POSTGRADUATE PROGRAM DIRECTORATE

Outcome and Characteristics of Mechanically Ventilated Patients in Central Intensive Care Unit at Hiwot Fana Specialized University Hospital, From January 1, 2017 to January 31, 2019, Harar Eastern Ethiopia.

Internal Medicine Specialty Training Thesis Research Proposal

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List of Acronyms and Abbreviations

A/C	Assist Control
ALI	Acute Lung Injury
ARDS	Acute Respiratory Distress Syndrome
ARF	Acute Respiratory Failure
BiPAP	Bi-level Positive Airway Pressure
CKD	Chronic Kidney Disease
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
DM	Diabetes Mellitus
ETT	Endotracheal Tube
FiO_2	Fraction of inspired oxygen
GCS	Glasgow Coma Scale
HFSUH	Hiwot Fana Specialized University Hospital
ICU	Intensive Care Unit
IMV	Invasive Mechanical Ventilation
IQR	Inter-Quartile Range
IHRERC	Institutional Health Research Ethics Review Committee
MOF	Multi-Organ Failure
NIMV	Non-Invasive Mechanical Ventilation
PEEP	Positive End Expiratory Pressure
PS	Pressure Support
SBT	Spontaneous Breathing Trial
SIMV	Synchronized Intermittent Mandatory Ventilation
SPSS	Statistical Packages for Social Sciences
Vt	Tidal Volume

Abstract

Background: The need for mechanical ventilation is a frequent reason for admission to an intensive care unit. Every year, hundreds of research papers are published that help us better understand the epidemiological trends, prognostic factors, and outcomes of patients on mechanical ventilation and also how our treatment strategies interact and thus alter a patient's course. It is mandatory for clinicians to understand the outcome and characteristics of mechanically ventilated patients so as to provide quality care for the critically ill patients.

Objective: The objective of the study is to assess the outcome and characteristics of mechanically ventilated patients in central intensive care unit at Hiwot Fana Specialized University Hospital from January 1, 2017 to January 31, 2019. Data was collected from January 1 to January 31, 2020.

Methods: Cross-sectional study design was employed to assess the outcome and characteristics of mechanically ventilated patients in central intensive care unit at Hiwot Fana Specialized University Hospital admitted from January 1, 2017 to January 31, 2019. Data was collected from the patients' medical record by trained health professionals using a checklist. Statistical packages for social sciences version 21 version software was used for analysis. The results are depicted using tables and figures, and summarized using mean, standard deviation or percentage.

Result: The main reason for initiation of mechanical ventilation was respiratory failure 34(51.5%). The most common diagnosis leading to MV was coma secondary to moderate to severe head injury 20(30.3%). Hypertension was the commonest comorbidity in 6(9.1%). SIMV 49(74.2%) was the frequently used mode. The preferred weaning mode was CPAP 25(37.9%). Complication occurred in 5(7.6%) of cases. Twenty nine (43.9%) patients did not survive. Severe head injury was the leading cause of death 9 (13.6%).

Conclusion and recommendation: The mortality rate of mechanically ventilated pediatric patients was high. Respiratory failure was the main indication for initiation of mechanical ventilation. Severe head injury was the leading cause of death. It is better to improve the quality of care and use severity score while admitting patients to central ICU.

Key words: Mechanical ventilation, Hiwot Fana Specialized University Hospital, Harar.

Chapter 1: Introduction

1.1 Background

The need for mechanical ventilation is a frequent reason for admission to ICU (Esteban et al, 2000). MV is introduced into practice in the 1940s (Kacmarek, 2011). The first studies on the use of MV coincide with the development of the first ICUs (Slutsky, 1993, Linton et al, 1965, Bigelow et al, 1967, and Noehren et al, 1968). During the first 5 years of MV use, Rogers et al. observed a very high mortality rate of 63 % in the 212 mechanically ventilated patients (Rogers et al, 1972). Seven years later, Nunn et al demonstrated that mechanically ventilated patients accounted for 23.5 % of the patients admitted to their ICU and had a hospital survival rate of 47 % (Nunn et al, 1979). More recently, a prospective study including 15,757 patients from 20 countries showed that 33 % of ICU admissions required mechanical ventilation (Esteban et al, 2002).

Mechanical ventilation (MV) is a lifesaving therapy, allowing the support of patients with respiratory failure with the objectives of improving gas exchange and decreasing work of breathing (Nardi et al, 2017). Mechanical ventilation can be delivered via positive-pressure breaths or negative-pressure breaths. Additionally, the positive-pressure breaths can be delivered invasively (ventilator techniques that bypass the patient's upper airway with an artificial airway (endotracheal tube [ETT], laryngeal mask airway, or tracheostomy tube) or noninvasively (defined as the use of a mask or nasal prongs to provide ventilator support through a patient's nose and/or mouth) (Keenan et al).

The goal of mechanical ventilation are to provide adequate oxygenation, provide adequate alveolar ventilation, avoid alveolar over distension, maintain alveolar recruitment, promote patient ventilator synchrony, avoid auto PEEP and use the lowest possible FIO2 (Ira et al, 2003).

There are a few studies that analyze the characteristics of patients receiving MV. Most of these studies are focused on specific pathologies such as COPD and ARDS. In international studies, the median age of mechanically ventilated patients was 61 years in 1996 [10] (IQR: 44–71), and 63 years (IQR: 48–73) in 1998 (Esteban et al, 2002). Approximately 25 % of the patients were older than 75 in both of the above studies. This finding seems to indicate that many physicians do not consider this age to be a contraindication to the use of mechanical ventilation. Gender distribution was equal in observational studies. This is in contrast to several clinical trials of

patients with ARDS, sepsis, or myocardial infarction, which all enrolled almost twice as many males as females (Esteban et al, 2002 and Esteban et al, 2000).

Indications for mechanical ventilation are similar among ICUs of different countries across the globe. Common indications for mechanical ventilation include acute respiratory failure (69%), coma (17%), acute on chronic respiratory failure (13%), and neuromuscular disorders (2%) (Esteban et al, 2002).

There are four commonly used modes of MV: assisted/controlled volume cycled ventilation, assisted/control pressure controlled ventilation, synchronized intermittent mandatory ventilation and pressure support ventilation. These modes are either volume-preset or pressure preset. In the volume-preset mode, the clinician sets the rate and tidal volume and the ventilator delivers whatever pressure is required to achieve it. In the pressure-preset mode the clinician sets the maximal inspiratory pressure and inspiratory time the ventilator delivers whatever tidal volume (Vt) is generated by that pressure (Robert, 2010).

Newer modes of ventilation are continually incorporated into daily practice; however these new methods do not have any associated studies demonstrating advantages over older methods, especially in terms of morbidity or mortality. There appears to be an incongruity of what modes or settings should be considered standard or conventional mechanical ventilation (Esteban et al, 2002).

Mechanical ventilation use has its own risks. Among them the main problems that can develop from using a ventilator include pneumothorax, acute lung injury (ALI), and ventilator-associated pneumonia (VAP) (develops at a rate of approximately 1% per day). And also side effects of medications like sedatives and pain medications can cause a person to seem confused or delirious, and these side effects may continue to affect a person even after the medications are stopped and inability to discontinue ventilator support (Tobi et al, 2017). Complications from the endotracheal tube itself include hard and soft palate injuries, laryngeal dysfunction, tracheal stenosis, tracheomalacia, and near-fatal or fatal obstruction (Tablan et al, 1994).

Another crucial aspect in the management of mechanically ventilated patients is weaning from ventilator support. Time spent in the weaning process represents 40–50% of the total duration of mechanical ventilation (Esteban et al, 2002). There are 4 methods of gradual weaning which are single daily T- Tube trial for up to two hours, intermittent mandatory ventilation (IMV), Pressure Support (PS) and trials of spontaneous breathing (SBT). The rate of successful weaning varies

between these modes. A single daily trial of spontaneous breathing achieved a threefold and twofold increase in the rate of successful weaning compared with IMV and PS, respectively (Vallverdu et al, 1998).

Most mechanically ventilated patients require short period of respiratory support, but a minority (6%) of mechanically ventilated patients requires prolonged mechanical ventilation (PMC) (Estenssoro et al, 2005). Patients with high severity of illness at admission to the ICU and those with chronic pulmonary disease other than COPD or pneumonia as the reason to start mechanical ventilation, a longer duration of mechanical ventilation before the start of and the need to be ventilated with a high PEEP during active ventilatory support were related to difficult/prolonged weaning (Oscar et al, 2011). In contrast, Esteban et al found that 41% of patients with COPD failed the first attempt at spontaneous breathing (Esteban et al, 2002).

The mortality rates of mechanically ventilated patients have been described with widely varying results, likely due to heterogeneity of the populations included in the studies. Mortality has been associated with baseline factors including age; severity of disease; coma, sepsis or ARDS as indications of mechanical ventilation; with factors related to the management of the patient such as the use of vasoactive drugs, use of neuromuscular blockers, peak pressure higher than 50 cmH2O, plateau pressure higher than 35 cmH2O; and with complications of MV such as barotrauma, ARDS, sepsis, hypoxemia and multiple organ failure [Esteban et al, 2002).

Mortality rates in patients with non-pulmonary diseases or mild pulmonary changes are reportedly less than 5%. Patients with type I respiratory failure were found to have a higher mortality (40%) as compared with 17% with type II failure. Mortality rate for type II respiratory failure ranging from 9% to 50% and from 54% to 72% in type I respiratory failure have been observed showing that parenchymal lung damage predicts a poorer outcome for patients on MV (Sudarsanam et al, 2005).

The presence of comorbidities is associated with poor outcome in mechanically ventilated patients. Studies on patients with type II respiratory failure showed older patients with lower mean arterial pressures, higher blood urea, poorer pre-morbid condition, patients requiring ventilation within first 24 hours, patients with lower serum albumin, in cor pulmonale with lower FEV1 to have poorer prognosis (Gupta et al, 2001).

Among patients with type I respiratory failure, sepsis, multi-organ system failure, cardiac failure, worsening renal function, a longer duration of mechanical ventilation, medically ill patients with

sepsis and multiple transfusions as compared with trauma patients with the above comorbidities were all found to have an adverse effect on the outcome. The use of inotrope support during mechanical ventilation is an independent predictor of outcome of these patients (Gupta et al, 2001).

In-hospital mortality of mechanically ventilated patients had improved by > 60% over the last decade, owing to advances in medicine and access to medical aid across the globe (Esteban et al, 2013). Mortality rate would have been modest in many ICUs across the globe if there had been judicious admission criteria as seen in studies which excluded patients ‘‘deemed irrecoverable” from the selection criteria (Nunn et al, 1979).

1.2 Statement of the problem

Mechanical ventilation has become a mainstay of therapy for critically ill patients (Esteban et al, 2000). However, providing effective medical care for mechanically ventilated patients is challenging and requires good planning and effective clinical decision making policies. In high-income countries, intensive care unit practices, mechanical ventilation strategies and their social costs are well documented. In United States, for example, 3% of inpatient hospitalizations required mechanical ventilation in 2005, accounting for 30% of all ICU admissions and approximately 30% of these patients died before ICU discharge (Wunsch et al, 2010). In resource limited settings, however, less is known about the clinical practices and MV strategies used, and the burden of caring for mechanically ventilated patients in these settings is higher than generally perceived (Dünser et al, 2006).

Disparities in mortality rates in ICUs of varying geographical and socioeconomic status are observed but the factors that may be contributing to these differences are not addressed (Esteban et al, 2002). Hence information on incidence, patient characteristics, and outcomes of patients requiring MV is critical in understanding the reasons for high mortality in these patients. It also helps for effective use of resources and making critical clinical decisions (Needham et al, 2004).

1.3 Significance of the study

The aim of the study is to understand the outcome and characteristics of mechanically ventilated patients in central intensive care unit at Hiwot Fana Specialized University Hospital. The study will serve as an audit, and help policy makers allocate more resources in order to increase the quality of care provided to mechanically ventilated patients. The study will also serve as a basis for further studies to be done on the related topic.

1.4 Objectives

1.4.1 General objective

The general objective of the study is to assess the outcomes and characteristics of mechanically ventilated patients in central ICU at HFSUH from January 1, 2017 to January 31, 2019. Data was collected from January 1 to January 31, 2020.

1.4.2 Specific objectives

To assess the outcomes of mechanically ventilated patients in central ICU at HFSUH.

To assess the characteristics of mechanically ventilated patients in central ICU at HFSUH.

Chapter 2: Literature Review

2.1 Outcome of mechanically ventilated patients

In a 1-d point-prevalence study in ICUs from North America, South America, Spain, and Portugal involving 412 medical-surgical ICUs, the commonest cause of mortality was ARDS (52%) and the second common cause of mortality was COPD which accounted for 22% of deaths (Esteban et al, 1994).

In a study done in India, out of 200 patients, at discharge 143 patients (71.5%) had died. Type I respiratory failure and the use of inotropes were the independent predictors of mortality. The least mortality was seen in the patients admitted for poisoning (46%) while the highest mortality seen in patients having a malignancy (100%) (Sudarsanam et al, 2005). In another study done in rural India, chronic kidney disease (17.23%) and coronary artery disease (14.65%) were commonest comorbidities followed by hypertension (12.27%) and diabetes (11.68%), and were found to be significantly associated with mortality (77%) (Anjalee et al, 2016).

In a study done in Egypt, the mortality rate was 16.15% among patients on IMV but no death was recorded in those ventilated with NIMV. The highest mortality was associated with ARDS (100%) and severe pneumonia (100%) followed by bronchial asthma (30%) and interstitial lung disease (23%) while the lowest mortality was recorded with COPD patients (11.1%). As regards with indication of MV, the highest mortality was associated with acute hypoxemic respiratory failure (53.3%) followed by post arrest (46.2%) while the lowest mortality was associated with acute on top of chronic respiratory failure which accounted for 6.9% of cases (Mohamed et al, 2015).

In a prospective observational study done at Ayder comprehensive specialized hospital adult intensive care unit, Mekelle, Ethiopia, the overall ICU mortality rate of the studied cases was 28.6%. Age above 60 years and new septic shock development were independently associated with increased mortality (Berhe et al, 2017).

2.2 Characteristics of mechanically ventilated patients

In a 1-d point-prevalence study in ICUs from North America, South America, Spain, and Portugal involving 412 medical-surgical ICUs, 1,638 patients received mechanical ventilation. A/C (47%) was the most common mode of ventilation in Argentina, Chile, and Spain. An almost equal proportion (46%) of patients was ventilated with SIMV, PS, or the combination of both.

The use of SIMV on its own was infrequent in all countries, with the exception of Uruguay (20%), and overall it was 6%. In no country was PS alone the most frequently used mode, and overall it was employed in 15% of patients. The combination of SIMV and PS showed considerable variation among countries, ranging from the 7% (Argentina) to 52% (Uruguay); in North America, this combination was used with the same frequency as A/C (34% in both instances) (Esteban et al, 1994).

The setting of tidal volume was remarkably constant among countries, with little interquartile variation in ICUs from North America, South America, Spain, and Portugal. The median tidal volume setting was 9 ml/kg in patients receiving A/C. The median level of PS [18 cm H2O] was also similar among countries, although interquartile variation was considerable. Tidal volume did not differ between patients with ARDS and those with other causes of acute respiratory failure receiving A/C. Positive end-expiratory pressure was not employed in 31% of patients (range: 16 to 50). In those receiving PEEP, the median value was 5 cm H2O with no difference among countries. A significantly higher level of PEEP was employed in patients with ARDS than in those with an acute exacerbation of chronic lung disease (Esteban et al, 1994).

The most frequent method of weaning in the above study was PS, used in 36% of the patients. The combination of SIMV and PS was used in 28% of the patients, but varied considerably among countries, ranging from 3% of patients in Argentina to 47% in Uruguay. A combination of two or more methods in succession was used 33% of patients (Esteban et al, 1994).

The median duration of MV in the above international study was 7 days; an exception was Portugal, where the median was 12 days. Tracheostomy was done in 24% of mechanically ventilated patients. It was performed at a median of 11 days after intubation, and this elapsed time did not differ among countries. Over the initial 3 weeks, a tracheostomy was performed more frequently in patients with neuromuscular disease (31.3%) than in those with COPD (14.8%) or acute respiratory failure (9.1%). After the third week, the proportion of patients with tracheostomy did not differ among the diagnostic categories. The median age was 61 year, and men predominated in every country (average, 60%) except Brazil. The recorded complications in the above 1-d prevalence study were barotrauma (3%), ARDS (22.1%), pneumonia (9.8%), shock (22.1%), acute renal failure (9.8%), hepatic failure (6.3%), and coagulopathy (10.6) (Esteban et al, 1994).

Sudarsanam et al (2005) recruited 200 consecutive patients (accounting for 41% of patients admitted to the MICU) requiring mechanical ventilation in a medical intensive care unit in India to predict outcome in patients requiring mechanical ventilation. Complications that were seen in our patients included tube block in 19 patients (9.5%), nosocomial pneumonia in 53 (26.5%), nosocomial sepsis 3 (1.5%), and other complications in 4 (2%). Altogether, 119 patients had no complications related to MV (Sudarsanam et al, 2005).

In a prospective study of indications and factors that affect outcome of mechanically ventilated patients in a tertiary hospital in Nigeria involving 44 mechanically ventilated patients (34.4% ICU admissions), respiratory distress and airway protection were the major indications for MV representing 38.6% and 27.3%, respectively. Other indications included deteriorating Glasgow coma score (GCS) and hyperventilation accounting for 20.5% and 13.6%, respectively. Males accounted for 45.5% of cases and the rest 54.5% is accounted by females. Duration of mechanical ventilation ranged from 1-36 days with the mean duration of 12.30 ± 10.10 days, most patients being ventilated for 1-7 days (38.6%). The more preferred mode of MV was SIMV (52.3%) followed by A/C employed in 47.7% of patients. Of the total number of patients who had endotrachael intubation, only 25% had tracheostomy (11 patients) (Tobi et al, 2017).

Mohamed et al (2015) recruited all adult patients receiving MV at EL-Mahalla Chest Hospital ICU between July 2013 and June 2014. Out of the 412 ICU patients, 130 received MV. Studied cases were classified into three groups: IMV (group A), NIMV (group B), and NIMV failure that needed IMV and thus, 40% received invasive MV, 50.7% noninvasive MV (9.2% of the patients showed noninvasive failure and needed invasive ventilation) (Mohamed et al, 2015).

The most common indication for MV in the study done in Egypt was acute on top of chronic respiratory failure (77.7%) followed by acute hypoxemic respiratory failure (11.54%), post arrest (10%) and coma (0.77%). The most prevalent diagnosis was COPD (38.5%, 51.5%, 75% in group A, B and C patients, respectively) followed by interstitial lung disease (25%), bronchial asthma (13.5%). The least common diagnosis was obesity hypoventilation (1.9%) in group A, obesity hypoventilation (30%), pulmonary edema (7.6%), interstitial lung disease (6.1%), and bronchial asthma (4.6%) in group B and obesity hypoventilation (25%) in group C (Mohamed et al, 2015).

The most common initial mode of MV among those receiving IMV was IPPV (76.9%) followed by SIMV (23.1%) while BiPAP (84.9%) and CPAP (15.2%) were the modes used in the noninvasively ventilated patients. The mean duration of MV was significantly highest in group C and lowest in group B (3.216±1.944, 2.242±0.634 and 4.306±4.580 in group A, B and C, respectively). The mean age was 58.47 ± 8.2 years and 82% of the studied cases were males, and 87.69% were from rural areas. The most common complication in group A was renal impairment or failure (11.5%) followed by ventilator associated pneumonia (5.77%) and cardiogenic shock (5.77%) (Mohamed et al, 2015).

In a prospective observational study done at Ayder comprehensive specialized hospital adult intensive care unit, Mekelle, Ethiopia, 105 out of 286 ICU admissions (36.7%) received invasive MV. The median age of the sampled patients was 32 [24-52] years and 16.2% were above the age of 60 years. The leading indications were acute ARF (50.5%) followed by coma (35.2%). The median duration of MV stay was eight [5, 14] days and 11.4% of them had prolonged [>21 days] MV use. Complications were observed in 63.8% and these include stress related gastric bleeding (28.6%), VAP (27.6%), AKI (22.9%) and septic shock (20%) (Berhe et al, 2017).

Chapter 3: Study methodology

3.1 Study area and study period

The study was conducted in HFSUH, Harar town, which is located at 526 km east of Addis Ababa. Harar is one of the most popular historical towns found in the eastern part of Ethiopia, surrounded by the regional State of Oromia. The Harari regional State has no administrative zones or woredas. The total numbers of kebeles in the city are 19, while the rural part of the State has 17 farmers associations. The State's size is estimated at 340km^2 (Girma, 2014).

The Harari national regional state is populated with 183,344 people. The percentage share of males and females is about 50% each. The urban residents of the State were 99,321 while its rural inhabitants were 84,023. This State is the only member state of FDRE where the majority of its population lives in urban area (Girma, 2014).

Hiwot Fana Specialized University Hospital is one of the two government hospitals. It is believed to be established between 1936 and 1941. It has been under the Harari regional health bureau since 2009. The hospital has been transferred to Haramaya University to serve as a teaching, community serving and research hospital. It has four main departments: gynecology and obstetrics, internal medicine, surgery, and pediatrics. It is well equipped with senior physicians & other staffs. It has a total of 210 beds and about 250 different categories of health professionals who are serving the community (Girma, 2014).

The study period was from January 1, 2017 to January 31, 2019. Data was collected from January 1 to January 31, 2020.

3.2 Study design

Cross-sectional study will be conducted using review of clinical records of patients admitted to central ICU at HFSUH from January 1, 2017 to January 31, 2019.

3.3 Population

3.3.1 Study population

All records of mechanically ventilated patients admitted to central ICU at HFSUH from January 1, 2017 to January 31, 2019.

3.3.2 Study subjects

All records of mechanically ventilated patients in central ICU at HFSUH from January 1, 2017 to January 31, 2019.

3.4 Inclusion and exclusion criteria

3.4.1 Inclusion criteria

All mechanically ventilated patients in the study area during the study period were included.

3.4.2 Exclusion criteria

Patients with incompletely filled charts were excluded.

3.5 Sample size

The sample size was calculated using single population proportion formula as follows:

$n = (Z\alpha/2)^2/w^2\ p(1-p)$, where n-is the sample size, p-is the anticipated population prevalence, w-is the precision error either side of the population, z- refers to cut off value of the normal distribution 95% confidence limit (1.96).

A study done at Ayder Comprehensive Specialized Hospital which showed the prevalence of mechanically ventilated patients of 36.7% was used to anticipate the prevalence of mechanically ventilated patients in central ICU at HFSUH.

A total of 5 percentages points of error tolerated on each side of the estimated proportion, expressed as w=0.05.

Therefore, the sample size calculated as $n = (1.96/0.05)^2\ (0.367)\ (0.633) = 357$.

Since the source population is less than 10,000, population correction formula was used to estimate the sample size:

$N = n_i/(1+n_i/N)$. Where N=72 $N = n_i/(1+n_i/N)=357/(1+357/72) = 60$

To compensate the non-response rate, 10% of the sample size was added and thus, a total of 66 mechanically ventilated patients were studied.

3.6 Sampling technique

Convenience sampling technique was used until the sample size was achieved.

3.7 Data collection methods

The clinical records of the study subjects were retrieved from card room using the card number obtained from central ICU's registration book, and data was collected by four medical interns from patient cards using a checklist after the study approval by the hospital's review board was obtained.

3.8 Variables

3.8.1 Dependent variables

Outcome of mechanically ventilated patients (survived or not survived at discharge).

3.8.2 Independent variables

Socio- demographic factors (sex, age, residence), reason for initiation of MV (acute on chronic pulmonary disease (COPD, asthma, chronic pulmonary disease other than COPD); coma;

neuromuscular disease; acute respiratory failure (acute respiratory distress syndrome [ARDS], postoperative, congestive heart failure, aspiration, pneumonia, sepsis, trauma, cardiac arrest, and others), length of stay on MV, mechanical ventilator mode (ACV, PCV, SIMV,IMV), complications (ARDS, barotrauma, VAP, sepsis, and multi-organ failure [cardiovascular, respiratory, renal, hepatic, and hematologic]), co morbidities (DM, HTN, CKD, liver disease, anemia), mode of weaning (SBT, PS, CPAP), tracheostomy use, re-intubation, medications (Inotropes, sedatives), initial ventilator settings (VT, respiratory rate, PEEP, peak pressure, plateau pressure).

3.9 Operational definitions

Outcome—does the patient survived or not after mechanical ventilation.

Characteristics—what was male to female ratio, the age of mechanically ventilated patients, what mode of mechanical ventilation was used, what were the initial ventilator settings, what was their indication for mechanical ventilation, what type of mechanical ventilation was employed, what medication (sedative) was used and for how long does patients stayed on mechanical ventilator and what was the main complications they developed and also the method of weaning from mechanical ventilator including tracheostomy for patients for prolonged mechanical ventilation.

MODS: Failure of 2 or more organs.

3.10 Data quality control

To ensure the completeness, accuracy and consistency of data collection, a session was held on each day of the data collection period. During these sessions, thorough checking was done before using the filled checklist. Data was cleaned and filled to SPSS statistical software version 20 by the principal investigator.

3.11 Data processing, analysis and management

Data was cleaned, coded, and prepared for analysis using SPSS version 21. The results are presented using tables and figures and summarized using mean, standard deviation ($X \pm SD$) or percentage.

3.12. Ethical Considerations

Before beginning data collection, official letter from Haramaya University, College of Health and Medical Sciences, Institutional Health Research Ethics Review Committee (IHRERC), and informed voluntary written and signed consent from head of the hospital was obtained. The letter was then submitted and the objective of the study thoroughly explained to all responsible bodies to ensure smooth and effective data collection. Confidentiality of all the obtained data was

seriously respected and was ensured by not mentioning the patients' names in the checklist and by using a password protected computer to prevent unauthorized access to the obtained data.

3.14 Dissemination plan

The finding of the study will be submitted to the school of medicine and college of health and medical sciences Haramaya University in partial fulfillment of the requirements for the degree of doctor of medicine. The copy of the research will be given to the hospital as well. The finding will also be presented for different work-shops and seminars and will be published in a peer reviewed journal.

Chapter 4: Work plan

Table 1: Work plan for the study on characteristics and outcome of mechanically ventilated patients

SN	Activities	Responsible body	Months							
			Aug 2019	Sep 2019	Oct 2019	Nov 2019	Dec 2019	Jan 2020	Feb 2020	Mar 2020
1.	Proposal development	PI								
2.	1st draft submission	PI								
3.	Final proposal submission	PI and data collectors								
4.	Ethical review	PI								
5.	Collection of material and budget	PI								
6.	Data collection									
7.	Data analysis									
8.	Preparation for 1st draft submission									
9.	Rearrangement of final report									
10.	Submission of final report									
11.	Thesis defense									

Chapter 5: Budget breakdown

Table 1: Budget breakdown of a study on characteristics and outcome of mechanically ventilated patients admitted to central intensive care unit of Hiwot Fana Specialized University Hospital from January 1, 2017 to January 31, 2019, Harar, Ethiopia.

S. No	Cost item	Unit	Amount required	Unit price	Total price
I. Personal Cost					
1	Data collector fee	Per person	4 person x 30 days	50.00	6000
2	Secretary fee	,,	100 pages	10.00	1000
II. Stationary cost					
1	Duplicate papers	Pack	10	100.00	1000
2	Pencil	Each	5	10.00	50
3	Pen	,,	5	10.00	50
4	Eraser /rubber	,,	5	10.00	50
5	Binder	,,	5	25.00	125
6	CD	,,	5	25.00	125
7	Ruler	,,	5	20.00	100
III. Miscellaneous cost					
1	Computer rent	Per hour	90 hours	50.00	4500
2	Telephone	,,	60 hours	50.00	3000
3	Internet	,,	50 hours	80.00	4000
4	Transport	“	400 hours	5.00	2000
5	Supervision fee				3000
				Total	**25,000**

Source of budget is Haramaya University.

Chapter 7: References

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Annex 1: Consent form

Annex 1: Consent form for head of Hiwot Fana Specialized University Hospital

My name is _____. I am working as a data collector for the study being conducted in this hospital by Dr. Tesfay Atsbaha who is studying for his internal medicine specialty certificate program at Haramaya University, College of Health and Medical Sciences. I kindly request you to lend me your attention to explain you about the study and your institution being selected as the study setting.

1. The study title

The study title is outcomes and characteristics of mechanically ventilated patients in central ICU at HFSUH, Harar.

2. Purpose/aim of study

The study will serve as an audit (baseline data) and thus, will clearly picture the problems related mechanical ventilator use, and give information about the outcome related to its use. It will also help policy makers allocate more resources in order to increase the quality of care. The study can also serve as a baseline for further studies to be done on the related topic. Moreover, the aim of this study is to write a thesis as a partial requirement for the fulfillment of Internal medicine Specialty Certificate program for the principal investigator.

3. Procedure and duration

I will use a checklist to collect data from records of mechanically ventilated patients. Every checklist will take about 20 minutes.

4. Risks and benefits

The risk of participating in this study is very minimal. There would not be any direct payment for participating in this study. But the findings from this study may reveal important information for the local health planners.

5. Confidentiality

The information taken from patient's record will be kept confidential. Confidentiality of all the data to be gained will be seriously respected and will be ensured by not mentioning patients names in the questioner and unauthorized individuals will not be allowed to access to the data which will be collected by using a password protected computer.

6. Rights

The patients by which the information is obtained from their records will not be labeled for any loss of benefits which they otherwise are entitled.

7. Contact address

If there is any questions or enquires any time about the study or the procedures, please contact: tamed08.ta@gmail.com; as well as contact address of the responsible Institutional Health Research Ethics Review Committee (IHRERC) at office phone 0254662011 or P.O.Box 235, Harar, Ethiopia.

8. Declaration of informed voluntary consent

I have clearly understood the purpose of the research, the procedures, the risks and benefits, issues of confidentiality, the rights of participating and the contact address for any queries. I have been given the opportunity to ask questions for things that may have been unclear. I am also informed that the hospital has the right to stop this study from being conducted if any misdeeds and unethical procedures are observed during data collection process in the hospital's premises. Therefore, I declare my voluntary consent to behalf of HFSUH management to allow this study to be conducted in this Hospital with my initials (signature).

Name and signature of Head of the Hospital: _____Date_____

Name and signature of Data Collector: _____Date_____

Annex 2: Checklist

Part I: Socio-demographic data

1. Age _____
2. Sex : Male_____ Female_____
3. Place of residence_____

Part II: Patients factors

1. Comorbidities, if any?

   A. DM B. Hypertension C. CKD D. Heart disease E. Others___
2. Use of inotropes, if any, given during the course of mechanical ventilation?

   A.Type_____

   B. Timing_____

   C. Duration_____

   D. Dose_____
3. Use of sedatives, if any, given during the course of mechanical ventilation?

   A.Type:_____

   B. Timing_____

   C. Duration_____

   D. Dose_____

Part III: Mechanical ventilation related factors

1. Types of mechanical ventilation:

   NIMV_____IMV_____
2. Indications for mechanical ventilation:

   A. ARDS B. Coma C. COPD D. Cardiac arrest E. Others____
3. Modes of mechanical ventilation:

   A. ACV B. SIMV alone C. PS alone D. E. Others_____
4. Initial ventilator settings:

   Tidal volume_____PEEP_____RR_____FiO_2_____PS_____
5. NIMV failure that needed IMV, if any_____
6. Complications of mechanical ventilation, if any?

   A. Barotrauma B. Volutrauma C. VAP D. Tracheostomy
7. Duration of MV (in hours if less than 72 hours and days if longer than three days)_____

8. Modes of weaning: daily SBT_____CPAP_____
9. Tracheostomy, if any_____
10. Re-intubation within 48 hours_____
11. Death at discharge, if any?_____

Curriculum Vitae (CV)

Name: Dr. Tesfay Atsbaha

Sex: Male

Marital status: Single

Nationality: Ethiopian

Date of birth: 1994

Contact address

- Physical address: Harer
- Phone number: 0943668028
- Email: tamed08.ta@gmail.com

Educational background

- August 2007: Certificate of high school completion
- Auguts 2009: Ethiopian higher education entrance qualification certificate
- 2014: Degree of Doctor of Medicine from Haramaya University
- Training taken: Certificate of basic ART training

Experience

- Two years of experience working as a general practitioner and lecturer at HFSUH, Harer.
- Currently final year internal medicine resident.

Languages spoken and ability

- English, Amharic and Tigrigna: Excellent

Reference

- Dr. Nejib Yusuf (Internist)
- Dr. Tekabe Abdosh (Internist)
- Dr. Obsie Temesgen (Internist)

Approval sheet

Haramaya University School of Graduate Studies

Outcome and characteristics of mechanically ventilated patients in central ICU at HFSUH, December, 2019.

Submitted by:

1. Dr. Tesfay Atsbaha _____ _____

   Name of student Signature Date

2. Dr. Obsie Temesgen _____ _____

   Name of major Advisor Signature Date

3. _____ _____ _____

   Name of co-Advisors Signature Date

4. _____ _____ _____

   Research thematic area leader Signature Date

5. _____ _____ _____

   Chairman, DGC/SGS Signature Date

6. _____ _____ _____

   PGPD Signature Date