)

1.7.1 Conceptual framework

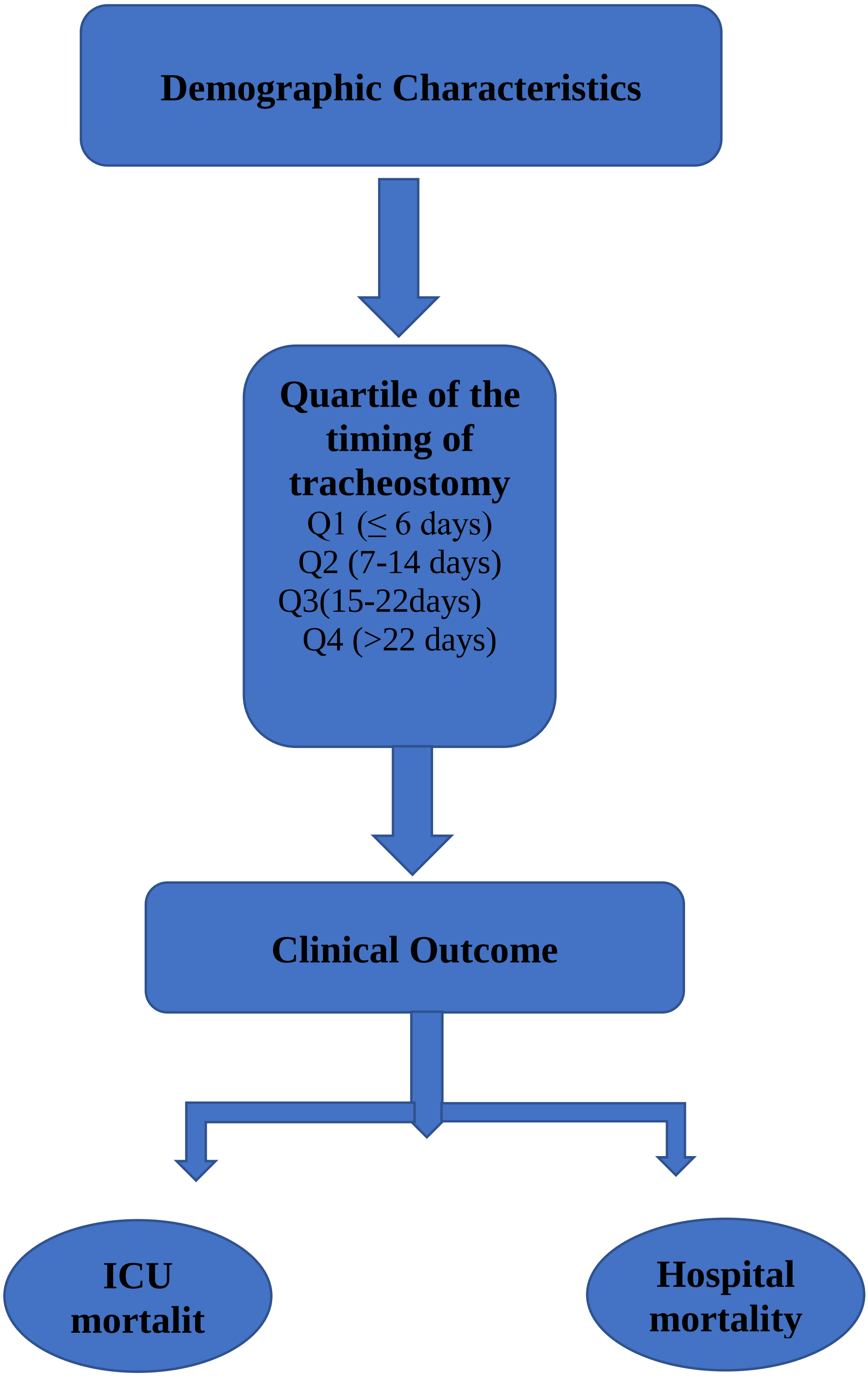

Figure 1: Conceptual framework of the study

B) Operational definitions:

The following definitions according to the study conceptual framework.

- **Demographic characteristics:** is divided into age, sex, body mass index.
- **Comorbidity:** measured by having any of the following disease**:**
- Chronic liver failure which categorized into liver cirrhosis and liver failure
- Immunodeficiency which categorized into immunosuppression and acquired immunodeficiency syndrome.
- Malignancy which categorized into acute leukemia, multiple myeloma and metastatic cancer
- Type of admission which categorized into Emergency and surgical admission.
- Systematic diagnosis for ICU admission which categorized into cardiac, neurological, sepsis, respiratory, gastrointestinal, trauma and others.
- If patient has Chronic heart failure and chronic respiratory failure.
- Acute physiology and chronic health evaluation score which categorized into temperature, mean arterial pressure, heart rate, respiratory rate, Pao2, PH, sodium, potassium, creatinine, hematocrit and WBC count.
- Data within 24 hours after ICU admission which categorized into incidence of acute kidney injury, lowest Pao2, lowest Fio2, Glasgow coma scale score, length of hospital stays before ICU admission.
- ICU treatment which categorized into extracorporeal membrane oxygenation and continuous renal replacement therapy.

- Duration of mechanical ventilation which categorized into before tracheostomy, in ICU and Liberation of mechanical ventilation during ICU stays.

- Length which categorized into of hospital stays and length of ICU.

- The quartile of the timing of tracheostomy is divided into four categories: Q1 (≤ 6 days), Q2 (7-14 days), Q3 (15-22 days), and Q4 (>22 days)

- Clinical outcomes: are divided into hospital mortality and ICU mortality

Hospital mortality: refers to the number or percentage of patients who die during their hospital stay, usually within a specified period after admission. It encompasses patients who die across various departments within the hospital, providing a comprehensive measure of mortality outcomes during the entire hospitalization period.

ICU mortality: refers to the number or percentage of patients who die while in the intensive care unit (ICU). It specifically focuses on assessing the mortality outcomes of patients who receive critical care in the ICU. This metric is valuable for evaluating the effectiveness of interventions and the quality of care provided in the intensive care setting.

1.8 Study variables

- **Dependent variables**: patient outcomes on mechanical ventilation (ICU mortality and hospital mortality).
- **Independent variables:** Demographic data of the patient, Timing of tracheostomy starting from ICU admission and ICU treatment (CRRT and ECMO).

1.9 Justification of the study

One of the most common procedures for critically ill patients requiring prolonged mechanical ventilation due to acute respiratory failure and airway issues is tracheostomy, i It has been demonstrated to be a safe bedside procedure when performed by professionals, and it can address several major factors that facilitate the weaning process, including dead space mitigation, decreased airway resistance due to improved secretion clearance, increased mobility, and a lower risk of aspiration (Nasr, 2020).

In the intensive care unit, early tracheostomy may significantly decrease the direct variable and, likely, the overall hospital costs, depending on the duration of stay , this is in addition to the previously established advantages of an early tracheostomy, such as fewer days on a ventilator, shorter hospital stays, less pain, and improved communication (Herritt et al., 2018).

According to revised meta-analysis, early tracheotomy is associated with higher rates and better outcomes compared to late tracheotomy, these outcomes include more ventilator-free days, shorter ICU stays, less sedation, and lower long-term mortality (Hosokawa et al., 2015).

Most studies suggest that early tracheostomy (ET) is superior to late tracheostomy (LT) in terms of the length of mechanical ventilation (MV), the duration of intensive care unit (ICU) stays, and hospital costs , according to Puentes et al.,2020 ET has a significant positive impact on reducing postoperative morbidities and can lead to shorter ICU and hospital stays overall , ultimately, these advantages contribute to quicker patient recovery at lower medical expenses (Moussa et al., 2020).

Due to its therapeutic benefits over prolonged trans-laryngeal endotracheal intubation, tracheostomy is frequently performed on critically ill patients, making it an area of interest, early tracheostomy has been demonstrated to reduce hospital stays and the duration of artificial ventilation required by patients (Tanaka et al., 2022).

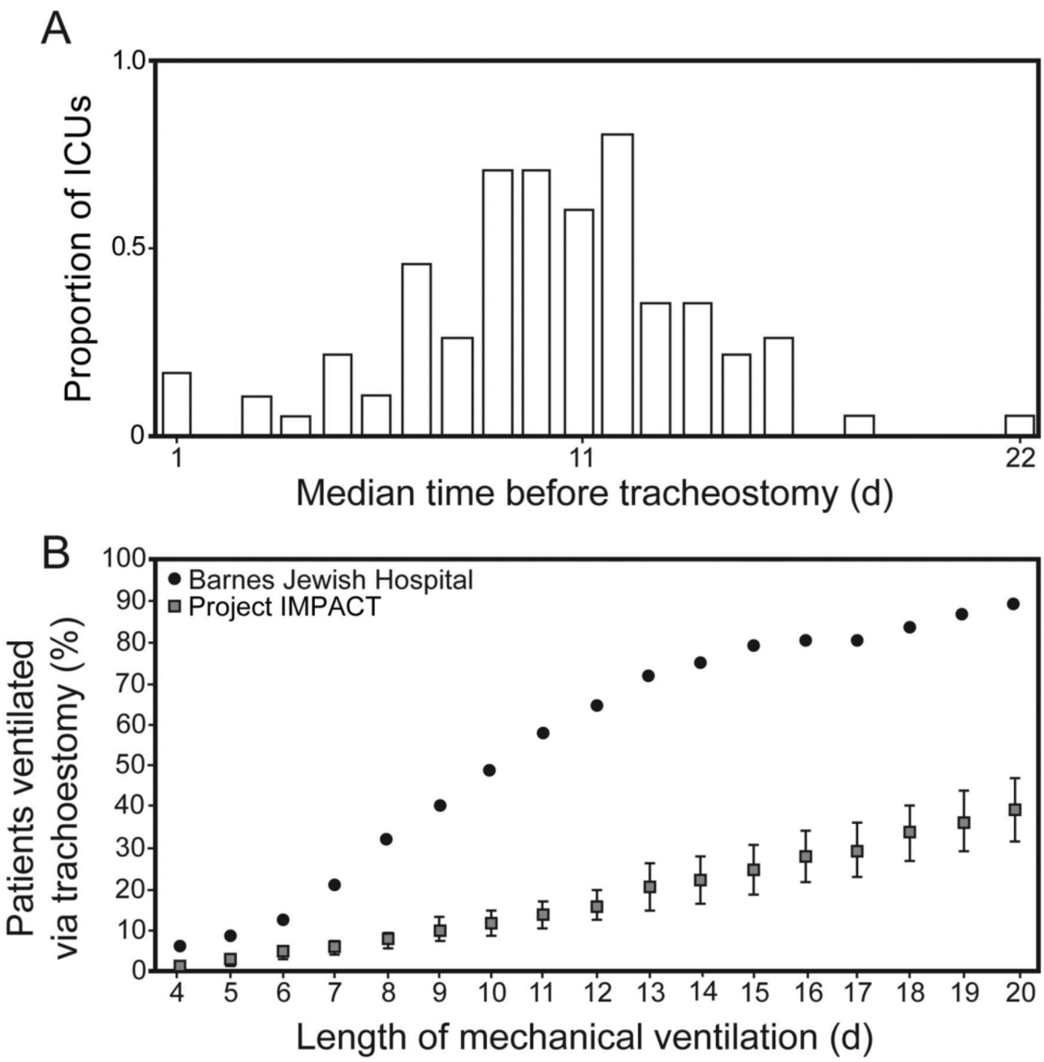

Figure 2: A: Tracheostomy timing in Project IMPACT surgical ICUs B: Tracheostomy utilization in Project IMPACT surgical ICUs and Barnes-Jewish Hospital surgical ICUs (Cheung & Napolitano, 2014).

1.10 Summary

With advancements in the treatment of severely ill patients, an increasing number now requires respiratory assistance and prolonged airway intubation, in cases where the duration of intubation is expected to extend for several weeks, tracheostomy is often recommended. Tracheostomy may lead to improved patient outcomes, enhanced communication skills, increased oral feeding options, and simpler, safer nursing care (Durbin et al., 2010). Additionally, it may result in lower airway resistance, reduced sedation requirements compared to an endotracheal tube, potentially expediting the weaning process and reducing the length of hospital and critical care unit stays (Durbin et al., 2010). Furthermore, tracheostomy may help prevent pneumonia linked to ventilator use by avoiding micro-aspiration of secretions (Durbin et al., 2010). Despite the benefits, there is ongoing disagreement over the optimal timing for the surgery ,while numerous randomized controlled trials on the timing of tracheostomies have been conducted, the capacity to identify significant variations is limited, and the variability among the initial research poses challenges for systematic reviews and meta-analyses ,based on the currently available evidence, there is a consensus that early intervention may be prudent , identifying patients who will require extended mechanical ventilation for a tracheostomy can be challenging, and predictive tools for prolonged ventilation are lacking in many patient groups (Durbin et al., 2010).

Chapter Two

Literature review

2.1 Introduction

Patients often enter an intensive care unit (ICU) due to the necessity for mechanical ventilation , since having an endotracheal tube can be painful, sedation and analgesics are frequently required, tracheostomies are commonly performed in patients who require extended mechanical ventilation, primarily to provide a better long-term airway and to facilitate the weaning process from ventilatory support , despite the widespread use of tracheostomy, few well-designed studies have explored how the timing of tracheostomy affects patients' prognosis, there is no universal agreement on the optimal time to perform a tracheostomy in patients undergoing artificial ventilation , according to a 1989 agreement, patients expected to be extubated within 10 days should undergo mechanical ventilation via trans laryngeal endotracheal intubation, while those anticipated to require mechanical ventilation for longer than 21 days should undergo tracheostomy, consequently, in severely ill patients, tracheostomy is often considered within the first 2 weeks of mechanical ventilation , in the current study, 76.3% (1174 of 1538) of the patients underwent tracheostomy during the first 2 weeks ,despite the crucial role of tracheostomy in the treatment of mechanical ventilation, the ideal timing of tracheostomy has yet to be defined by a worldwide expert task team , moreover, recent international recommendations on acute respiratory failure do not specifically address tracheostomy (Tanaka et al., 2022b).

Large-scale randomized controlled trials have not demonstrated a correlation between tracheostomy and death (Tanaka et al., 2022c).However, it has been associated with various patient outcomes, including durations of stay in the intensive care unit and hospital, duration of mechanical ventilation, and cost (Tanaka et al., 2022c).

2.2 Previous studies

Age

It has been demonstrated that major risk factors for in-hospital mortality in patients urgently hospitalized with tracheostomy problems as their primary diagnosis include age, length of hospital stay, and multiple medical conditions ,the probability of mortality increased by 0.7% for each year of age and by 0.8% for each additional day spent in the hospital (Levy et al., 2022).

Furthermore, the age carries a significant risk, as indicated by its correlation with rising comorbidities, higher rates of complications, and higher non-elderly death rates (Levy et al., 2022). The patient's chance of survival decreases with age, these findings align with (Tamir et al.,2022) results, which suggested that comorbid conditions and subject age had a stronger correlation with the 30-day death rate , overall, the death rate from tracheostomy difficulties was 3.8% for adults and 4.9% for elderly patients; nevertheless, this is higher than the 1.4% found in a cohort of 38,293 patients with tracheostomy complications as the major diagnosis in Kligerman et al.'s study (Levy et al., 2022)

Gender

The death rate in the ICU was 8.8% Gender did not affect hospital mortality, ICU stays, or the severity of illness, at the time of ICU admission, women were older than males (62.6 vs. 61.3 years; P <.001) , men had higher odds of tracheostomy (OR = 1.39 [1.26-1.54]), ECMO (OR = 1.37 [1.02-1.83]), dialysis (OR = 1.29 [1.18-1.41]), and PAC insertion (OR = 1.81 [1.40-2.33]) after multivariable correction(Blecha et al., 2020). They also had longer durations of mechanical ventilation than women (IRR = 1.07 [1.02-1.12]). There was no gender-specific variations in the frequency of endotracheal intubation (OR = 1.04 [0.98-1.11]) or the installation of CVC (OR = 1.05 [0.98-1.11]) (Blecha et al., 2020).

Men were more likely than women to have tracheostomy (20.1% vs. 15.3%; P = .004), dialysis (54% vs. 46.4%; P < .001), and mechanical ventilation (6.3 vs. 5.4 days; P = .015) among ICU non-survivors (Blecha et al., 2020). Thus, men and women receive different ICU treatments after adjusting for illness severity and outcome, compared to women, men were more likely to have tracheostomies and ECMOs (Blecha et al., 2020).

Body Mass Index

The optimal timing of tracheotomy remains a subject of ongoing debate, particularly regarding its impact on the weaning process from mechanical ventilation in critically ill, morbidly obese patients (Alhajhusain et al., 2014) . retrospective chart analysis, they focused on patients with a body mass index (BMI) of ≥40 kg/m² or BMI ≥35 kg/m² with one or more concomitant illnesses, who underwent tracheotomy in a medical intensive care unit (ICU) between July 2008 and June 2013 (Alhajhusain et al., 2014) .Among the 102 participants (60 women and 40 men), with a mean age of 56.3 ± 15.1 years and BMI of 53.3 ± 13.6 kg/m², we examined clinical features, nosocomial pneumonia (NP) rates, weaning from mechanical ventilation (MV), and mortality rates(Alhajhusain et al., 2014).

The analysis revealed that NP rates did not significantly differ between groups categorized based on successful MV weaning (Alhajhusain et al., 2014). However, those unable to wean had a significantly higher mortality rate (Alhajhusain et al., 2014). A cutoff value of nine days for the time to tracheotomy demonstrated the best balance between sensitivity (72%) and specificity (59.8%) for predicting the onset of NP (Alhajhusain et al., 2014).

Patients with tracheostomies lasting longer than nine days experienced significantly higher NP rates and total MV duration (Alhajhusain et al., 2014). Importantly, tracheotomies performed within the first nine days of treatment in morbidly obese patients appeared to lower NP and MV but had no discernible effect on hospital mortality (Alhajhusain et al., 2014).

Hospital mortality:

Based on the findings, the hospital death rates as the primary outcome progressively increased with the rising quartiles of the timing of tracheostomy (Q1, 17.7%; Q2, 25.4%; Q3, 29.7%; Q4, 32.4%, p for trend < 0.001) (Tanaka et al., 2022d) .In the adjusted multivariable analysis, hospital death rates exhibited a stepwise increase across quartiles (adjusted odds ratio [OR] for quartile increment: 1.30, 95% confidence interval [CI]: 1.17–1.44, p for trend < 0.001) (Tanaka et al., 2022d) . Specifically, the Q4 group had a significantly higher risk of hospital mortality compared to the Q1 group (adjusted OR: 2.26, 95% CI: 1.61–3.16) (Tanaka et al., 2022d).

ICU mortality

The secondary outcome increased gradually as the quartile of the tracheostomy time increased (adjusted odds ratio [OR] for quartile increment: 1.73, 95% confidence interval [CI]: 1.45–2.07, p for trend < 0.001) (Tanaka et al., 2022d). Specifically, the Q4 group had a greater risk of ICU death compared to the Q1 group (OR: 4.57, 95% CI: 2.59–8.04) (Tanaka et al., 2022d). Furthermore, the timing of tracheostomy was found to significantly increase both ICU and hospital mortality according to the limited cubic spline analysis (Tanaka et al., 2022d).

In a different trial, researchers investigated whether early tracheostomy, compared to late tracheostomy, might result in a lower mortality rate for adult patients in intensive care units who need mechanical ventilation (Young et al., 2013).The open multicenter randomized clinical trial was conducted between 2004 and 2011 at 13 university and 59 non-university hospitals in the United Kingdom, including 70 adult general and 2 cardiothoracic critical care units (Young et al., 2013).

The main outcome measure was 30-day mortality, and the analysis utilized an intention-totreat approach (Young et al., 2013).Tracheostomy-related problems were recorded in 6.3% of patients, with 5.5% in the early group and 7.8% in the late group among the 455 patients assigned to early tracheostomy and the 454 patients assigned to late tracheostomy (Young et al., 2013).

The findings indicated that early tracheostomy (performed during the first 4 days of admission) among mechanically ventilated critically ill patients in adult general critical care units in the United Kingdom was not associated with an improvement in 30-day mortality or other significant secondary outcomes (Young et al., 2013).Therefore, the study suggested that early tracheostomy should be avoided until techniques are developed and validated to precisely anticipate how long each patient would require artificial ventilation (Young et al., 2013).

In a comprehensive investigation at an urban academic tertiary-care hospital, every tracheostomy patient in 2016-2017 underwent retrospective review (Park et al., 2020). The study assessed various tracheostomy timings and methods, generating Kaplan-Meier curves and employing Cox proportional hazard models to analyze multivariate impacts (Park et al., 2020). Primary outcomes were overall survival and tracheostomy-related deaths, with secondary outcomes including in-hospital, 30-day, and 90-day mortality (Park et al., 2020). Among 523 patients, hemorrhage and tracheoesophageal fistula were common causes of six tracheostomy-related fatalities (Park et al., 2020). No correlation was found between timing/method combinations and all-cause mortality or post-discharge survival (Park et al., 2020). However, non-percutaneous and late tracheostomies were associated with more fatalities, while higher comorbidities and unclear partner status independently predicted worse survival (Park et al., 2020). Proceduralists were advised to collaborate with medical teams on scheduling, method, and patient social factors for post-discharge management (Park et al., 2020).

In a 2022 retrospective cohort analysis, adult ICU patients who underwent tracheostomy between April 2015 and March 2019 were studied. Using Japanese ICU data, 1538 patients out of 85558 admitted to 46 ICUs were analyzed (Tanaka, 2022). Tracheostomy timing was categorized into quartiles: quartile 1 (≤6 days), quartile 2 (7–10 days), quartile 3 (11–14 days), and quartile 4 (>14 days). Hospital mortality was the main outcome, with regression analysis assessing the relationship (Tanaka, 2022). Mortality was notably higher in quartiles 2, 3, and 4 compared to quartile 1, with adjusted odds ratios of 1.52, 1.82, and 2.26, respectively. Patients with impaired consciousness and respiratory failure upon ICU admission showed a similar trend (Tanaka, 2022). The study concluded that tracheostomy timing significantly and independently influenced hospital mortality, suggesting potential benefits of early tracheostomy (Tanaka, 2022). Further research was recommended (Tanaka, 2022).

This sub-study, derived from the LUNG-SAFE trial, investigated tracheostomy usage in ICU patients with Acute Respiratory Distress Syndrome (ARDS) requiring mechanical ventilation (Abe, 2018). It involved adult patients meeting ARDS criteria and undergoing invasive mechanical ventilation within the first two days of acute hypoxemic respiratory failure (Abe, 2018). Patients were categorized into tracheostomy and non-tracheostomy groups based on tracheostomy within 28 days of ARDS onset (Abe, 2018). Key findings showed 13.9% of ARDS patients received tracheostomy, with variations in tracheostomy rates among nations. Median tracheostomy timing was 14 days, with longer ICU and hospital stays for tracheostomy patients (Abe, 2018). Tracheostomy did not significantly affect 60- or 90-day mortality rates (Abe, 2018). In summary, most tracheostomies occurred after the first week of illness, and while they may enhance survival, they show limited impact on mortality at 60 or 90 days (Abe, 2018).

A prospective cohort study focused on adult tracheostomy patients, excluding those with prior tracheostomies (Cordes et al., 2014b). Complications were categorized as intraoperative, early (within two weeks), and late (Cordes et al., 2014b). The study included 151 eligible patients (Cordes et al., 2014b). Key findings revealed that 55% of obese patients experienced at least one tracheostomy-related issue, compared to 19.5% of controls (Cordes et al., 2014b). Procedure time was significantly longer for obese individuals, with BMI showing a significant impact on both operation time and complication rate (Cordes et al., 2014b). So, an obese patient, particularly those with a BMI of 35 or higher, faced greater risks of tracheostomy-related complications, especially intraoperative and early postoperative, with longer procedure times observed (Cordes et al., 2014b).

The study, using the Japanese Intensive Care Patient Database, analyzed adult COVID-19 patients requiring prolonged mechanical ventilation (PMV) or tracheostomy (Tanaka et al., 2023). Among 453 patients, 109 needed PMV, with 60.6% undergoing tracheostomy and 34.9% dying. Tracheostomy was significantly linked to reduced hospital mortality (HR: 0.316) after adjusting for variables (Tanaka et al., 2023). Similar reductions were seen in ICU and 28-day mortality (HR: 0.269, HR: 0.281), with consistent findings in sensitivity analyses (Tanaka et al., 2023). The study concludes that tracheostomy may improve prognosis for COVID-19 patients requiring prolonged ventilation, suggesting preemptive tracheostomy consideration for those needing ventilation over 14 days (Tanaka et al., 2023).

This study, conducted in a surgical ICU from July 2008 to June 2011, focused on adult patients expected to require prolonged mechanical ventilation (MV) via endotracheal intubation (Zheng et al., 2012). Patients meeting the criteria were randomized into early and late percutaneous dilatational tracheostomy (PDT) groups (Zheng et al., 2012). Early PDT led to significantly more ventilator-free days at Day 28 (9.57 ± 5.64 vs. 7.38 ± 6.17 days, $P < 0.05$) and higher sedation-free and ICU-free days(Zheng et al., 2012). Early PDT also improved weaning rates, ICU discharge, and reduced ventilator-associated pneumonia (VAP) (Zheng et al., 2012). However, there was no significant difference in the predicted 60-day cumulative death rate between groups (P = 0.949) (Zheng et al., 2012).

67 adults were involved for ICU patients who underwent open surgical tracheostomy, the study divided them into two groups: 30 of them received early tracheostomy (ET) within 1–10 days after intubation, and 37 received late tracheostomy (LT) within 11–21 days (Khammas & Dawood, 2018). The aim was to explore the relationship between tracheostomy timing and various ICU clinical characteristics (Khammas & Dawood, 2018). findings showed significantly lower sedentary time and shorter mechanical ventilation duration in the ET group (Khammas & Dawood, 2018). ET also exhibited lower weaning failure rates and shorter weaning process times compared to LT (Khammas & Dawood, 2018). However, ICU length of stay and incidence of ventilator-associated pneumonia (VAP) did not significantly differ between groups(Khammas & Dawood, 2018). Therefore, early tracheostomy was associated with benefits such as reduced mechanical ventilation duration and lower weaning failure rates, but no significant impact on ICU stay or VAP incidence was observed (Khammas & Dawood, 2018).

A prospective, randomized trial, researchers compared early percutaneous dilatational tracheostomy with delayed tracheostomy in severely ill medical patients requiring mechanical ventilation for acute respiratory failure (Rumbak et al., 2004). Conducted at three academic medical centers, the study included patients over 18 years with anticipated mechanical ventilation duration >14 days and APACHE II score >25 (Rumbak et al., 2004). The findings showed that early tracheostomy group had significantly lower rates of pneumonia, hospital mortality, and unintentional extubating. They also required fewer days of mechanical ventilation and spent less time in the ICU (Rumbak et al., 2004). While the early tracheostomy group experienced less harm to the mouth and larynx, there was no significant difference in tracheal harm(Rumbak et al., 2004). Overall, early tracheostomy demonstrated advantages over prolonged intubation, supporting its preference in severely ill patients requiring prolonged mechanical ventilation (Rumbak et al., 2004).

In a retrospective analysis at a single institution, researchers studied consecutive adult patients who underwent extracorporeal membrane oxygenation (ECMO) from 2016 to 2020 (Jones et al., 2022). Out of 545 screened patients, 521 on venovenous (VV) or venoarterial (VA) ECMO were included (Jones et al., 2022).Tracheostomy was performed on 54 patients, with 29 during ECMO and 25 after successful ECMO removal, with a mean delay of 19 and 10 days, respectively (Jones et al., 2022).VV ECMO patients had a significantly higher tracheostomy rate than VA ECMO patients (Jones et al., 2022). Timing of tracheostomy did not differ significantly by ECMO modality (Jones et al., 2022). Patients who underwent tracheostomy during ECMO had a higher prevalence of mild problems, but this did not affect survival until hospital discharge (Jones et al., 2022). Tracheostomy improved patient mobility, reduced sedative usage, and did not cause significant bleeding (Jones et al., 2022). Further research is needed to optimize ECMO courses (Jones et al., 2022).

Examining data from a tertiary medical center's ICU between July 1998 and June 2001, researchers analyzed outcomes of tracheostomy patients (Hsu et al., 2004). Of 163 patients, divided into successful weaning (n=78) and weaning failure (n=85) groups, those who successfully weaned had shorter intubation times, longer ICU stays, and shorter post-tracheostomy ICU stay (Hsu et al., 2004).   Weaning failure and ICU death rates were higher in patients with tracheostomies performed after three weeks of intubation (Hsu et al., 2004). Tracheostomy timing, low oxygenation pre-tracheostomy, and post-tracheostomy pneumonia independently predicted weaning failure(Hsu et al., 2004). The study suggests tracheostomy after 21 days of intubation is associated with longer ICU stays, increased ICU mortality, and higher weaning failure rates (Hsu et al., 2004).

Between June 2004 and June 2008, a study in 12 Italian ICUs compared early tracheotomy (6–8 days after intubation) with late tracheotomy (13–15 days) in mechanically ventilated adult ICU patients (Terragni et al., 2010). The randomized controlled trial included 600 patients ventilated for 24 hours without chest infections, with specific severity scores (Terragni et al., 2010). The primary goal was to assess ventilator-associated pneumonia incidence, with secondary endpoints including ventilator-free days, ICU-free days, and 28-day survival (Terragni et al., 2010). While early tracheotomy showed a trend towards reducing pneumonia incidence compared to late tracheotomy, the difference was not statistically significant (Terragni et al., 2010). However, early tracheotomy was associated with reduced ventilation continuation, ICU stay, and mortality risk (Terragni et al., 2010).

In their study, Dunham (2014) analyzed the effects of early tracheostomy on severe brain injury outcomes, comparing their findings to previous trials and conducting a meta-analysis. While early tracheostomy didn't reduce ventilator-associated pneumonia incidence, it did decrease ICU/ventilator days (Dunham, 2014). However, it was associated with higher hospital mortality rates (Dunham, 2014). Retrospective studies echoed these findings (Dunham, 2014). Consequently, early tracheostomy might not be advisable for severe brain injury cases (Dunham, 2014).

In a retrospective observational analysis conducted at a single tertiary care facility from April 2014 to December 2021, consecutively admitted patients receiving ECMO assistance and undergoing tracheostomy during ICU admission were studied. The main outcome measure was hospital mortality, and the analysis involved four groups of patients categorized based on the quartiles of tracheostomy timing (Nukiwa et al., 2022). Out of the 293 patients who underwent ECMO treatment, 98 qualifying patients were divided into four groups: Group 1 (tracheostomy performed in less than 15 days), Group 2 (tracheostomy performed between 16–19 days), Group 3 (tracheostomy performed between 20–26 days), and Group 4 (tracheostomy performed after more than 26 days) (Nukiwa et al., 2022). All patients in the study had surgical tracheostomies, and 35 of them had tracheostomies during ECMO, while tracheostomy difficulties were similar across the groups, the length of stay in the intensive care unit (ICU) and the duration of time spent on ECMO increased with the quartiles of tracheostomy timing (Nukiwa et al., 2022). Hospital mortality rates were lowest (19.2%) for patients in quartile 1 and highest (50.0%) for those in quartile 4(Nukiwa et al., 2022). Multivariate logistic regression analysis demonstrated a significant correlation between hospital mortality and the increment of the quartiles of tracheostomy timing (adjusted odds ratio for quartile increment: 1.55, 95% confidence range 1.03–2.35, p for trend = 0.037) (Nukiwa et al., 2022). In conclusion, the timing of tracheostomy in patients requiring ECMO was substantially and time-dependently related to patient outcomes (Nukiwa et al., 2022). The study suggests that hospital mortality increased as the quartiles of tracheostomy timing increased (Nukiwa et al., 2022). Further research is deemed necessary to determine the optimal timing for tracheostomy in terms of mortality outcomes (Nukiwa et al., 2022).

In another study conducted a systematic review comparing early (within 10 days) versus late tracheostomy in severe brain injury patients (McCredie et al., 2016). Ten studies (503 patients) were analyzed for outcomes like mortality and ventilation duration. Early tracheostomy didn't reduce short-term mortality but decreased long-term mortality, mechanical ventilation duration, and ICU stay (McCredie et al., 2016). However, it increased the likelihood of requiring tracheostomy (McCredie et al., 2016). The study suggests early tracheostomy might benefit long-term outcomes, but more patient-centered studies are needed for comprehensive evaluation (McCredie et al., 2016).

In a prospective randomized trial spanning two years, one hundred critically ill patients, predominantly surgical patients, were included (Koch et al., 2012). The trial involved the performance of percutaneous dilatational tracheostomy either early (≤4 days, median 2.8

days) or late (≥6 days, median 8.1 days) after intubation (Koch et al., 2012). The study aimed to assess the impact of early tracheostomy (ET) compared to late tracheostomy (LT) on mortality and other outcomes (Koch et al., 2012). Contrary to expectations, the results of the study indicated that early tracheostomy did not result in a discernible decrease in mortality compared to the late tracheostomy group (Koch et al., 2012). However, early tracheostomy was associated with several benefits, including a lower incidence of ventilator-associated pneumonia (VAP) in the ET group (38% vs. LT 64%) (Koch et al., 2012). Additionally, patients in the ET group experienced a shorter length of hospital stay (ET 31.5 days vs. LT 68 days) and a reduced time spent in the intensive care unit (ET 21.5 days vs. LT 27 days) (Koch et al., 2012). In conclusion, while early tracheostomy did not show a significant reduction in mortality for critically ill patients, it did demonstrate positive outcomes such as a lower incidence of VAP and shorter hospital stays and ventilation times, as observed in the study conducted (Koch et al., 2012).

Masoudifar et al. (2012) conducted a retrospective analysis over two years at Al-Zahra Hospital, focusing on adult ICU patients requiring extended mechanical ventilation and endotracheal intubation (Masoudifar et al., 2012). They aimed to explore the relationship between tracheostomy timing and mechanical ventilation duration, data on patient demographics, ventilation, and tracheostomy timing were collected and analyzed (Masoudifar et al., 2012).Key findings showed no significant correlation between ventilation duration, tracheostomy timing, or patient age (Masoudifar et al., 2012). The study concluded that there was no statistically significant association between mechanical ventilation duration and tracheostomy timing in ICU patients (Masoudifar et al., 2012).

Tobin & Santamaria (2008b) conducted a three-year systematic data collection on ICU patients discharged with tracheostomy, comparing it with previous data (Tobin & Santamaria, 2008b). They assessed outcomes like post-ICU stay duration, time to decannulation, and stays within the upper DRG limit, the analysis showed a decrease in ICU stay duration, higher rates of discharge below the DRG limit, and shorter time to decannulation (Tobin & Santamaria, 2008b). Multivariate analysis indicated an annual increase in decannulation likelihood, the findings suggest benefits of intensivist-led tracheostomy teams, potentially leading to cost savings for hospitals (Tobin & Santamaria, 2008b).

Freeman et al. (2005) examined tracheostomy practices using Project Impact, analyzing data from 43,916 individuals, of these, 2,473 (5.6%) underwent tracheostomy, typically after a median of 9.0 days on ventilation (Freeman et al., 2005). Tracheostomy patients had a higher survival rate (Freeman et al., 2005). Significant variations in tracheostomy frequency and timing were noted across patient, ICU, and hospital factors (Freeman et al., 2005). Tracheostomy timing strongly correlated with ICU and hospital stays, as well as mechanical ventilation duration (Freeman et al., 2005). Although tracheostomy patients were a minority, they occupied a substantial portion of hospital resources (Freeman et al., 2005). The study highlights the need for further research to determine the clinical impact of tracheostomy timing (Freeman et al., 2005).

In another study, researchers compared standard non-protocolized practices in critical care with protocolized weaning from mechanical ventilation using a before-and-after research design , the study involved assessing baseline outcomes (Phase I) and outcomes after implementing protocolized weaning (Phase II), including the length of mechanical ventilation, duration of intubation, and critical care stay, as well as complications such as re-intubations, tracheostomy, and death(Blackwood et al., 2006). Data were also collected in a second unit to track changes in practice over time and serve as a comparison ,the results in Phase II of the intervention unit showed longer outcomes than Phase I (all $p < 0.005$) (Blackwood et al., 2006).However, only the duration of intensive care stay remained significantly longer ($p = 0.002$) after adjusting for the entry APACHE II score and diagnostic category , there was a substantial increase in tracheostomies during Phase II ($p = 0.004$) (Blackwood et al., 2006). No statistically significant differences in outcomes or complications were observed between Phases in the reference unit. The study concluded that protocolized weaning was not associated with a higher risk of re-intubation or death in the critical care unit, and it did not shorten the time spent on mechanical ventilation (Blackwood et al., 2006).

They utilized computerized methods to search PubMed, EMBASE, and the Cochrane register of controlled trials (through July 2013) for relevant papers (Huang et al., 2014). In addition, we contacted manufacturers and professionals worldwide (Huang et al., 2014). The study focused on critically ill adult patients admitted to intensive care units (ICUs) and included randomized controlled trials (RCTs) comparing Early Tracheostomy (ET) with Late Tracheostomy (LT) or Prolonged Intubation (PI) performed within 10 days after initial laryngeal intubation (Huang et al., 2014). Two investigators assessed the articles, resolving any disagreements through consensus (Huang et al., 2014). The primary objective was to evaluate key differences in outcomes between PI and ET for critically ill patients undergoing long-term ventilation (Huang et al., 2014). The meta-analysis included data from 2,072 individuals across nine RCTs (Huang et al., 2014). Contrary to LT/PI, ET did not significantly reduce long-term mortality, short-term mortality, ICU stay, ventilator-associated pneumonia (VAP), or the duration of mechanical ventilation (Huang et al., 2014). So, compared to the LT/PI group, ET did not exhibit statistically significant differences in clinical outcomes for patients requiring extended mechanical ventilation (Huang et al., 2014). However, further well-designed and adequately powered RCTs are necessary to validate these findings (Huang et al., 2014).

From January 2011 to August 2016, this study observed patients in ICU or high dependency units requiring emergency intubation, with or without tracheostomy (Dochi et al., 2019). They were split into early tracheostomy ($\leq$10 days, $n = 88$) and late tracheostomy (>10 days, $n =$

132) (Dochi et al., 2019). In a key study, 198 patients needing ventilation for over 10 days were categorized similarly (Dochi et al., 2019). Early tracheostomy significantly correlated with early ventilation withdrawal (P = .001 for early and late tracheostomy; P = .021 for landmark) (Dochi et al., 2019). Multivariable analysis showed a higher likelihood of ventilation withdrawal in the early tracheostomy group (aHR = 1.69, 95% CI = 1.20–2.39, P = .003; landmark: aHR = 1.61, 95% CI = 1.06–2.38, P = .027) (Dochi et al., 2019). However, early tracheostomy did not improve 60-day mortality (aHR = 1.46; 95% CI = 0.58–3.66; P = .42 for landmark; aHR = 0.88, 95% CI = 0.46–1.69, P = .71 for early and late tracheostomy) (Dochi et al., 2019). In conclusion, timing of tracheostomy wasn't linked to 60-day mortality, but completing it within 10 days was related to shorter mechanical ventilation. Patients receiving late tracheostomy may experience longer time-to-event (Dochi et al., 2019). Future research should develop criteria to predict prolonged ventilation need at admission for safe prospective trials of early tracheostomy (Dochi et al., 2019).

2.3 Summary

The study underscores the prevalent use of tracheostomy in adult ICUs and the absence of definitive guidelines for its timing. It suggests that early tracheostomy in critically ill patients needing mechanical ventilation might lower mortality rates compared to delayed procedures.

Tracheostomy is considered advantageous over prolonged trans laryngeal endotracheal intubation, with anticipated benefits such as improved patient comfort, reduced need for sedative medications, expedited weaning from mechanical ventilation, a lower risk of nosocomial pneumonia, and shorter hospital stays. The research posits that if tracheostomy is conducted early in the course of a patient's illness, these positive outcomes could be maximized.

The passage raises questions about the engagement of nurses with available literature and their translation of knowledge into practical applications. It emphasizes the significant role of the timing of tracheostomy in managing patients' airways. The mention of open variations in practice regarding the timing of this treatment underscores the need for standardized approaches.

Moreover, the text points out a gap in recent literature specifically in Palestine , highlighted the lack of studies that explore the relationship between the advantages and risks of prolonged ventilation, patient compliance, hospital stays, and mortality rates. The call for understanding compliance and factors influencing early tracheostomy before 14 days suggests a need for comprehensive research and a strategic plan to address these aspects in the clinical and educational settings in Palestine.

Chapter Three

Methodology

3.1 Introduction

This section delineates the research methodology employed in this study, encompassing details on the study environment, research framework, participant selection procedures, eligibility criteria, data analysis methods, and data collection instruments. Additionally, it addresses the ethical aspects considered during the research process.

3.2 Study design

A quantitative research design was employed to examine the study hypothesis and address the research queries. This approach focuses on numerical data, emphasizing measurable relationships rather than subjective opinions or traits. It is recognized for its precision and reliability, involving the study and analysis of numerical data to draw meaningful conclusions that can be further utilized.

The research adopted a retrospective cohort study design, utilizing data extracted from the hospital's intensive care unit database registration. This design choice was motivated by the necessity to track patients over an extended duration, aiming to save time, effort, and costs. Additionally, it was implemented to enhance result accuracy and diminish the potential for bias in the study

3.3 Study setting and framework

The research encompassed the governorates in the West Bank, specifically targeting individuals who underwent Tracheostomy on Mechanical Ventilation at Beit-Jala Governmental Hospital, Arab Society for Rehabilitation Hospital, Alia Governmental Hospital and Al-Ahli Hospital Collaboration was established with the directors of these hospitals' ICU departments for the study's implementation.

Regarding the characteristics of the West Bank, it is the term Jordan assigned to the remaining portion of Palestine, not incorporated after the Nakba. Jordan annexed this region following the Battle of Jerusalem at the Jericho Conference in 1951. Covering around 21% of the historical Palestine area, it spans approximately 5860 km², including the Nablus Mountains, Jerusalem Mountains (encompassing the eastern part of Jerusalem), Hebron Mountains, and the western Jordan Valley. The designation "West Bank" originates from its location west of the Jordan River, distinguishing it from the predominantly eastward territory of the Hashemite Kingdom of Jordan (Marfeh, 2021).

Bethlehem governorate:

Situated in the southern region of the West Bank, it boasts a population of approximately 229,884 residents, spans an area of 575 square kilometers, and comprises five principal cities, seventy villages, and three Palestinian refugee camps (PCBS, 2020).

Hebron governorate:

Situated in the southern part of the West Bank, it is adjacent to the Bethlehem Governorate in the north and is surrounded by the Green Line and the Dead Sea on the remaining sides. It holds the distinction of being the largest among the West Bank governorates both in terms of area and population. Covering an expanse of 1,060 square kilometers, it constitutes 16% of the West Bank's land, and as of 2020, it accommodates a population of 762,541 (PCBS, 2020)

3.4 Study population and sampling method

The sample size is 60 patients this was determined by considering the overall count of patients admitted to the ICU departments and intubated for a period exceeding 14 days across the study locations (Beit-Jala Governmental Hospital, Alia Governmental Hospital, and Arab Society for Rehabilitation Hospital), as well as the total count of patients undergoing tracheostomy.

Study Sample:

The sample size **60** patients

Inclusion criteria for this convenience sample include individuals who were admitted to the ICU department of Beit-Jala Governmental Hospital, Arab Society for Rehabilitation Hospital, and Alia Governmental Hospital between January 2021 and December 2022

3.5 Inclusion and exclusion criteria

Inclusion:

Patients will be chosen through age-stratified random sampling if they meet the following criteria:

- Have been on mechanical ventilation for over 14 days
- Are aged 18 years or older

Exclusion:

Excluded from the study will be patients with recurring ICU admissions within the same hospital episode, those who underwent tracheostomy either before the current ICU admission or beyond 29 days after ICU admission, and individuals for whom tracheostomy dates are not available.

3.6 Data collection

Following approval from the university, permissions were sought from the Ministry of Health and the directors of Beit-Jala Governmental Hospital, Alia Governmental Hospital, and Arab Society for Rehabilitation Hospital. These permissions were necessary to conduct the study within the intensive care units (ICU) of these hospitals.

3.7 Study instrument

The study will utilize the Japanese Intensive Care Patient Database (JIPAD), a comprehensive repository of deidentified data from intensive care unit (ICU) patients. Launched in 2014 by the ICU Assessment Committee under the Japanese Society of Intensive Care Medicine

(JSICM), JIPAD aims to facilitate standardized institutional comparability of ICU patients in Japan, contributing to the enhancement of patient care quality and the advancement of ICU medicine. The database encompasses demographic information, disease condition and severity, ICU admission and discharge details, chronic heart failure, chronic respiratory failure, and more. The Acute Physiology and Chronic Health Evaluation (APACHE II) score will be employed to gauge illness severity, considering physiologic measurements, age, and prior health conditions. Ranging from 0 to 71 points, the APACHE II score can be calculated within the initial 24 hours of ICU admission. Additional information can be found in Appendices (4) and (5) related to APACHE II.

1) sociodemographic characteristic.

2) Clinical characteristic.

3) APACHE II score.

4) Quartile of the timing of tracheostomy.

5) Data within 24 h after ICU admission (lowest Pao2: Fio2, Glasgow coma scale, Length of hospital stay before ICU admission days)

6) Processes of treatment during ICU stay (CRRT, ECMO)

7) Clinical Outcomes (ICU and Hospital mortality)

3.8 Validity of the study:

Eight experts, comprising epidemiologists, researchers, statisticians, and field experts (see Appendix 4), assessed the study instrument. Their task involved conducting content validity to assess the effectiveness of the items in each section in measuring the intended parameters and enhancing the instrument's relevance. All feedback and recommendations for modifying the instrument were documented and considered.

3.9 Data analysis:

SPSS version 28 will be employed for data analysis. Continuous data will be presented using medians and interquartile ranges (IQRs), while categorical data will be expressed as numbers and percentages. The timing of tracheostomy, measured from ICU admission, will be categorized into quartiles: Q1 (≤ 6 days), Q2 (7–14 days), Q3 (15–22 days), and Q4 (> 22 days). Differences in proportions will be assessed using the Chi-square test or Fisher's exact test. Univariable and multivariate logistic regression models was developed to explore the relationships between the quartiles of tracheostomy timing and the study outcome (ICU patient mortality). Crude and adjusted odds ratios (ORs) along with their 95% confidence intervals (CIs) will be calculated.

3.10 Ethical considerations:

The study underwent review and discussion by the Arab American University-School of Critical Care Research Committee, leading to its approval. Ethical approval was subsequently secured from the Arab American University Ethical Research Committee (REC).

Chapter Four

The Results

4.1 Introduction

This chapter deals with the data collected for analysis. The statistical method allowed the investigator to deduce, analyze, coordinate, measure, evaluate and convey the numerical information. The aim of data analysis is to provide answers to the questions of the study. The data analysis strategy comes directly from the question, the design and the data collection process and the level of measurement of the data. This chapter edits, tabulates, analyzes and interprets the collected data.

This chapter expresses the findings concerning to assess between early tracheostomy and patient's outcome in critically ill patients on mechanical ventilation.

Statistical analyses were directed to explore six research questions:

1. Is there significant difference between timing of tracheotomy and demographic characteristics?

2. Is there significant difference between timing of tracheotomy and ICU treatment?

3. Is there significant difference between timing of tracheotomy and duration of length on mechanical ventilation?

4. Is there significant difference between timing of tracheotomy and duration of length stay ?

5. Is there significant difference between timing of tracheotomy and clinical outcomes?

4.2 participants Characteristics

Among 60 patients who underwent tracheostomy and required mechanical ventilation were advanced for eligibility. All of the 60 patients were included in the analysis.

Table (1) shows the patients characteristics as the mean age was 56.36±15.44 ranged between (23-86) years old. (73.3%) of them were males while only (26.7%) of them were females. Also, the study sample was obese represented by (66.7%).

Figure (3) shows the distribution of the participants according to the comorbidity as (18.30%) of the participant have malignancy diseases, (15%) of them have chronic respiratory failure disease. Also, (8.30%) represented in both immunodeficiency diseases and chronic heart failure.

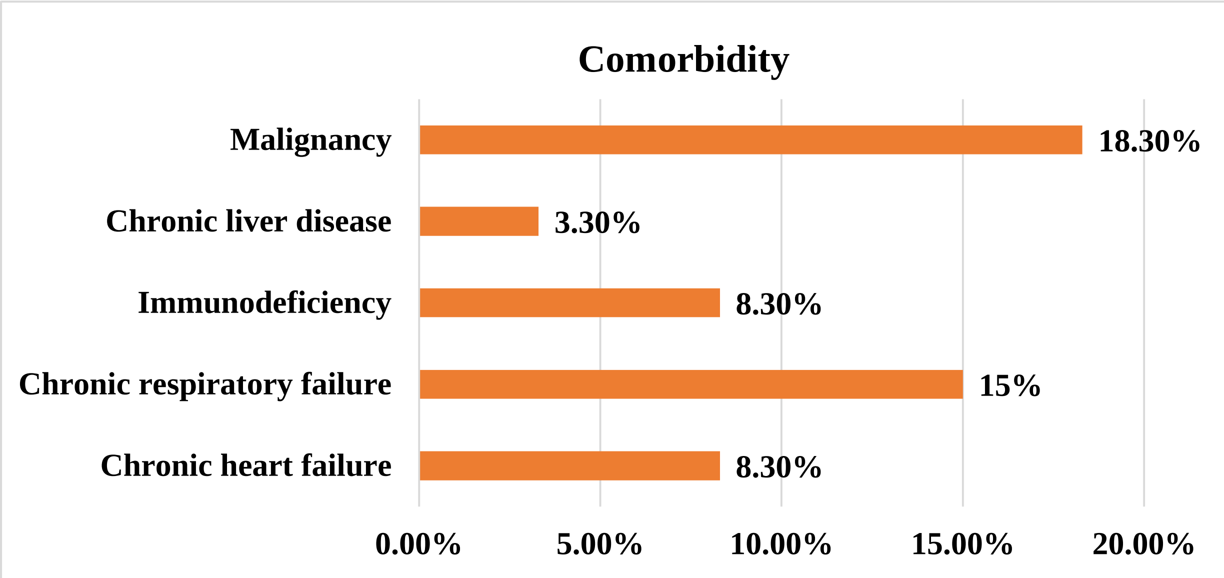

Figure 3: Distribution of the participants according to the comorbidity.

The majority of participants admitted as an emergency while 16.60% admitted as a surgical type as shown in Figure (4).

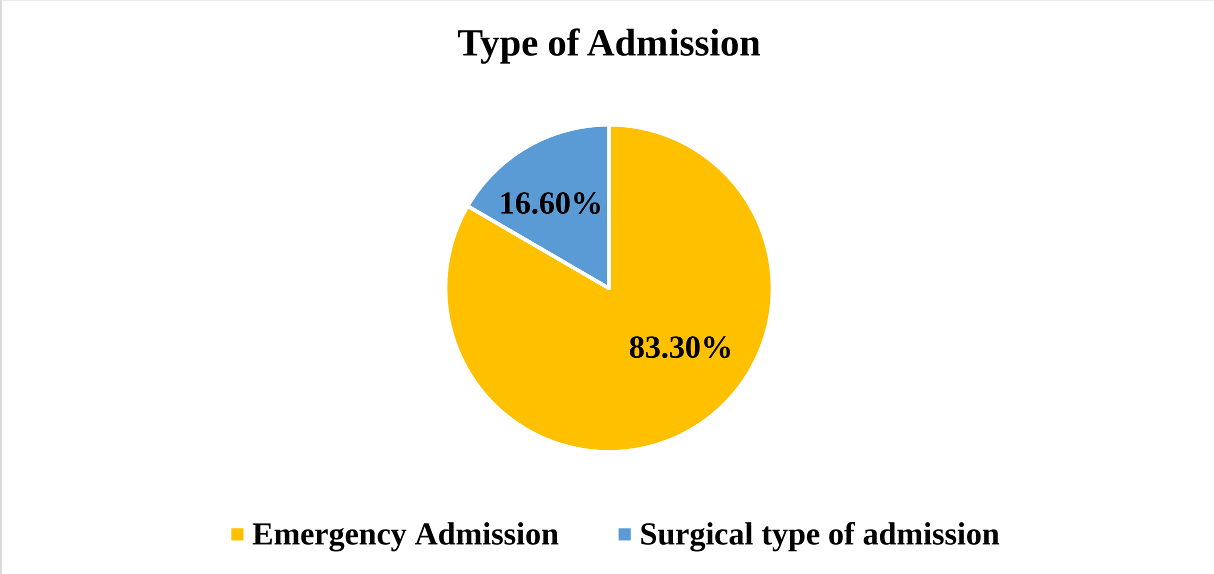

Figure 4: Distribution of the participants according to the type of admission

figure (5) showed the timing of tracheostomy which was categorized into four groups and represented as the followings:

The first group who had a tracheostomy through (≤6 days) and represented by (28.30%), the second group represented by (26.70%) who had a tracheostomy during (7-14) days. While the third group and fourth group had a tracheostomy during (15-22), (> 22) days represented by (23.30%, 21.70%) respectively.

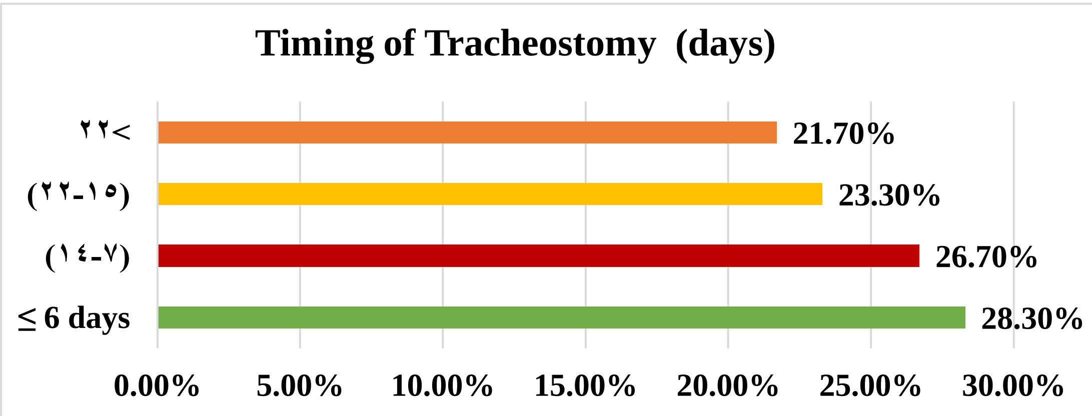

Figure 5: Distribution of the participants according to the timing groups of tracheostomy replacement in days.

The average of APACHE score was 30 ranged between (11.00- 50.00) as the increasing score of APACHE score is associated with an increasing risk of hospital death.

Moreover, the data which collected for the first 24 hours after ICU admission confirmed that the half of the participants had an incidence of acute kidney injury with 119.53 lowest mean score for the PaO2:FiO2 and the Glasgow coma scale score ranged between (3-15)) with 7.50 mean and 2.49 standard deviation. Also, the average length of hospital stay before ICU admission was 2.62 days with 4.88 standard deviation. With regard to the systematic diagnosis for ICU admission, more than the half of the participants (55%) diagnosed with respiratory system, (31.70%) with neurological system, (25%) of them diagnosed with sepsis. Also, (20%) of them diagnosed with trauma and (8.30%) diagnosed with gastrointestinal system as shown in figure (6)

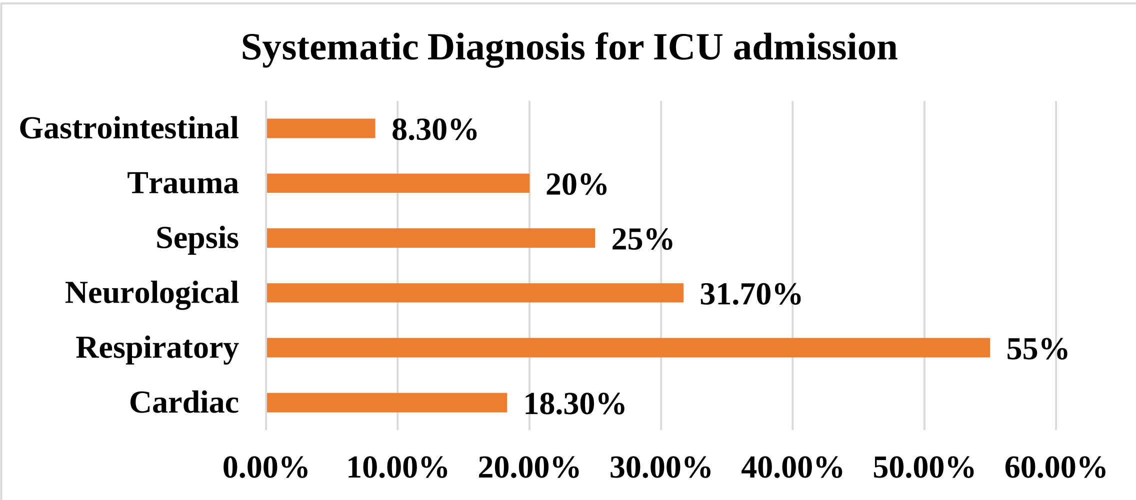

Figure 6: Distribution of the participants according to the systematic diagnosis for ICU admission

Table 1: Patient Characteristics (N=60)

Variables	Categories	Frequency (N)	Percentage (%)
Age	Mean ± SD (Min-Max)	56.36±15.44 (23-86)	
Gender	Male	44	73.3
	Female	16	26.7
Body Mass Index	Underweight (<18.5)	1	1.7
	Normal (18.5-24.9)	4	6.7
	Overweight (25.0-29.9)	15	25.0
	Obese (≥30)	40	66.7
Comorbidity	Chronic heart failure	5	8.3
	Chronic respiratory failure	9	15.0
	Immunodeficiency	5	8.3
	Chronic liver disease	2	3.3
	Malignancy	11	18.3
Emergency Admission	Yes (%)	50	83.3
Surgical Admission	Yes (%)	10	16.6
Timing of tracheostomy replacement (days)	≤ 6 days	17	28.3
	(7-14) days	16	26.7
	(15-22) days	14	23.3
	>22 days	13	21.7
Systematic diagnosis for ICU admission	Cardiac	11	18.3
	Respiratory	33	55.0
	Neurological	19	31.7
	Sepsis	15	25.0
	Trauma	12	20.0
	Gastrointestinal	5	8.3
APACHE* II score	Mean ±SD (Min-Max)	30.02±6.60	(11.00-50)
Data within 24 h after ICU admission			
Incidence of Acute Kidney Injury Yes (%)		30	50.0
		Mean ±SD	(Min- Max)
Lowest PaO2:FiO2**		119.53 ± 43.30	(45.00-240.00)
Glasgow Coma Scale (GCS)		7.50 ± 2.49	(3.00-15.00)
Length of hospital stay before ICU admission, days		2.62±4.88	(0.00-30.00)

*APACHE: Acute Physiology and Chronic Health Evaluation, ICU: Intensive care unit

** $PaO_2:FiO_2$: Arterial partial pressure of O_2 and the fraction of inspired oxygen

Processes of treatment during ICU stay and length of hospital stay characteristics

Table (2) shows the processes of treatment during ICU stay and length of hospital stay characteristics as (18.30%) of the participants received CRRT treatment and (15%) received an ECMO treatment as shown in figure (5). (86.7%) of the participants weaned from mechanical ventilation during ICU stay as shown in figure (6).

Table 2: Processes of treatment during ICU stay and length of hospital stay characteristics (N=60)

Variables	Frequency (N)	Percentage (%)
Extracorporeal membrane oxygenation (ECMO)	9	15.0%
Continuous renal replacement therapy (CRRT)	11	18.3%
Duration of mechanical ventilation before tracheostomy, days (Mean ± SD)	14.03 ± 8.01	
Duration of mechanical ventilation in ICU, days (Mean ± SD)	31.10 ± 18.89	
Weaning from mechanical ventilation during ICU stay		
Yes	52	86.7%
No	8	13.3%
Length of ICU stay, days (Mean ± SD)	31.13 ± 18.51	
Length of hospital stay, days (Mean ± SD)	41.38 ± 24.01	

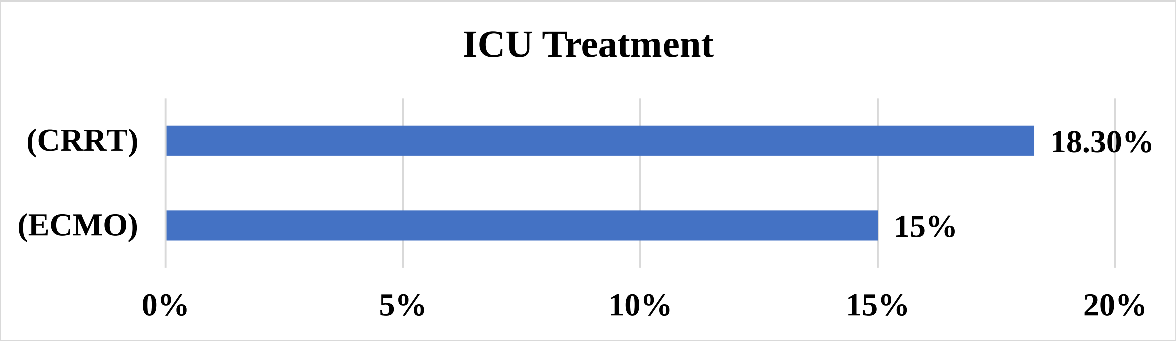

Figure 7: The distribution of participants according to the ICU treatment

Variables	Frequency (N)	Percentage (%)
ICU Mortality	31	51.7 %
Hospital Mortality	7	11.7%

Table 3: Clinical Outcomes characteristics (N=60)

The average duration of mechanical ventilation before tracheostomy was 14 days while 31 days on mechanical ventilation in ICU. Also, the length of ICU stay scored with mean (31.13 days) and 18.51 standard deviation while 41.39 days Was the average length of the days in the hospital.

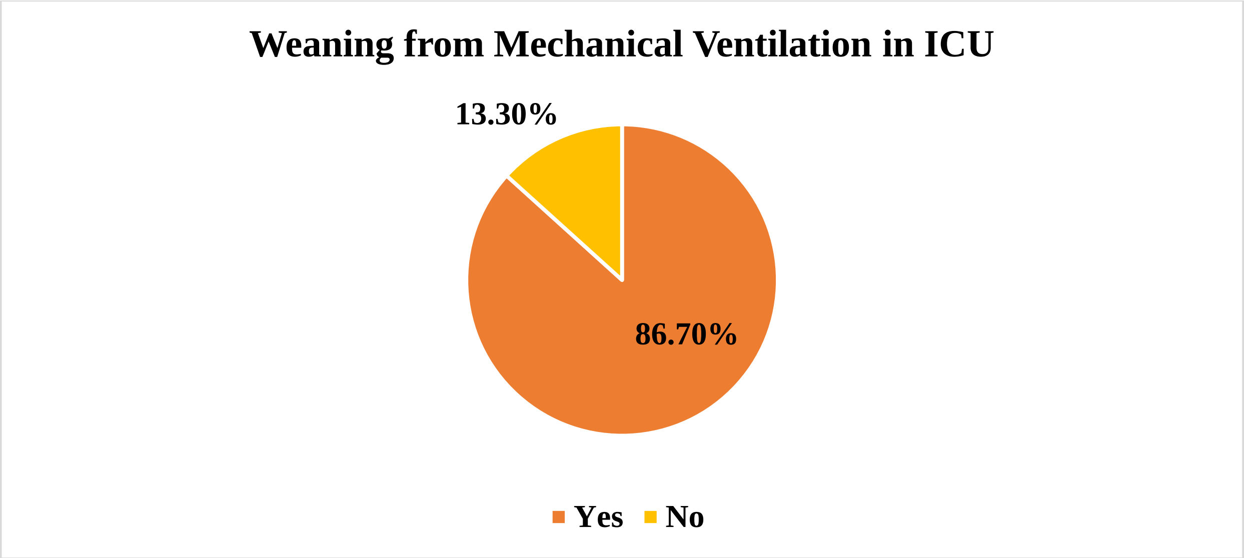

Figure 8: The distribution of participants according to weaning from mechanical ventilation in ICU

Clinical Outcomes characteristics

For the clinical outcomes, (51.7%) of the patients died in ICU while (11.7%) of them died after the transferring to another department of the hospital as shown in table (3) and figure (9).

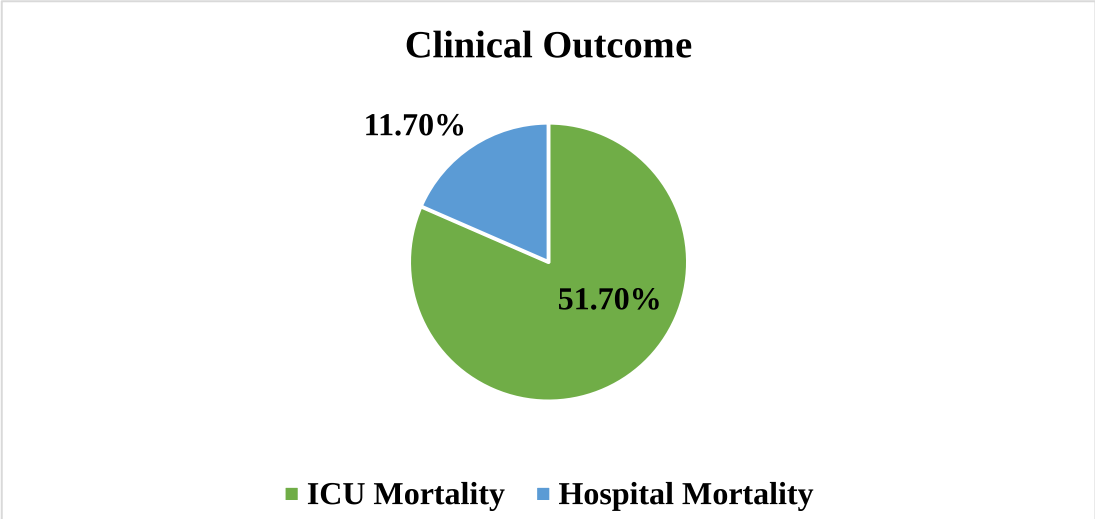

Figure 9: Clinical outcome distribution according to the ICU and Hospital Mortality

4.3 Testing research questions

Inferential Analysis

Patient characteristics by quartile of the timing of tracheostomy

Table (4) shows the characteristics of the study population divided by the quartiles of the timing of tracheostomy are presented in Table1 as the following Q1 Tracheostomy ≤ 6 days, (n=17), Q2 Tracheostomy 7–14 days (n = 16) , Q3 Tracheostomy 15–22 days (n = 14), Q4 Tracheostomy > 22 days (n = 13).

25% of the participants who were aged between (42-52) years categorized within the first group as half of them 6(50%) categorized within the second group. Also, 9 (52.9%) of the participants who aged more than 63 years categorized within the third group and 7 (35%) of the participants who aged between (53-63) years categorized within the fourth group.

There is a statistically significant difference between the age and timing of tracheostomy (P.value= 0.005 < 0.05) which indicates that the older the age group, the longer it takes for timing on the tracheostomy. Post hoc test was used to identify the source of difference which had between the Q3 and Q4 as shown in (4.1).

Regarding the gender, the proportions of patients who were males needed a tracheostomy more than females as the highest proportion of males 15 (34.1%) categorized within the first group. On the other hand, the highest proportions of females categorized within the third and fourth groups. Also, there is a statistically significant difference between the gender and timing of tracheostomy (P.value =0.04 <0.05). As the males categorized within the early timing groups of tracheostomy and females categorized with the late timing group.

Based on the body mass index, the highest proportion of participants were as high as 14 (35%) of them categorized within the third group. 12 (24%) of the participant who admitted emergency categorized within the second and fourth groups and 4 (36.4%) who admitted surgically categorized within the second group.

Also, there is no statistically significant difference between each group according to the (systematic diagnosis for ICU admission, APACHE score, the data within first 24 hours of ICU admission, nor the length of hospital stay before ICU admission) (P.value >0.05).

Table 4: Patient characteristics by quartile of the timing of tracheostomy

Variables	Q1 Tracheostomy ≤ 6 days (*n*=*17*)	Q2 Tracheostomy 7–14 days (*n* = 16)	Q3 Tracheostomy 15–22 days (*n* = 14)	Q4 Tracheostomy > 22 days (*n* = 13)	P. Value	Test Used
Age						
Mean ± SD (Min-Max)	55.88±14.58 (25-85)	47.31±15.09 (23-86)	66.92±10.90 (48-83)	56.76±15.35 (28-81)	0.005*	One Way-Anova
Gender						
Male	15 (34.1%)	14(31.8%)	8 (18.2%)	7 (15.9%)	0.04*	Chi-square
Female	2 (12.5%)	2 (12.5%)	6 (37.5%)	6 (37.5%)		
Body Mass Index						
Underweight (<18.5)	1 (100.0%)	-	-	-	0.09	Chi-square
Normal (18.5-24.9)	-	2 (50.0%)	-	2 (50.0%)		
Overweight (25.0-29.9)	5 (33.3%)	6 (40.0%)	-	4 (26.7%)		
Obese (≥30)	11 (27.5%)	8 (20.0%)	14 (35.0%)	7 (17.5%)		
Comorbidity						
Chronic heart failure	2 (40.0%)	2 (40.0%)	1 (20.0%)	-	0.60	Chi-square
Chronic respiratory failure	3(33.3%)	3 (33.3%)	3(33.3%)	-	0.38	Chi-square
Immunodeficiency	2 (40.0%)	1 (20.0%)	1(20.0%)	1(20.0%)	0.94	Chi-square

Chronic liver disease	1(50.0%)	1(50.0%)	-	-	0.21	Chi-square
Malignancy	3(27.3%)	3 (27.3%)	3 (27.3%)	2 (18.2%)	0.98	Chi-square
Emergency Admission	15 (30.0%)	12(24.0%)	11(22.0%)	12 (24.0%)	0.55	Chi-square
Surgical type of admission	2 (20.0%)	4 (40.0%)	3 (30.0%)	1 (10.01%)	0.77	Chi-square
Systematic diagnosis for ICU admission						
Cardiac	3 (27.3%)	3 (27.3%)	2 (18.2%)	3 (27.3%)	0.49	Chi-square
Respiratory	5 (15.2%)	10 (30.3%)	8 (24.2%)	10 (30.3%)	0.06	Chi-square
Neurological	8 (42.1%)	3 (15.8%)	5 (26.3%)	3 (15.8%)	0.30	Chi-square
Sepsis	2 (13.3%)	3 (20.0%)	7 (46.7%)	3 (20.0%)	0.08	Chi-square
Trauma	3 (25.0%)	2(16.7%)	2 (16.7%)	5 (41.7%)	0.29	Chi-square
Gastrointestinal	4 (80.0%)	-	1(20.0%)	-	0.06	Chi-square
APACHE II score						
Mean (Min-Max)	29.11 (12.00-42.00)	28.81 (11.00-35.00)	31.07 (21.00-50.00)	31.53 (22.00-38.00)	0.60	One-Way Anova
Data within 24 h after ICU admission						
Incidence of Acute Kidney Injury						
Yes	8 (26.7%)	7 (23.3%)	7 (23.3%)	8 (26.7%	0.32	Chi-square
No	9 (30.0%)	9 (30.0%)	7 (23.3%)	5 (16.7%)		

Lowest PaO2:FiO2						
Mean (Min-Max)	125.93 (45.00-240.00)	105.62 (50.00-166.67)	118.12 (60.00 - 200.00)	129.80 (60.00-200.00)	0.43	One-Way Anova
Glasgow Coma Score (GCS) score						
Mean (Min- Max)	7.41 (3.00-12.00)	7.43(3.00-12.00)	6.92(3.00-9.00)	8.30(5.00-12.00)	0.55	One-Way Anova
Length of hospital stay before ICU admission, days Mean (Min-Max)	1.88 (0.00-20.00)	1.87 (0.00-5.00)	5.50 (.00-30.00)	1.38 (0.00-5.00)	0.08	One-Way Anova

Table 4. Post Hoc for Age according to the timing groups

Multiple Comparisons
Dependent Variable: age of participant
Tukey HSD

(I) timing groups	(J) timing groups	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
≤ 6 days	(7-14)	8.56985	4.92514	.313	-4.4714	21.6111
	(15-22)	-11.04622	5.10315	.146	-24.5588	2.4663
	>22	-.88688	5.20967	.998	-14.6815	12.9077
(7-14)	≤ 6 days	-8.56985	4.92514	.313	-21.6111	4.4714
	(15-22)	-19.61607*	5.17467	.002	-33.3180	-5.9141
	>22	-9.45673	5.27975	.288	-23.4369	4.5234
(15-22)	≤ 6 days	11.04622	5.10315	.146	-2.4663	24.5588
	(7-14)	19.61607*	5.17467	.002	5.9141	33.3180
	>22	10.15934	5.44618	.255	-4.2615	24.5802
>22	≤ 6 days	.88688	5.20967	.998	-12.9077	14.6815
	(7-14)	9.45673	5.27975	.288	-4.5234	23.4369
	(15-22)	-10.15934	5.44618	.255	-24.5802	4.2615

*. The mean difference is significant at the 0.05 level.

Processes of treatment during ICU stay and length of hospital stay

Table (5) shows the process of treatment during ICU stay and length of hospital stay as the results indicated that, the proportions of patients who received extracorporeal membrane oxygenation (ECMO) was higher in the Q3 group represented by 4 (28.6%) during ICU admission and continuous renal replacement therapy (CRRT) was higher in the Q4 group 7 (53.8%) than in the other groups (P.value=0.19, 0.001, respectively).

There is no statistically significant difference between the tracheostomy timing groups according to the duration of mechanical ventilation before tracheostomy and weaning process (P.value >0.05). On the other hand, the duration on mechanical ventilation in ICU was significantly longer in the Q4 group than in other quartile groups (57.53 [IQR, 28–90] days (P.value=0.001).

Moreover, the length of ICU and Hospital stays were the longest in the Q4 group (55.15 [IQR, 7–90] days, (63.07 [IQR, 10–120] (P.value=0.001, 0.001 <0.05) respectively). Post hoc test (Tukey test) used to determine the source of difference between each group as shown in table (6).

Table 5: Processes of treatment during ICU stay and length of hospital stay

Variables	Q1 Tracheostomy ≤ 6 days (n=17)	Q2 Tracheostomy 7–14 days ($n = 16$)	Q3 Tracheostomy 15–22 days ($n = 14$)	Q4 Tracheostomy > 22 days ($n = 13$)	P. Value	Test Used
Extracorporeal membrane oxygenation (ECMO)	1 (5.9%)	1 (6.3%)	4 (28.6%)	3 (23.1%)	0.19	Chi-Square
Continuous renal replaceme	-	1 (6.3%)	3 (21.4%)	7 (53.8%)	0.001*	Chi-Square

nt therapy (CRRT)						
Duration of mechanical ventilation before tracheostomy, days	13.94 (1.00-30.00)	13.68 (1.00-30.00)	14.35 (10.00-38.00)	14.23 (3.00-25.00)	0.99	One-Way Anova
Duration of mechanical ventilation in ICU, days	17.52 (2-32)	22.87 (10-40)	32.42 (30-60)	57.53 (28-90)	0.001*	One-Way Anova
Weaning from mechanical ventilation during ICU stay	14 (82.4%)	14 (87.5%)	14 (100.0%)	10 (76.9%)	0.32	Chi-Square
Length of ICU stay, days	18.41 (3-32)	23.75 (10-40)	32.71 (30-60)	55.15 (7-90)	0.001*	One-Way Anova
Length of hospital stay, days	30.41 (5-90)	33.18 (10-60)	43.92 (30-60)	63.07 (10-120)	0.001*	One-Way Anova

Table 6: Post Hoc test *Tukey test

Multiple Comparisons							
Tukey HSD							
Dependent Variable	(I) timing groups	(J) timing groups	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
						Lower Bound	Upper Bound
Duration of mechanical ventilation in ICU	≤ 6 days	(7-14)	-5.34559	4.08877	.562	-16.1722	5.4810
		(15-22)	-14.89916*	4.23655	.005	-26.1171	-3.6812
		>22	-40.00905*	4.32499	.000	-51.4611	-28.5570
	(7-14)	≤ 6 days	5.34559	4.08877	.562	-5.4810	16.1722
		(15-22)	-9.55357	4.29593	.129	-20.9287	1.8216
		>22	-34.66346*	4.38316	.000	-46.2696	-23.0573
	(15-22)	≤ 6 days	14.89916*	4.23655	.005	3.6812	26.1171
		(7-14)	9.55357	4.29593	.129	-1.8216	20.9287
		>22	-25.10989*	4.52133	.000	-37.0819	-13.1379
	>22	≤ 6 days	40.00905*	4.32499	.000	28.5570	51.4611
		(7-14)	34.66346*	4.38316	.000	23.0573	46.2696
		(15-22)	25.10989*	4.52133	.000	13.1379	37.0819
Length of hospital stays	≤ 6 days	(7-14)	-2.77574	7.31379	.981	-22.1418	16.5904
		(15-22)	-13.51681	7.57814	.292	-33.5829	6.5492
		>22	-32.66516*	7.73632	.001	-53.1501	-12.1802
	(7-14)	≤ 6 days	2.77574	7.31379	.981	-16.5904	22.1418
		(15-22)	-10.74107	7.68434	.506	-31.0883	9.6062
		>22	-29.88942*	7.84039	.002	-50.6499	-9.1290
	(15-22)	≤ 6 days	13.51681	7.57814	.292	-6.5492	33.5829
		(7-14)	10.74107	7.68434	.506	-9.6062	31.0883
		>22	-19.14835	8.0875	.095	-40.5632	2.2665

				4			
	>22	≤ 6 days	32.66516*	7.73632	.001	12.1802	53.1501
		(7-14)	29.88942*	7.84039	.002	9.1290	50.6499
		(15-22)	19.14835	8.08754	.095	-2.2665	40.5632
Length of ICU	≤ 6 days	(7-14)	-5.33824	4.42738	.626	-17.0614	6.3850
		(15-22)	-14.30252*	4.58740	.015	-26.4494	-2.1556
		>22	-36.74208*	4.68316	.000	-49.1426	-24.3416
	(7-14)	≤ 6 days	5.33824	4.42738	.626	-6.3850	17.0614
		(15-22)	-8.96429	4.65169	.229	-21.2814	3.3529
		>22	-31.40385*	4.74615	.000	-43.9711	-18.8366
	(15-22)	≤ 6 days	14.30252*	4.58740	.015	2.1556	26.4494
		(7-14)	8.96429	4.65169	.229	-3.3529	21.2814
		>22	-22.43956*	4.89576	.000	-35.4030	-9.4761
	>22	≤ 6 days	36.74208*	4.68316	.000	24.3416	49.1426
		(7-14)	31.40385*	4.74615	.000	18.8366	43.9711
		(15-22)	22.43956*	4.89576	.000	9.4761	35.4030
*. The mean difference is significant at the 0.05 level.							

Clinical Outcomes

Hospital mortality, as the primary outcome, progressively increased with increasing quartiles of the timing of tracheostomy (Q1, 5.9%; Q2, 12.5%; Q3, 28.6%; Q4, 30.77%, (P.value= 0.001) The risk of hospital mortality was significantly higher in the Q4 group than in the Q1 group (adjusted OR: 3.04, 95% CI: 0.22–40.82). ICU mortality, as the secondary outcome, similarly showed a gradual increase as the quartile of the timing of tracheostomy increased (P. Value >0.05).The Q4 group also had a higher risk for ICU mortality than did the Q1 group (OR: 4.12, 95% CI: 0.88–19.27) as shown in table (7).

Table 7: Patient outcomes by quartile of the timing of tracheostomy

Variables	Q1 Tracheostomy ≤ 6 days (n=17)	Q2 Tracheostomy 7–14 days (n = 16)	Q3 Tracheostomy 15–22 days (n = 14)	Q4 Tracheostomy > 2 2 days (n = 13)	P. Value
ICU Mortality					
N (%)	1 (5.9%)	1 (6.3%)	4 (28.6%)	3 (23.1%)	
Crude OR (95%)	1 (reference)	1.68(0.34-8.22)	2.25 (0.48-10.41)	4.12 (0.88- 19.27)	0.19
Adjusted OR (95%)	1 (reference)	1.67 (0.33-8.34)	1.80 (0.36-8.82)	3.31 (0.67-16.31)	0.50
Hospital Mortality					
N (%)	1(5.9%)	2 (12.5%)	4 (28.6%)	4 (30.77%)	
Crude OR (95%)	1 (reference)	1.09 (0.13-9.12)	1.27(0.15-10.53)	2.90 (0.23- 36.16)	0.001
Adjusted OR (95%)	1 (reference)	1.09 (0.13-9.17)	1.330 (0.14-11.99)	3.04 (0.22-40.82)	0.001

- *Adjusted OR for gender
- *OR*: odds ratio, *CI*: confidence interval, *ICU*: intensive care unit

Chapter Five

Discussion, Recommendations and Conclusion

5.1 Introduction

This chapter encapsulates the central findings, drawing comparisons with existing studies. The results are interpreted and discussed, while addressing the limitations encountered during the study. The concluding section encapsulates the study's final remarks, including conclusions and recommendations.

5.2 Discussion

5.2.1 determine the relationship between timing of tracheostomy and demographic Characteristics (Age, Gender, Body mass index).

A statistically significant difference exists between age and the timing of tracheostomy (P-value = 0.005 < 0.05), indicating that older age groups experience a longer duration before tracheostomy. This finding aligns with a study demonstrating a 0.7% increase in the probability of mortality for each year of age and a 0.8% increase for each additional day in the hospital (Levy et al., 2022). Additionally, age is associated with higher comorbidities, increased complications, and elevated non-elderly mortality rates, resulting in a decreased chance of survival with advancing age. However, this contradicts another study that found no significant correlation between the timing and method combinations of tracheostomies and variations in all-cause mortality or post-discharge survival. Cox proportional hazard models identified a worse survival rate linked to Charlson Comorbidity Index (CCI) and unknown partner status (P = 0.05 and P < 0.01, respectively), while no independent correlation was observed between changes in survival and age, gender, race, CCI, and body mass index (Park et al., 2020). Furthermore, an additional study refutes the relationship between patients' ages and the timing of tracheostomy (P = 0.20, r = 0.129) (Masoudifar et al., 2012)

Concerning gender, a statistically significant difference in the timing of tracheostomy is observed (P-value = 0.04 < 0.05). The proportions of male patients requiring tracheostomy exceed those of females. This finding is consistent with a study indicating that men were more likely than women to undergo tracheostomy (20.1% vs. 15.3%; P = 0.004) and to necessitate prolonged mechanical ventilation among non-survivors in the ICU (6.3 vs. 5.4 days; P = 0.015) (Blecha et al., 2020). However, another study presents contrasting results, demonstrating that the timing of tracheostomy was similar in men and women (P = 0.5), and the duration of mechanical ventilation did not significantly differ between both genders (P = 0.89) (Masoudifar et al., 2012).

In terms of body mass index (BMI), the largest proportion of participants, comprising 35%, fell into the obese category, specifically within the third group. Among those admitted for emergency reasons, 24% were distributed across the second and fourth groups, while 36.4% of surgically admitted participants were in the second group. Given the prevalence of obesity in the sample and variations in sample characteristics, the study indicates that gender, BMI, APACHE II scores, and the type of tracheotomy did not exhibit significant differences between the groups that successfully weaned and those that failed to wean. However, in contrast, individuals unable to wean were notably older and carried a higher burden of comorbidities (Alhajhusain et al., 2014).

Conversely, a conflicting study found that BMI had a statistically significant impact on both operation time (P < 0.0001) and complication rate (P < 0.0001). BMI was significantly correlated with both intraoperative complications (P = 0.027) and early postoperative complications (P = 0.001). Moreover, patients with obesity, particularly those with a BMI of 35, experienced a significantly higher rate of tracheostomy-related complications, especially during the intraoperative and early postoperative periods. The procedure duration was notably longer in individuals with higher body mass (Cordes et al., 2014b)

Moreover, there is no statistically significant difference observed among the groups concerning systematic diagnosis for ICU admission, APACHE score, data within the first 24 hours of ICU admission, or the length of hospital stay before ICU admission (P-value > 0.05). The study also concurs that gender, BMI, APACHE II scores, and the type of tracheotomy did not exhibit significant differences between the groups that successfully weaned and those that failed to wean. However, in comparison to individuals successfully liberated from mechanical ventilation, those unable to wean were notably older and bore a greater burden of comorbidities (Alhajhusain et al., 2014).

5.2.2 Assess the relationship between timing of tracheostomy and ICU treatment .

Regarding the treatment regimen during ICU stay and the duration of hospitalization, the findings revealed that the Q3 group had a higher proportion of patients receiving extracorporeal membrane oxygenation (ECMO), accounting for 28.6% (4 patients) during ICU admission. Additionally, the Q4 group exhibited a higher percentage of patients receiving continuous renal replacement therapy (CRRT), with 53.8% (7 patients), compared to the other groups (P-value = 0.19 and 0.001, respectively)

No statistically significant difference exists between the timing of tracheostomy and ICU treatment for extracorporeal membrane oxygenation (ECMO) (P-value = 0.19). This finding aligns with a study that reported no statistically significant difference in the timing of tracheostomy when stratified by ECMO modality, specifically venoarterial (VA) and venovenous (VV) ECMO (51.51% after explant vs. 38.10% after explant, p = 0.33) (Jones et al., 2022).

Contrary to the findings of this study, Nukiwa et al. (2022) reported that the timing of tracheostomy in patients requiring extracorporeal membrane oxygenation (ECMO) was significantly associated with patient outcomes in a time-dependent manner.

A statistically significant difference exists between the timing of tracheostomy and ICU treatment for continuous renal replacement therapy (CRRT) (P-value = 0.001). This finding is consistent with a study by Tanaka (2022), which reported higher proportions of patients who received extracorporeal membrane oxygenation and continuous renal replacement therapy during ICU admission in the Q4 group (18.7% and 44.2%, respectively) compared to the other groups ($p < 0.001$ for both).

Contrary to this study, similar percentages of patients who underwent prolonged mechanical ventilation (PMV) without tracheostomy (23.3%, $p = 0.658$) were observed in those who had tracheostomy. Furthermore, no significant difference was found between the two groups in terms of the percentage of patients undergoing continuous renal replacement therapy (CRRT) and venarterial extracorporeal membrane oxygenation (VA-ECMO) (Tanaka et al., 2023).

5.2.3 Assess the relationship between timing of tracheostomy and duration of length on mechanical ventilation.

There is no statistically significant difference between the tracheostomy timing groups concerning the duration of mechanical ventilation before tracheostomy and the weaning process (P-value > 0.05). However, the duration of mechanical ventilation in the ICU was notably longer in the Q4 group than in the other quartile groups (57.53 [IQR, 28–90] days, P-value = 0.001). A study also reported no discernible relationship between the duration of artificial ventilation and the timing of tracheostomy (duration of endotracheal intubation to tracheostomy; $P = 0.43$, $r = 0.08$). In summary, the sample size utilized in this study was insufficient to identify any correlation between the length of mechanical ventilation and the timing of tracheostomy in ICU patients receiving mechanical ventilation and having adequate pulmonary function (Masoudifar et al., 2012).

In another study, it was found that weaning failure and ICU death rates were higher in patients who underwent tracheostomies more than three weeks after intubation. The length of ICU stay in the successful weaning group was positively correlated ($r = 0.70$; $P < 0.001$) with the duration of intubation (Hsu et al., 2004).

In other studies, it was observed that when adjusted for admission APACHE II score and diagnostic category, only the duration of intensive care stay remained significantly longer ($p = 0.002$) (Blackwood et al., 2006)

For studies with dissenting findings, pooling of estimates using the random-effects method (REM) revealed that, irrespective of the definition of early and late tracheostomy, all studies showed a standardized mean difference (SMD) of −1.06 (95% CI, CL = −1.3 to −0.82), which was statistically significant (p-value < 0.01). This favored early tracheostomy over late tracheostomy concerning the duration of mechanical ventilation in adults (Adly et al., 2017b)

5.2.4 Assess the relationship between timing of tracheostomy and duration of length stay.

The lengths of ICU and hospital stays were the longest in the Q4 group (55.15 [IQR, 7–90] days, 63.07 [IQR, 10–120] days) with a statistically significant difference (P-value = 0.001, 0.001 < 0.05). This aligns with findings over the research period, indicating differences between 2006 and 2003 were 34.5 [26 to 53] versus 42 [29 to 73] days ($P = 0.06$) and 19 [10 to 34] versus 30 [13 to 52] days ($P < 0.05$), respectively. Notably, the trend in hospital length of stay and hospital stay after ICU release was statistically significant ($P < 0.05$ for both), even though the distributions by year did not differ significantly (Tobin & Santamaria, 2008)

In agreement with another study, utilizing the random effects method (REM) to pool estimates revealed that all studies, regardless of the definitions of early and late tracheostomy, exhibited a standardized mean difference (SMD) of −0.82 (95% CI, CL = −1.06 to −0.58) concerning the length of stay at the ICU for adults. This difference was statistically significant (p-value <

0.01) and favored early tracheostomy over late tracheostomy (Adly et al., 2017b)

In contrast, dissenting studies demonstrated no significant findings, with no statistically significant result observed for the overall duration of the ICU stay (p = 0.879). Nevertheless, it was noted that this had no discernible effect on the total length of the ICU stay or the incidence of ventilator-associated pneumonia (VAP) (Khammas & Dawood, 2018).

5.2.5 Assess the relationship between timing of tracheostomy and clinical outcomes.

Hospital mortality, the primary outcome, exhibited a progressive increase with rising quartiles of the timing of tracheostomy (Q1, 5.9%; Q2, 12.5%; Q3, 28.6%; Q4, 30.77%, P-value = 0.001). The risk of hospital mortality was significantly higher in the Q4 group compared to the Q1 group (adjusted OR: 3.04, 95% CI: 0.22–40.82). This finding is consistent with other studies, such as one where hospital mortality, as the primary outcome, increased progressively with quartiles of tracheostomy timing (Q1, 17.7%; Q2, 25.4%; Q3, 29.7%; Q4, 32.4%, p for trend < 0.001). Hospital death rates also rose incrementally across quartiles in the adjusted multivariable analysis (adjusted OR for quartile increment: 1.30, 95% CI: 1.17–1.44, p for trend < 0.001). The Q4 group exhibited a substantially higher risk of hospital mortality than the Q1 group (adjusted OR: 2.26, 95% CI: 1.61–3.16) (Tanaka et al., 2022d).

In studies where the impact on hospital mortality was not found to be significant, comparable hospital mortality rates were observed across all arms of four studies (112 patients; 29 events) that recorded death at hospital discharge or within 60 days (RR 1.17, 95% CI, 0.46, 2.94; p = 0·18; I2 38%) (McCredie et al., 2016).

Regarding ICU mortality, considered as a secondary outcome, a gradual increase was similarly observed as the quartile of the timing of tracheostomy increased (P-value > 0.05). The Q4 group also exhibited a higher risk for ICU mortality compared to the Q1 group (OR: 4.12, 95% CI: 0.88–19.27). This finding aligns with a study that reported no significant difference in ICU mortality between the early tracheostomy (ET) group (9 patients, 18%) and the late tracheostomy (LT) group (7 patients, 14%) (P = 0.79) (Koch et al., 2012).

In contrast to a study, there is disagreement with the findings. The secondary outcome exhibited a gradual increase as the quartile of the tracheostomy time increased, with the adjusted odds ratio for quartile increment being 1.73 (95% CI: 1.45–2.07, p for trend < 0.001). Furthermore, in comparison to the Q1 group, the Q4 group had a higher risk of ICU death (OR: 4.57, 95% CI: 2.59–8.04). Similarly, the timing of tracheostomy was identified to significantly elevate ICU and hospital mortality in the limited cubic spline analysis (Tanaka et al., 2022d)

In a different study, it was demonstrated that an early tracheostomy was linked to a reduced ICU death rate (RR 0.46, 95% CI, 0.24, 0.89; p = 0·02; I2 21%), as evidenced by three studies involving 197 patients and 49 events, which evaluated mortality at ICU discharge or within 28 days (McCredie et al., 2016).

5.3 Discussion Summary

In this observational study conducted across multiple institutions, the impact of tracheostomy timing on patient outcomes was evaluated. The results revealed that patients undergoing delayed tracheostomy experienced prolonged stays in both the intensive care unit and the hospital. A time-dependent association was observed, indicating that an extended period of mechanical ventilation before tracheostomy was correlated with a higher mortality rate. This pattern persisted irrespective of the patient's diagnosis or level of consciousness at the time of ICU admission.

5.4 Study strengths and limitations

Our study exhibited various strengths, highlighted as follows:

1. The inaugural research endeavor of its kind in Palestine.

2. Incorporation of multiple variables to address potential confounding factors.

3. Adoption of a case-control study design.

4. Capability to gauge early tracheostomy, symptom severity, and study outcomes.

5. Utilization of a study tool known for its validity and reliability.

Limitation of the study

1. Insufficient financial backing.

2. Potential for recall bias in recalling specific symptom severity.

3. Likelihood of misclassification of cases and controls due to false negative or positive results.

4. Challenges associated with conducting matching.

5. Limited resources for addressing potential confounding variables.

6. Impediments posed by lockdown restrictions.

7. Some hospitals restricted access to complete patient information.

5.5 Conclusion

Based on our study, a noticeable and statistically significant association was identified between the timing of tracheostomy and mortality. This pattern was consistently observed across various illnesses and levels of consciousness at the time of ICU admission. Emphasizing patient outcomes, our findings underscore the importance of early tracheostomy in critically ill patients requiring mechanical ventilation

5.6 Recommendation

The study recommended

Researchers

- This study is unique in the northern, central, and southern regions of Palestine, given the scarcity of published studies on this subject. Therefore, it can serve as foundational data for future research.

- Future investigations should delve into more comprehensive research with an expanded sample size, encompassing additional risk factors, and evaluating the effects of confounders.

- A dearth of recent literature in Palestine highlights the need for studies elucidating the interplay between the benefits and risks of prolonged ventilation in critically ill patients, particularly in relation to hospital stay compliance and elevated mortality rates.

Ministry of Health & Nurses administrators

- Although there is considerable variation in the practice of timing this treatment, the initiation of Tracheostomy holds significance in managing the airways of these patients.
- It is strongly recommended to establish robust support and supervision, possibly through the creation of a collaborative community of practice. This community could implement reward and punishment strategies to ensure adherence to implementation standards.

- A consensus conference has recommended trans laryngeal intubation for patients requiring an artificial airway for up to 10 days, with tracheostomy performed after 21 days of intubation. However, the timing of tracheostomy remains a subject of ongoing debate.

- To comprehensively address this issue and formulate an effective strategic plan, clinical and educational institutions in Palestine would benefit from understanding the adherence to and factors influencing early tracheostomy use within the first 14 days.

- There is a need to promote reporting and surveillance systems, particularly within hospital infection administration departments, to gather more information on hospital infections. Immediate feedback from monitoring results can strengthen the education of medical workers and the dissemination of standard precautions.

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Appendices

Appendix 1: Approval letter from the Palestinian MOH

State of Palestine
Ministry of Health
ation in Health and Scientific Research Unit

دولة فلسطين
وزارة الصحة
وحدة التعليم الصحي والبحث العلمي

....
....

الرقـــم: ١٤٢/٨٤٠/٢٠٢٣
التــاريخ: ١٧/٤/٢٠٢٣

ق. أ. الوكيل المساعد لشؤون المستشفيات والطوارئ المحترم،،،
الأخ مدير عام الادارة العامة لتكنولوجيا المعلومات المحترم،،،
تحيــة واحتــرام،،،

<u>الموضــــوع: تسهيل مهمة بحث</u>

يرجى تسهيل مهمة الطالبة: **براءة توفيق ياسر عودة – ماجستير عناية مكثفة**- الجامعة العربية الامريكية، لعمل بحث بعنوان:

"Association between early tracheostomy and patient outcomes in critically ill patients on mechanical ventilation"

حيث ستقوم الطالبة بجمع معلومات من ملفات المرضى، (لذا يرجى الايعاز لمن يلزم من الادارة العامة لتكنولوجيا المعلومات بتسهيل المهمة بدون استخدام المعلومات الشخصية للمرضى)، وذلك **في:**

-مستشفى عاليه - مستشفى بيت جالا

على ان يتم الالتزام بالمحافظة على اخلاقيات البحث العلمي وسرية المعلومات. وعدم التعرض للمعلومات الشخصية للمرضى.
على ان يتم تزويد الوزارة بنسخة PDF من نتائج البحث، التعهد بعدم النشر لحين الحصول على موافقة وزارة الصحة.

مع الاحترام،،،

د. عبد الله القواسمي
رئيس وحدة التعليم الصحي والبحث العلمي

نسخة: عميد كلية الدراسات العليا المحترم/ الجامعة العربية الامريكية

دولة فلسطين وزارة الصحة
وحدة التعليم الصحي والبحث العلمي

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Appendix 2: The ethical approval to start the study for the private hospital.

Arab American University

Faculty of Graduate Studies

الجامعـــة العربيـــة الأمريكيـــة

كلية الدراسات العليا

2023/7/6

إلى من يهمه الأمر

<u>تسهيل مهمة بحثية</u>

تحية طيبة وبعد،

تُهديكم كلية الدراسات العُليا في الجامعة العربية الأمريكية أطيب التحيات، وبالإشارة إلى الموضوع أعلاه، تشهد كلية الدراسات العُليا في الجامعة أن الطالبة **براءة توفيق ياسر عودة** والتي تحمل الرقم الجامعي 202112511هي طالبة ماجستير في برنامج العناية المكثفة وتعمل على رسالة الماجستير الخاصة بها بعنوان:

" العلاقة بين النتائج في المرضى الذين يخضعون للتهوية الميكانيكية وفترة فتح القصبة الهوائية"، تحت إشراف الدكتورة بسمة سلامة. نأمل من حضرتكم الإيعاز لمن يلزم لمساعدتها للحصول على المعلومات اللازمة للدراسة، علماً أن المعلومات ستستخدم لغاية البحث فقط وسيتم التعامل معها بغاية السرية، وقد أُعطيت هذه الرسالة بناءً على طلبها.

وتفضلوا بقبول فائق الاحترام

ق. أ.عميد كلية الدراسات العليا

د. حسين الأحمد

كلية الدراسات العليا
CULTY OF GRADUATE STUDIES

Page 1 of 1

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Appendix 3: The ethical approval to start the study from IRB

Arab American University- Palestine
Deanship of Scientific Research
IRB committee
Tel: 04-241-8888, ext 1196
E-mail: irb.aaup@aaup.edu

الجامعة العربية الامريكية- فلسطين
عمادة البحث العلمي
لجنة أخلاقيات البحث العلمي
تلفون: 8888-241-04 ext 1196
البريد الالكتروني: irb.aaup@aaup.edu

IRB Approval Letter

Study Title: Association between early tracheostomy and patient outcomes in critically ill patients on mechanical ventilation

Submitted by: Baraa Odeh

Date received: 24th February 2023

Date reviewed: 28th April 2023

Date approved: 28th April 2023

Your Study titled "**Association between early tracheostomy and patient outcomes in critically ill patients on mechanical ventilation**" With archived number 2023/A/47/N was reviewed by the Arab American University IRB committee and was approved on 28th April 2023.

Reham Khalaf-Nazzal, MD, PhD
IRB committee chairman
Arab American University of Palestine

IRB
الجامعة العربية الأمريكية
ARAB AMERICAN UNIVERSITY

General Conditions:

1. Valid for 4 months from date of approval.
2. It is important to inform the committee with any modification of the approved study protocol.
3. The committee appreciates a copy of the research when accomplished.

Appendix 4 : The Data base for collected data .

Demographic Data				
Age	______________			
Sex	□ Male	□ Female		
Body mass index, kg/m^2	□ Weight ___________	□Height ____________		
Comorbidity				
Chronic liver disease	□ liver cirrhosis	□ liver failure		
Immunodeficiency.	□ immunosuppression	□ Acquired immunodeficiency syndrome		
Cardiovascular disease	□ Yes	□ No		
Malignancy	□ Acute leukemia	multiple myeloma	lymphoma	metastatic cancer
Emergency admission	□ Yes	□ No		
Surgical type of admission	□ Yes	□ No		
Systematic diagnosis for ICU admission	□ Cardiac □ Neurological,	□ Respiratory □ Sepsis	□ Gastrointestinal □ Trauma	□ Others _________

Acute Physiology and Chronic Health Evaluation score

Temperature (ºC)	MAP (mm Hg)	Heart rate (/min)	RR (/min)	PaO2 (mm hg)	pH.	Sodium (mEq/L).	Potassium (mEq/L)	Creatinine (mg/dL)

Hematocrit (%)	WBC count (x103/µL)

Data within 24 h after ICU admission		
Incidence of acute kidney injury	□ Yes	□ No
lowest PaO_2	______________	
Lowest FiO_2	______________	
Glasgow Coma Scale [GCS] score	______________	
Length of hospital stays before ICU admission	_______________	
ICU treatment (extracorporeal membrane oxygenation	□ Yes	□ No
Continuous renal replacement therapy	□ Yes	□ No
Duration of mechanical ventilation before tracheostomy	________________	
Duration of mechanical ventilation in ICU	________________	
Liberation of mechanical ventilation during ICU stays	□ Yes	□ No
Length of hospital stays	____________________	
Length of ICU	____________________	
Hospital mortality	□ Yes	□ No
ICU mortality	□ Yes	□ No

Appendix 5: Acute Physiology and Chronic Health Evaluation score (APACHE) II score

Physiologic Variable	Points								
	+4	+3	+2	+1	0	+1	+2	+3	+4
1. Temperature (°C)	≥41	39-40.9		38.5-38.9	36-38.4	34-35.9	32-33.9	30-31.9	≤29.9
2. Mean arterial pressure (mmHg)	≥160	130-159	110-129		70-109		50-69		≤49
3. Heart rate (/min)	≥180	140-179	110-139		70-109		55-69	40-54	≤39
4. Respiratory rate (/min)	≥50	35-49		25-34	12-24	10-11	6-9		≤5
5. Oxygenation (mmHg)									
a. A-aDO_2 if FiO_2 ≥0.5	500	350-499	200-349		<200				
b. PaO_2 if FiO_2 <0.5					>70	61-70		55-60	<55
6. Acid-base balance									
a. Arterial pH	≥7.7	7.6-7.69		7.5-7.59	7.33-7.49		7.25-7.32	7.15-7.24	<7.15
b. Serum HCO_3 (mEq/l) if no arterial blood gas	≥52	41-51.9		32-40.9	22-31.9		18-21.9	15-17.9	<15
7. Sodium (mEq/l)	≥180	160-179	155-159	150-154	130-149		120-129	111-119	≤110
8. Potassium (mEq/l)	≥7	6-6.9		5.5-5.9	3.5-5.4	3-3.4	2.5-2.9		<2.5
9. Creatinine (mg/dl)	≥3.5	2-3.4	1.5-1.9		0.6-1.4		<0.6		
10. Hematocirt (%)	≥60		50-59.9	46-49.9	30-45.9		20-29.9		<2.5
11. White blood count (×1000/mm³)	≥40		20-39.9	15.19.9	3-14.9		1-2.9		<1
12. Glasgow Coma Score (GCS)	Score = 15 minus actual GCS								
A. Total Acute Physiology Score (sum of 12 above points)									
B. Age points (years) ≤44=0; 45 to 54=2; 55 to 64=3; 65 to 74=5; ≥75=6									
C. Chronic Health Points*									
Total APACHE II Score (add together the points from A+B+C)									

* Chronic Health Points: If the patient has a history of severe organ system insufficiency or is immune-compromised as defined below, assign points as follows:

الملخص

الخلفية

تقدم القصبة الهوائية الروتينية للمرضى الحرجين فوائد علاجية على الأنبوب الليلي المطول، بفترات تنفس وإقامة في المستشفى أقصر. ومع ذلك، فإن تأثيرها على الوفيات غير مؤكد. تحققت هذه الدراسة في الرابط بين جراحة القصبة الهوائية المبكرة والنتائج للمرضى الموصولين بأجهزة التنفس

الطريقة:

أجرت دراسة التحقيق المتعين عليها إحصاء البالغين الذين يقيمون في وحدة العناية المركزة وكانوا قد أجروا جراحات قصبة الهواء بين يناير 2021 ويوليو 2023، باستثناء الذين أجروا ذلك خلال 29 يومًا من الدخول. باستخدام قاعدة بيانات مرضى العناية المركزة في اليابان، درست الوفيات في المستشفى ووحدة العناية المركزة. استخدم تحليل الانحدار لتقييم النتائج بالنسبة لتوقيت جراحة القصبة الهوائية، مقسمة حسب الربع

النتائج

شملت التحليل 60 مريضًا في وحدة العناية المركزة، مصنفين حسب أرباع توقيت جراحة القصبة الهوائية: ربع 6≤) Q1 أيام(، 7-14) Q2يومًا(، Q3(15–22 يومًا)، و Q4 (>22 يومًا). ارتفعت نسبة الوفيات في المستشفى مع الربع الأعلى5.9 :Q1) ٪، 12.5 :Q2٪، 28.6 :Q3٪، 30.77 :Q4٪؛ (P=0.001كان Q4 يحمل مخاطر وفاة أهم بشكل كبير مقارنة بـــ OR) Q1 المعدل: 3.04، 95 :CI % (0.22-40.82أظهر تحليل الفرع لفشل التنفس وضعف الوعي عند القبول في وحدة العناية المركزة اتجاهات مماثلة. لم يتم العثور (P>0.05)على فروقات كبيرة في معلمات أخرى

الاستنتاج

كشفت الدراسة عن رابط مستقل مهم بين توقيت جراحة القصبة الهوائية وكل من وفيات المستشفى ووحدة العناية المركزة. يبدو أن جراحة القصبة الهوائية المبكرة ترتبط بتحسين نتائج المرضى، مما قد يقلل من معدلات الوفيات. يشير النهج التدريجي إلى وجود تأثير تدريجي، مما يشير إلى مستويات مختلفة من الوفيات المرتبطة بتوقيت مختلف.