INCIDENCE AND ASSOCIATED RISK FACTORS FOR AIRWAY ADVERSE EVENTS IN INTUBATED ICU PATIENTS AT MUHIMBILI NATIONAL HOSPITAL

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By

Lukansola Makubula

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine (anaesthesiology) of

Muhimbili University of Health and Allied Sciences
October, 2018

CERTIFICATION

The undersigned certifies that he has read and hereby recommends for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled: **''Incidence and associated risk factors for airway adverse events in intubated ICU patients at Muhimbili national hospital '',** in (partial) fulfillment of the requirements for the Degree of Master of Medicine (Anaesthesiology) of Muhimbili University of Health and Allied Sciences.

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Senior Lecturer MUHAS

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Date

DECLARATION AND COPYRIGHT

I, **Dr. Lukansola Makubula** declare that this **dissertation** is my own original work and that it has not been presented, and will not be presented, to any other university for a similar or any other degree award.

Signature…… **Date**…….....

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I would like to thank Dr Tim Baker and Dr Victoria Howell for their inputs during development of this dissertation.

Lastly I would like to thank the Management of MNH for granting me permission to conduct this study in their ICUs, with the help of the few nurses they have plus my classmates I was able to finish the study.

DEDICATIONS

This work is dedicated to my late uncle Everist M. Mabusi and to Seed Global Heath for their help has helped to be here today.

ABSTRACT

Introduction

Airway adverse events in intubated intensive care unit patients have been reported all over the world. The patterns of these events include Unplanned Extubation, Tube blocking, Endobronchial intubation, Tube kinking and leaking cuffs. However the most common ones are reported to be unplanned extubation and tube blocking. Low level of sedation and low number of ICU staff has been reported to play a role in unplanned extubation whereas prolonged intubation was associated with tube blocking among other factors.

All these adverse airway events could lead to catastrophic effect to the patient since most of these patients had cardiopulmonary compromise. This was also accompanied by difficult airway management yet intervention was needed as soon as possible to minimize the effects.
This study looked at the incidence, patterns, associated risk factors and the outcome of these airway adverse events.

Methodology

An observational prospective cohort study was conducted among intubated ICU patients at Muhimbili National Hospital. All intubated patients admitted to ICU were followed up after obtaining proxy consent from next of kin. A structured data collecting form which was updated every day during patient stay with endotracheal tube or tracheostomy tube was used.
Patterns of airway adverse events plus associated complications were recorded from day of intubation till when the patient was extubated either due to improvement or death.
Level of sedation, use of Humidifiers, Primary diagnosis, Physical restraints and technique used to secure the endotracheal tube plus numbers of tube days were also recorded.

Results

98 patients with a total of 521 tube days were studied. There were overall 22 airway adverse events occurring in 22 patients with an incidence of 22.45% of patients and 4.22% / 100 tube days.

The airway adverse events were 17.39% of patient and 3.40 %/100 tube days due to unplanned extubation and 6.52% of patients and 1.24%/ 100 tube days due to tube blockade.

Unplanned extubation and tube blockade were the most common adverse events, no other airway adverse event were noted during a study period.

Of the 22 adverse events majority of them did not get serious complications, apart from one case who sustained cardiac arrest following unplanned extubation.

Conclusion and recommendations

From this study it was noted that the overall incidence of 4.22%/100 tube days was quite high compared to studies from other Intensive Care Units. Tube blockade and unplanned extubation were the commonly observed airway adverse events. This was contributed by inadequate staff during night shifts, non routine use of Heat and Moisture Exchangers plus presence of auxiliary and less experienced staff in the units.

We recommended training of critical care nurses and strict one nurse to one ventilated patient to be observed during all shifts.

TABLE OF CONTENTS

CERTIFICATION i
DECLARATION AND COPYRIGHT ii
ACKNOWLEDGEMENT iii
DEDICATIONS iv
ABSTRACT v
TABLE OF CONTENTS vii
LIST OF TABLES ix
LIST OF ABBREVIATIONS x
DEFINITION OF TERMS xi
CHAPTER ONE 1
1.0 INTRODUCTION 1
1.1 Review of Literature 7
1.2 Conceptual Framework 13
1.3 Problem Statement 15
1.4 Rationale of the study 16
1.5 Research Questions 16
1.6 Objectives 17
1.6.1 Broad Objective 17
1.6.2 Specific Objectives 17
CHAPTER TWO 18
2.0 METHODOLOGY 18
2.1 Study Type 18
2.2 Study Area 18
2.3 Study Population 18
2.3.1 Inclusion Criteria 18
2.3.2 Exclusion Criteria 19
2.4 Sample size 19
2.5 Sampling 19

2.6 Description of study stool 19
2.7 Variables 20
2.8 Data collection and analysis 20
2.9 Ethical Clearance 20
2.10 Study Limitation 20
2.11 Dissemination of results 21
2.12 Confidediality issues 21
CHAPTER THREE 22
3.0 RESULTS 22
CHAPTER FOUR 27
4.0 DISCUSSION OF RESULTS 27
4.1 Incidence 27
4.2 Pattern of airway adverse events 27
4.3 Associated risk factors for airway adverse events. 28
4.4 Outcome of the airway events 32
4.5 Study Limitations 32
CHAPTER FIVE 33
5.0 CONCULUSION AND RECOMMENDATIONS 33
5.1 Conclusion 33
5.2 Recommendation 33
REFERENCES 34
APPENDICES 38
Appendix I: Data Collecting Form 38
Appendix II: Ramsay Sedation Scale 40
Appendix III: Severity of outcome scale: from National Patient Safety Agency 41
Appendix IV: Consent Form (English version) 42
Appendix V: Consent Form (Swahili Version) 45

LIST OF TABLES

Table1: Overall incidence of airway accidents……...23

Table 2: Incidence of specific airway adverse events……..23

Table 3: Individual airway adverse events per associated risk factors……25

Table 4: Severity of airway events and rate of reintubation……26

LIST OF ABBREVIATIONS

ASA	:	American society of anesthesiologists
COPD	:	chronic obstructive airway diseases
CPR	:	cardiopulmonary resuscitation
EA	:	East Africa
ETT	:	Endotracheal tube
FIO2	:	Fraction of Inspired Oxygen
HMEs	:	Heat and Moisture Exchangers
ICU	:	Intensive Care Unit
MNH	:	Muhimbili National Hospital
SE	:	Self Extubation
TT	:	Tracheal tube
UE	:	Unplanned extubation.
VAP	:	Ventilator Associated Pneumonia

DEFINITION OF TERMS

Surgical patient- This is any patient with pathological process/condition that needs surgical correction. But because of physiological or physical derangement they need supportive airway management in form of intubation.

Medical patient- this is any patient with any pathological condition that does not need surgical correction, but due to physiological derangements they need supportive airway management in form of intubation.

Cardiopulmonary resuscitation- is an emergency procedure that combines chest compression and artificial ventilation in an effort to restore spontaneous breathing and circulation in persons with cardiac arrest.

Body mass index- this is the ratio of weight of the patient in kilograms to height of patient in square meter.

Sedatives – these are drugs/agents given to the patient to reduce level of consciousness and therefore increase state of calmness.

Ventilator Associated Pneumonia- This is a type of lung infection that occur in patients who are on mechanical ventilator.

Cardiac arrest- This is an abrupt loss of heart function, if not revised then death is imminent

Endobronchial intubation- This is migration of endotracheal tube below the level of the carina in such a way that only one lung will be ventilated due to its presence in one of the main bronchus.

Self Extubation – this is removal of endo tracheal tube by the patient himself/her self

Tracheostomy – is the process whereby an opening is done into the tracheal through the neck to facilitate passage of air.

Tube days – this is the total number of days patient spent with endotracheal tube or tracheal tube.

Unplanned Extubation -This is defined as unplanned removal of tracheal tube that is not intended by the health care provider.

Capnography- is graphical measurements of carbon dioxide partial pressure (in mmhg) during expiration.

Pulse oximiter- is a non invasive measurement for person's haemoglobin oxygen saturation

Inotropes – these are drug agents that change the force of contraction of blood vessel smooth muscles and the heart

CHAPTER ONE

1.0 INTRODUCTION

Cardiopulmonary support is one of the main reasons for admission of patients to Intensive Care Unit (ICU). This may involve advanced airway management which employs the use of tracheal tubes to secure the airway. These tubes are either endotracheal tube (ETT) or tracheostomy tubes (TT).

However the use of these tubes is reported to be associated with incidence of adverse airway events such as unplanned extubation(UE), tube blocking, tube displacement, Endobronchial intubation, tube kinking and leaking cuffs(1,2)

Unplanned extubation (UE) is one of the most common air way adverse events that occur in the ICU. This was defined as unplanned removal of tracheal tube that is not intended by the health care provider and was further classified as accidental extubation or self extubation (SE)(3).

Accidental unplanned extubation occurred mainly during routine ICU procedures such as patient change in position, suctioning of the patient, physiotherapy and radiological procedures. Self extubation in the other hand occurred mainly on patients with high level of consciousness. Discomfort from trachea tube such as pain and delirium are some of the reason they were self extubate themselves.(4)

Unplanned extubation is likely to lead into hypoventilation and desaturation which in turn causes increased morbidity to the patient and therefore long hospital stay.(5) However airway adverse events due to accidental extubation is likely to require re intubation compared to those due to self extubation.(1,5–7)

Tube blocking occurs mainly due to impaction of thick mucus or blood to the tracheal tube, however it can also occur as a result of biting or kinking of the tube(2,3,6,8). Tube blocking can be partial or complete .It may be suspected if suction catheter passes with difficulty

through the tracheal tube or any difficulty is encountered on ventilating the patient. The mechanical ventilator will be alarming for high airway pressure.

Long duration of tracheal tube stay is associated with increased risk of tube blocking(2,8). The use of heat and moisture exchanger (HME) has been reported to reduce the incidence of tube blocking.(9) Some diseases processes such as tetanus infection are associated with high rate of secretion production which in turn increases chance of getting blocked tubes. Therefore tube blocking is reported more often in medical patients compared to surgical ones.

Other airway adverse events such as tube displacement are diagnosed by visualization of tip of the ETT outside the vocal cords on direct laryngoscope. This is also associated high tidal volume leak and poor chest expansion on mechanical ventilator.(6)

Tube kinking is diagnosed by direct visualization of the tube and is also associated with high airway pressure on mechanical ventilation and failure to pass the suctioning catheter. Endo bronchial intubation is suspected if there is unequal chest expansion during ventilation and can be confirmed by auscultation of the chest.

Although all these airway adverse events can have detrimental effect to the patient's condition, studies have shown that the most common ones are unplanned extubation and tube blocking. If intervention is not done on time they may lead to hypoventilation and hypoxia and eventually cardiac arrest.(1,5)

The incidences of airway adverse events ranges between 0.3 to 30 % for intubated ICU patients in which unplanned extubation plays a big role followed by tube blocking. Other airway adverse events such as leaking cuffs, endo bronchial intubation and tube kinking are reported in lower rates.

All these adverse events are capable of causing serious morbidity to the patient which in turn may lead to long hospital stay. Early intervention and adherence of ICU protocols on airway management can reduce the severity. No study has been done at MNH to assess the incidence, associated risk factors and outcomes of these adverse events.

Patients care by ICU staff involves making sure the airway is patent and appropriate level of sedations and analgesia are given. To reduce the rate of these airway events on patients, various protocol have been put forward at Muhimbili National Hospital.

The daily endotracheal tube care makes sure that these adverse airway events and other tracheal complications are avoided. The ETT case involves monitoring of cuff pressure to avoid leaking, oral and endotracheal suctioning to avoid blockade and tube securing technique to avoid tube displacement

The ETT cuff provides a seal between the ETT and the tracheal wall to ensure that accurate delivery of tidal volume during mechanical ventilation is achieved. Over inflation and under inflation can have damaging effect to the patient such as mucosal necrosis and low tidal volume delivery respectively. Therefore cuff pressure must be adequately set to avoid these complications.(10)

Suctioning and oral care is an important aspect of preventing ETT –associated infections and mucus plugs which can lead to tube blocking. Since intubated patient cannot cough and clear their own lower airway secretions, patient are suctioned regularly via ETT/TT using a sterile technique that should have a sealed technique to reduce contamination. (11)

When a patient is in supine position in whom swallowing reflexes is impaired nasal and oral secretions collect posteriorly and therefore regular oropharyngeal suctioning is needed. This is done manually with oral suction catheter.

Medical adhesive tape is used to secure the ETT at the level of the lip, usually one side of the mouth. Occasionally, the tape needs to be replaced when it loses adhesive properties e.g. due to drooling. The tube is rotated daily to avoid pressure induced ulceration.

Sometimes use of commercially available securing devices (ETT holders) which mechanically secure the ETT without the use of tape. Some ICU use both holders and tape especially in those patients considered high risk of displacement.

Some ICUs use piece of gauze and medical tape to secure these tubes. This is more common in those areas where they cannot afford the commercially available tapes and this is the common practice at MNH.

Patients with tracheal tubes have their upper airway bypassed whose role is to filter, warm, and humidifies the inspired air. Administration of cold and dry inspired air puts a patient into risk of tube blockade through formation of thick secretions among other complications. The use of Heat and Moisture Exchanger (HMEs) devices protect patients from formation of such secretions and therefore tube blockade.

Outcome of airway adverse events can be fatal if not recognized and intervened early. The use of capnography as one of the monitoring tool in all ventilated patients can detect such events instantly and therefore early intervention.(12,13)

Following airway adverse events, securing a patient airway through re intubation can be challenging. This is due to high possibility of difficult airway as it is edematous and their oxygen reserve is limited from their illness. Therefore any delay in intervention either due to presence of unskilled personnel or difficult intubation can lead poor outcome.

Protocol of air way care at MNH

An ETT bypasses the upper airway mechanism that warm, humidify and filter the inspired gas into the lower respiratory tract. In addition the ETT is the foreign body and over time will produce additional secretions.

Suctioning of ETT was done based on clinical findings such as oxygen desaturation, bradycardia, audible crackles on auscultation, obvious secretion on the tube and decreased chest movement.

Low pressure- high volume cuffs polyvinyl chloride ETTs were used and are secured using bandage or medical tapes to prevent displacement. Depth of the ETT is marked so as to avoid endobronchial intubation .Tracheostomy tubes are secured with bandages which are tied around the neck.

Sedation of patients on mechanical ventilators is individualized; however various drugs are used to sedate them. Commonly a combination of midazolam and fentanyl is used. Other drugs used are diazepam, propofol , morphine, pethidine and some time muscle relaxants such as atracurium is added.

Patients on weaning process and aware of the surrounding are explained not to remove the tracheal tube since their level of sedation is light. However arm and leg restraints are used some time to agitated and confused patients until they are either calm and understand or sedation is re instated.

Heat and Moisture Exchange with or without microbe filters are used if available to all patients on mechanical ventilators; otherwise they are not used at all.

Staffing of medical ICU

The nurses work in two shifts which are day shift and night shift. Dayshift starts from 07.30 to 18.00.There is an anesthesiologist and a physician on call everyday and one resident from anesthesia department plus one intern doctor. There is no intensivist at MNH.

The nurse to patient ratio during daytime is 1:1. However during night shifts the ratio is unpredictable but it is always less than day shift.50 % of nurses are degree holders whereas 50% are diploma holders

One physiotherapist does an ICU round to those patients in need and radiographers only come when they are consulted.

Staffing of surgical ICU

They have the same shift and staffing as in medical ICU, however surgeons not physicians are also involved in management of these patients such as wound dressing.

Severity of airway adverse events (adopted from National Patient Safety Agency(13)

Severity of outcome scale: from National Patient Safety Agency

Grade of severity	Description
None	No harm(whether lack of harm was due to prevention or not)
Low	Minimal harm , but necessitating extra observation or minor treatment*
Moderate	Significant but not permanent harm or moderate increase in treatment**
Severe	Permanent harm due to incident***
Death	Death due to the incident

* First aid addition therapy or additional medication. Excludes extra stay in the hospital, return to surgery or re admission

**return to surgery, unplanned re admission, prolonged episode of care as in or out patient transfer to another area such as ICU

***permanent lessening of bodily functions, sensory, motor, physiologic or intellectual

The intent of this study is to examine the prevalence of airway adverse events and associated risk factors for intubated ICU patients at MNH

1.1 Review of Literature

Incidence of airway adverse events

Most studies on adverse airway events have been focusing on unplanned extubation of ETT or tracheostomy related problems.(1)

The incidences of airway adverse events in intubated ICU patients have been reported to range between 0.3 to 30% from various parts of the world. (2,9)One explanation for these variations was that the calculation for the frequency of these adverse events took the number of intubated patients, but not the days at risk. (14) This was significant since the number of intubated patients did not take into account for those patients with more than one episode. (15)However for ETT group no statistical significance was found between total number of airway accidents per total number of patients and airway adverse events per total number of intubation days.(6)

There were many patterns of these events such as unplanned extubation, tube blocking, tube kinking, leaking cuffs, and endobronchial intubation. However unplanned extubation had been studied extensively and its incidence lies between 0.3 t0 30%.(5,6,8,15)In most studies, UE incidence per intubated patients ranged between0·5% and 14·2%, with the exception of two studies which reported a 22·5% and a 33·3% incidence .(15)(16,17)

Much narrower range was observed when UE incidence is calculated per 100 intubation days, between 0·3% and 4·2%, with the exception of one study reporting a 35·8% incidence .(15) However blocked tube were found to be the most common airway adverse events in one study.(1) High number of blocked tube events was attributed to non use of HMEFs since they could not be afforded during that study

The incidence of airway adverse events in patients with tracheostomy tube was found to be similar to ETT group. However the incidence was found to be higher in ETT group per Tube days compared to tracheostomy group(1.3% versus 0.9%)(1). One study found that there was no statistical significance between adverse events in patients with ETT and patients with

tracheostomy in terms of total accidents per tube days and total events per total number of patients.(6)

Patient related risk factors

Agitation was the most patient related factor associated with UE.(4,17,18) And was more common in self- extubation.(15) Patients with high level of GCS of 9-15 points also had high rate of self extubation.(15) These patients were likely to cause tube biting and this could lead to tube kinking and blocking as well.

Male gender patients and patients with delirium were likely to develop SE and tube displacement. Again two studies had shown that previous UE episodes and hospital-acquired adverse events, such as adverse drug reactions or hemorrhage had been reported as significant determinants for UE. (15)

Airway adverse events due to UE had been identified to be significantly more common in surgical and chronic obstructive pulmonary disease .(4,5,15). However patients with COPD were also associated with tube blocking, since they stayed on mechanical ventilators for long time.

ICU staff- related factors

Routine ICU activities such as oral care, change of patient positions, physiotherapy services , and some radiographic procedures were associated with accidental extubation(2,5,17). However low number of nurse to patient ratio and presence of inexperienced nurses contributed to SE.(15)

With regard to ICU staff shifts, high number of accidental extubation was observed more during day time shifts since there various activities being done on patients.(2,15)However SE and tube blocking was observed more during knight hours since the number of surveillance was low and therefore even level of sedation and suctioning was inadequately given.(1,5) Another explanation could be high risk of delirium because of lack of day light and relative's visits.(15)(19)

Physical restraints

Self-extubation prevention has been reported as the primary reason for using physical restraints in European ICUs.(15) At the same time, critical care clinicians considered lack of restraints as the most significant risk factor for UE. While not adequately restrained agitated patients were significantly more prone to self-extubation.(4) However, the effect of restraints on self-extubation prevention had been challenged. Significantly higher self-extubation incidence has been reported in restrained patients .(15)While in countries where restraints are minimally used, self- extubation incidence is relatively low.(15)

On the other hand, restraint use evoked or worsened agitation and delirium, thus resulting in increased self-extubation risk. This explanation was supported by the higher delirium risk among patients whose restraint application preceded delirium manifestation.(20)(21)

It was important to know that head-up position, a 30◦ elevation of the bed head, brought patient's hands closer to the tube, thus increased self- extubation risk despite restraint use. (22)Although this position was beneficial for avoiding aspiration, promoting ventilation and decreasing risk for ventilator-associated pneumonia its use was to be balanced with increased self-extubation risk.(15)

Wrist restraints could also be followed by physical and psychological adverse effects for patients, mainly hypertension, tachycardia, impaired circulation, nerve injury, pressure sores and post-traumatic stress disorder and therefore strong patient surveillance was recommended during their use.(15)

Sedation level

The discomfort patient could experience while intubated was a major indication for sedation.(15) Moreover patients with low level of sedation had been associated with high degree of self extubation .(2,15,16,23). On the other hand, it was considered as a double sword since it could lead to delayed weaning of patient from mechanical ventilator and therefore put a patient at a risk of prolonged intubation, ventilator associated pneumonia(VAP) and therefore risk of tube blocking (24)

On basis of administered doses of sedatives, sedation level can be difficult to determine because of simultaneous administration of multiple medications and considerable differences in drug metabolism among ICU patients. (15)

Sedation- agitation scales (such as Richmond Agitation-Sedation Scale, Ramsay Sedation Scale and Motor Activity Assessment Scale) have therefore been used for grading sedation depth and titrating sedation to avoid over- sedation along with preventing adverse consequences of agitation .(15,25)

The use of a sedation protocol based on Modified Ramsay Sedation Scale was reported to decrease self-extubation incidence from 7% to 3% within 1-year period, by effective agitation management .(15) However, goal-directed sedation based on sedation- agitation and pain scales, despite resulting in decreased time to extubation, was followed by increased long stay to mechanical ventilators which in turn put a patient into risk of VAP and tube blocking.(12)

The majority of self-extubations occurred during the weaning period reflected the effect of progressive sedation.(15)

Use of HMEs

Use of HME in intubated ventilated ICU patients is associated with increased reduction of episodes of tube blocking. HMEs have been reported to provide humidification to the inspired air with no occlusion for 48 hours to 7 days without changing the filter.(1) However, their use was associated with increase of dead space and they are expensive and therefore low setting ICUs were not capable of affording them.

Tube fixation and route of intubation

Endotracheal tube stabilization was necessary for avoiding displacement. Materials, such as tapes, gauges and tube holder devices, but also different taping methods, have been used for securing the tube and providing fixation durability .(15) Lack of strong tube fixation (e.g. with only thin adhesive tape) had been significantly associated with increased UE incidence.

However, clinical studies had not confirmed the superiority of any taping method used or of any single fixation material in preventing tube movement or accidental extubation except for waterproof cloth.(15)

Because of the high mobility of the orally placed tube, lightly sedated patients were able to move the tube with their tongues, by strongly coughing and by extending or flexing their heads.(26)

Outcome of airway adverse event

This depended on the patient's primary diagnosis and co morbidities, very sick patients such as ASA 4 patients were unlikely to tolerate the event compared to ASA 1 patients. However the duration of the event prior to intervention matters a lot(27)(28). Patients who got adverse events while receiving lower fraction of inspired oxygen were able to tolerate the event for sometime compared to those who were above 60% FIO2

Extubation with the tube cuff inflated was likely to injure the larynx followed by severe hemodynamic or airway complications, including hypotension, arrhythmias, bronchospasm, aspiration and laryngeal bleeding or oedema.(15)

Difficult re-intubation after UE, defined as multiple attempts or the need for fiber optic bronchoscope use, may reach up to 20% of cases .(15) UE has been associated with significantly increased risk for hospital-acquired pneumonia.(15)

However SE usually occurred in patients planned for elective extubation in the next few hours and therefore they are much less dangerous accidental cases. (6)As many patients of this group were able to breathe spontaneously; SE actually decreased duration of weaning and intubation.

Re-intubation incidence after UE varied considerably among studies, ranging between 28·5% and 74·7% .(15) However reintubation incidence within 72 hours of planned extubation did not exceed 14%, highlighting the importance of terminating mechanical ventilation in a planned manner. Re-intubation was mandatory for the majority of accidental extubation, blocked tubes and leaking cuff cases, mainly for ensuring airway protection. On the contrary,

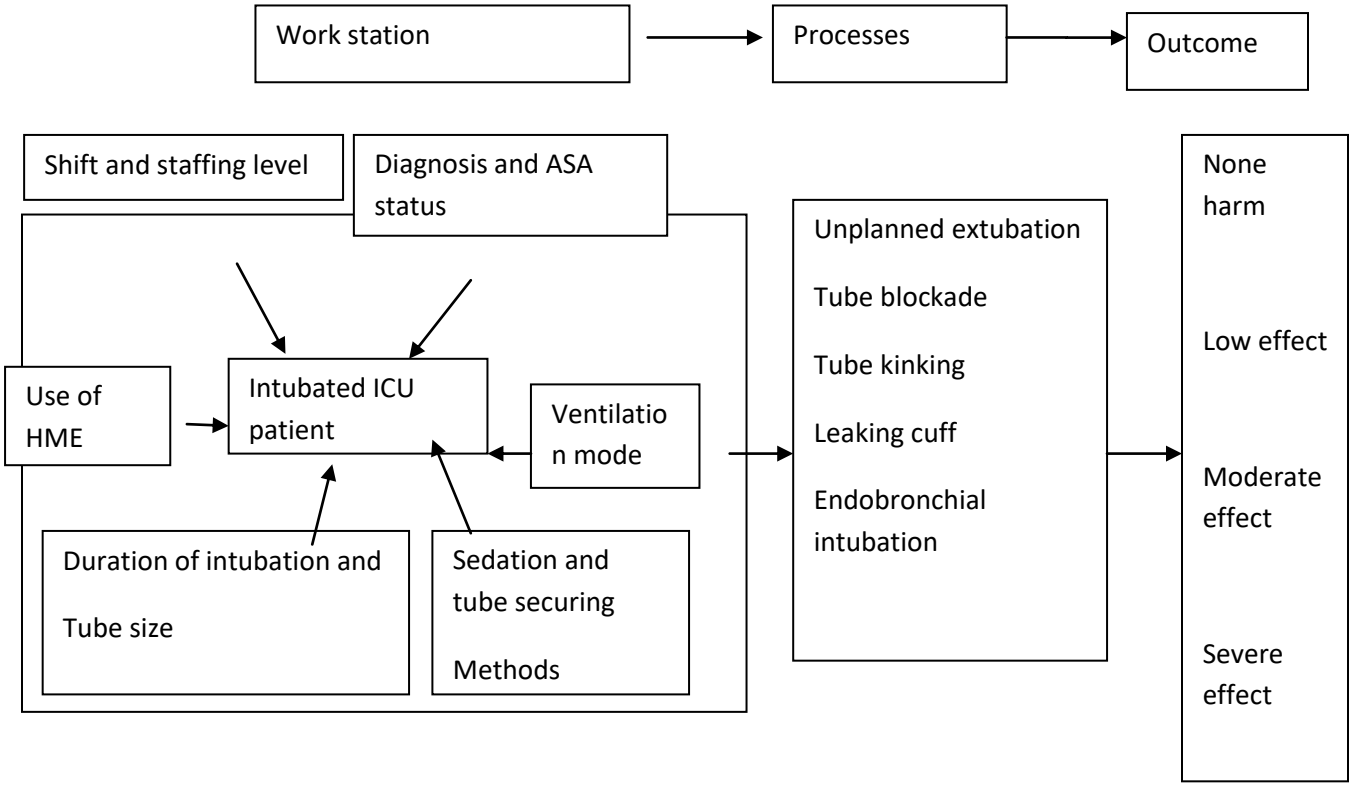
re-intubation incidence after SE did not exceed 45%, with respiratory insufficiency being the primary indication .(15)

The outcome of UE primarily depended on the need for re-intubation. Re-intubated patients demonstrate up to seven times higher ICU mortality rates or Hospital acquired pneumonia compared with those who successfully tolerate UE .(5)

Re intubation was necessary for patients whose tracheal tubes have blocked kinked or leaking cuff since they were still ventilator dependant.

Generally intervention was done in time and therefore very few cases had lead to serious complication like death.(9)

1.2 Conceptual Framework



This conceptual framework was adopted from a study S. Cook et al, 2017 and modified by Dr Lukansola Makubula and was separated into three parts as follows

Work station- This looked into factors that an intubated patient is exposed to and therefore played a role on leading into adverse airway events.

Tube size and duration of intubation

Sedation

Tube securing method

Nursing shifts at which the adverse event occurred

Staffing levels of both medical and surgical ICUs

Diagnosis and reason intubation of the patient

ASA status of patients

HMEs use.

Processes- This looked into patterns of airway adverse events as primary outcome. They included.

Tube blockade

Unplanned Extubation

Tube kinking

Leaking cuff

Endobronchial intubation

Outcome of airway adverse events-This looked into outcomes following an incident of airway adverse event, they were the secondary outcomes

None harm- No harm (whether lack of harm was due to prevention or not

Low effect- Minimal harm, but necessitating extra observation or minor treatment

Moderate effect- Significant but not permanent harm or moderate increase in treatment

Severe effect- Permanent harm due to incident.

1.3 Problem Statement

Various studies have shown the incidence of airway adverse events in intubated ICU patients ranged from 0.4 to 30 %. Patterns of these events included unplanned extubation, tube blocking, endobronchial intubation, tube kinking and leaking cuffs. However the most common ones were unplanned extubation and tube blocking.

These events were catastrophic to intubated ICU patients, due to the fact that these had already debilitated from their primary disease conditions. Also airway management was difficult due to already developed physiological response to the disease condition and management they are receiving.(5)Yet any delay in recognition and intervention of any of these events led to poor patient outcome from primary diagnosis.(6)

In a pilot study done at Muhimbili National Hospital's ICUs, which has a total of 14 ventilator enabled beds and serve for both medical and surgical patients. 3 episode of unplanned extubation were reported out of 20 intubated patients in duration of 2 weeks. One of them got 2 episode of unplanned extubation and died from the primary diagnosis.

No such study had been done in any Tanzanian Intensive Care Unit as one of the low resources setting thus there is no baseline information for comparisons purposes.

This study aimed at determining the incidences of these airway adverse events, their associated risk factors but also the outcome. I proposed to do it at Muhimbili National hospital ICUs.

1.4 Rationale of the study

Although the use of tracheal tubes were mandatory for advanced airway support in intensive care patients. Their uses were associated with various airway adverse events such as tube blocking and unplanned extubation among others. Depending on the primary condition of the patient and the duration to which the event lasted before intervention, these events could lead to catastrophic effect on patients such as cardiac arrest, hypoxic brain injury. This in turn could lead to long hospital stay and poor outcome and even death.

Also due to poor general condition of intensive care patients from their primary illness, airway edema from ICU management, these patients were not able to tolerate any airway compromise. However restoration of patent airway in terms of re intubation could be challenging due presence of edema and therefore risk of difficult intubation was very high, yet intervention was needed without delay.

The findings of this study were intended to identify the magnitude of these airway events, their associated risk factors and the catastrophic effect they imposed on the affected patients. These findings could be used on setting new guidelines for airway care of intubated intensive patients. This could help on the reducing the magnitude of these events and therefore improve health care. This study also served the role for fulfilling requirement of MMed degree at MUHAS.

1.5 Research Questions

Are intubated intensive care patients at Muhimbili National Hospital at risk of airway adverse events?

Are there any associated risk factors for these airway adverse events?

What are the outcomes of patients following incidences of airway adverse events?

1.6 Objectives

1.6.1 Broad Objective

To determine the incidences of airway adverse events, associated risk factors and outcomes in intubated Intensive care patients admitted at Muhimbili National Hospital.

1.6.2 Specific Objectives

To determine incidences of airway adverse events among intubated intensive Care Unit patients for a period of six months..

To determine the pattern of airway adverse events in intubated Intensive Care Unit's patients.

To determine the associated risk factors for airway adverse events in intubated Intensive Care patients at Muhimbili National Hospital

To determine the outcome of these airway adverse events.

CHAPTER TWO

2.0 METHODOLOGY

2.1 Study Type

Prospective observational cohort study was conducted.

2.2 Study Area

This was done at Muhimbili National Hospital‘s medical and surgical ICUs. The hospital is located in Dar es Salaam, in Tanzania which is the largest city in the country. The hospital is also as teaching center for MUHAS and is considered as the centre of Excellency in Tanzania. MNH is a 1500 bed capacity hospital with three intensive care units which has a total of 14 ventilator enabled beds.

There was a general surgical ICU, which has 6 ventilator enabled beds and admits any surgical cases. This includes pediatric surgical cases.

There were two ventilator enabled beds in obstetrics ICU which was admitting only obstetrics cases

Medical ICU also had a capacity of six ventilator enabled beds and it was admitting all non surgical cases.

2.3 Study Population

All intubated patients admitted to both medical and surgical ICUs between August, 2017 and March 2018 were enrolled. Patients were followed up till the day of extubation either due to improvement or death.

2.3.1 Inclusion Criteria

All intubated ICU patients with more than four hours of intubation

2.3.2 Exclusion Criteria

None intubated ICU patients

Patients whom couldn't get proxy consent

Intubated patients who lasted less than four hours with endotracheal tube.

2.4 Sample size

All intubated patients with more than four hours of intubation admitted to both medical and surgical ICU at Muhimbili National Hospital were enrolled in this study. However the minimum sample size was calculated from a study done by Aprna c; et al, 2003. Where by the incidence of adverse airway events among short term (considered as unexposed and long time intubated patients (considered as exposed) was found to be 4.02% and 32.14% respectively . where the ratio of exposed to un exposed was 4:1. With confidence interval of 0.95, desired power of 0.8.

Using software epi info statistical calculator (sample size for cohort), a minimum sample size of 83 patients was required in total.

2.5 Sampling

All intubated ICU patients were involved.

2.6 Description of study stool

A structured quantitative data collecting form was formed. This form was updated daily from day of admission of patient to ICU till day of discharge. The form was filled by selected nurses in the ICU every morning. Information filled included baseline patient information, factors relating to risk of airway adverse events and was updated every day. For those patients whom the events occurred , addition information such as type of airway adverse event, nursing shift to which it occurred and frequency to which it has occurred were recorded .Also severity to which the event lead to and whether the patient was re intubated or not were also recorded.

2.7 Variables

Outcome (dependent) variables were airway adverse events and the outcome of the adverse events.

Independent variables were be tracheal intubation and risk factors for airway adverse events.

2.8 Data collection and analysis

For every intubated patient in the ICU, a form was filled by a trained nurse or resident .Forms were updated daily during patient stay with tracheal tube. Univariate analysis was used for characteristics assessed which was considered as categorical and were expressed as proportions with their corresponding percentage. The association between the independent variables and dependent ones were tested by Chi square test. The association was considered statistically significance if p value is less than 0.05

The information gathered was entered into the computer system using Statistical Package for Social Scientists (IBM-SSPS) software version 20 for data analysis.

2.9 Ethical Clearance

The ethical clearance for this study was sought from the Muhimbili University Science and allied sciences' Institutional Review Board (IRB) ethical review committee. Proxy consent was sought from next of kin. Adequate information was provided to the next of kin and their right to withdrawal from study and how doesn't affect the management of the patient. The information gathered was confidential and no names or file numbers of the patient that was involved. The Director of MNH was consulted to give permission for study conduction.

2.10 Study Limitation

It was anticipated that some of the ICU staff may not provide accurate information since it may be binding them directly. To overcome this, there was no identification of either a patient or staff involved in this study, therefore there was no pointing of fingers to each other

Time for the study was not long enough, this is due to the fact that bed capacity for ICU is just 14 beds and therefore, much time was needed to come up with big sample size.

2.11 Dissemination of results

Upon final analysis a manuscript was prepared and submitted to relevant journal for publication.

2.12 Confidediality issues

The information gathered in this study was very sensitive; therefore patient identification was not exposed on study's report. Results were presented as proportion or percentages**.** Access to collected data was limited to member of the study**.**

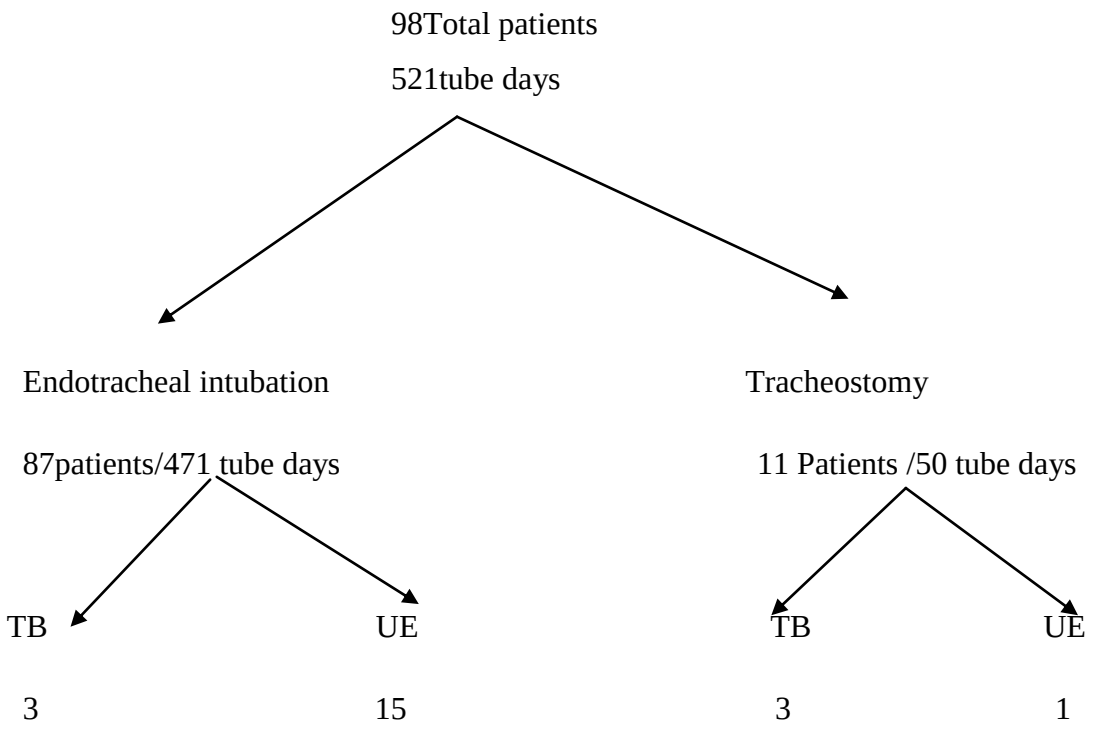
CHAPTER THREE

3.0 RESULTS

Incidence

This study enrolled a total of 98 patients with 521 tube days whom required respiratory support through either endotracheal intubation or tracheostomy for a period of 5 months. Details of patients are shown on figure1. During this period there was a total of 22 airway adverse events with an incidence of 22.4% of patients and incidence density of 4.2/100 tube days.

Figure1: The study population and airway accidents



TB; Tube Blockade, UE; Unplanned Extubation

Table1: Overall incidence of airway accidents

	Airway adverse events No of patients (Tube days)	Incidence (% of patients)	Incidence (per 100 tube days)
Total	22/98 (521 TDS)	22.45	4.22
ETI	19/87	21.83	4.03
TR	3/11	27.27	6.00

Patterns of airway adverse events

Unplanned extubation and tube blocking were the most common airway adverse events observed. Endobronchial intubation, leaking cuffs and tube kinking were not observed during the study period. More details are shown on table 1.

Unplanned extubations were more common airway adverse events overly with incidence density of 3.07/100 tube days, however blocked tube were observed more among patients with tracheostomy with incidence density of 6.0/ 100 tube days as shown on table 1 and 2

Table 2: Incidence of specific airway adverse events

Specific complication	Total % (n= 22)	I(% patients) (n=98)	I (/100TDS) (n=521)
BT (n=6)	27.27	6.12	1.15
UE (n=16)	72.73	16.32	3.07
TK (n=0)	0	0	0
LC (n=0)	0	0	0
EI(n=0)	0	0	0

BT, Blocked Tube; UE, Unplanned Extubation; TK, tube kinking; LC, Leaking Cuff;EI, Endobronchial

Associated risk factors for airway adverse events

As shown in table 3; patients with endotracheal tube less than 5mm internal diameter were likely to get un planned extubation (p=0.03) compared to bigger size.

Tube blockade among medical patients was found to be 15.8% compared with their surgical counterpart 6.1% (p=0.02)

Unplanned extubation were also observed more during day time shift for ICU nurses 75% compared to 15% of tube blockade (p=0.03) , However tube blockade were observed more during night shift compared with unplanned estuation (p=0.03)

There was no much significance difference in term of tube blockade among those who used HMEs and those who did not 3.6% compared 7.1% respectively (p=0.67)

The rate of blocked tube among patients with long intubation time was 7.0% compared to 6.1% in short intubation time. This could be due to frequent suctioning and nebulization of these patients by the ICU nurses. At the same time the rate of unplanned extubation was 25% in short intubation time patients compared to 14% of long time intubation which may indicate that there is a delay of patients weaning from mechanical ventilators.

The rate of unplanned extubation among sedated patients was 25% compared to 10.2 % in non sedated. The high rate in sedated group could be due to accidental extubation during routine ICU procedures. But also the ability to comply with commands in the non sedated group played a role to why their rate was low.

Table 3: Individual airway adverse events per associated risk factors

		Unplanned extubation	P vale	Tube blockade	P value
Associated risk for airway adverse events					
HME	Yes	17.2	0.72	3.6	0.67
	No	14.2		7.1	
SEDATION	Yes	23.1	0.09	0	0.79
	No	10.2		10.6	
DI	STI	25%	0.38	7.0	1
	LTI	14%			
				6.1	
ETT SIZE	< 5	42.9	0.03	0	1
	>5	13.2		6.4	
DIAGNOSIS	SURGICAL	45	1	6.1	
	MEDICAL	45.8		15.8	0.02
AIRWAY DEVICE	ETT	16.5	0.59	3.3	0.04
	TR	0		42..2	
NURSING SHIFT	DAY	75	0.03	45	0.03
	KNIGHT	50		75	

Outcome of the airway adverse events

Of the 22 cases with adverse airway events, 8 needed immediate re intubation which is equivalent to 36%. 50% of Patients with blocked tubes needed reintubation compared to 31% of patients who got unplanned extubation.

About 68.2% of patients with adverse airway event got moderate complications whose management involved both residents/registrar on call and nurses. One patient (4.5%) sustained cardiac arrest whose intervention involved the ICU intensivist.

Of the 22 patients, 8(36.4%) patients needed reintubation within the next three hours. This was seen more in patients with blocked tubes 50% compared to unplanned extubation which stand at 31.3%. The main reason for intubation was due to increased work of breathing and low level of alertness, however no major complications were observed apart from one patient who sustained cardiac arrest.

Table 4: Severity of airway events and rate of reintubation

	Mild n (%)	**Moderate n (%)**	**Severe n (%)**	**Re intubation n (%)**
Blocked tube n=6	0	6 (27.3)	0	3(50)
Unplanned extubation n=16	6 (27.3)	9 (40.9)	1(4.5)	5(31.3)
Total n=22	6(27.3)	15(68.2)	1(4.5)	8(36.4)

CHAPTER FOUR

4.0 DISCUSSION OF RESULTS

4.1 Incidence

The amount of airway adverse events can be measured in different forms, however to adequately analyze, the rate of these events was expressed as the number of episodes observed per 100 ventilated days. This model includes the concept of days at risk for airway adverse events and allows comparisons among different ICUs.(5)

The result of this prospective study involving 98 patients who got ventilated for a total of 521 days found overall incidence of 4.22%/100 tube days. This rate is quite high compared to study done by Kapadia which was found to be 1.6%/100 tube days(6). However these findings are lower compared to one study which reported it be 35%/100 tube days.(26) The higher rate in our ICU may due to lower number of ICU nurses especially during night shifts where sometime they depend on nurse interns to care for the ventilated patients. Strict ICU protocols need to be followed up and training of critical care nurses should be given a priority as one of the means of reducing it. However in the future another study with long duration is needed so as to come up with big sample size and assess whether there is any improvement or not.

4.2 Patterns of airway adverse events

Of the 22 adverse events 16 (72.3%) were due to unplanned extubation which mostly occurred in patients with endotracheal tube. Six (40%) cases of unplanned extubation were due to self extubation (SE) while ten cases 60% were due to accidental extubation. This is supported by one study where accidental extubation were reportedly higher compared to self extubation.(5) The increased rate of accidental extubation was contributed by involvement medical personnel with limited knowledge of airway protection during some ICU routine procedures such as physiotherapy and radiological activities. Also presence of large number of nurses in the ICU with limited critical care background had some contribution to this.

The rate of tube blockade was observed more in tracheostomy patients 27.3% compared to patients with endotracheal tube 18%. This high rate among patients with tracheostomy was also observed in a study done by Kapadia(6) . Tube blockade was mainly due to blood clots or thick secretion and it was seen more in patients without HMEs. The large number of these blockades in patients with tracheostomy was contributed by non use of HMEs in this group of patients due to their unavailability and lack of nebulization. The use of HMEs and routine nebulization of these patients are recommended so as to reduce them. Again more time for study is needed to come up with a big sample size in the future.

Despite the large number of patients being able to be nebulized in the ICU, the low number of tube blockade among patients with ETT was also contributed by underreporting of these events by the ICU nurses. This is due to the fact that they were bound to standard of care meaning that a nurse whose patient had tube blockade was considered to have had not done suctioning on time.

Other airway adverse events such as tube kinking, Endobronchial intubation and leaking cuff were not observed during a study period. For the case of leaking cuffs this may be contributed by the fact that cuff pressures are not routinely checked by the nurses , the availability cuff pressure measurement devices are not always assured. However staff knowledge on how to use these devices is limited and therefore it's not considered as routine.

Cases of endobronchial intubation being corrected without documentation is the main reason why were not noted during this study. However marking of tracheal tube with medical tape at the correct depth which was to be observed at the angle of the mouth, made easy for nurses to know whether the ETT is too deep so that it can be pulled back. This technique has improved the quality of care and it can easily be noted by even inexperienced nurses.

4.3 Associated risk factors for airway adverse events.

Patient diagnosis

The study found that the rate of unplanned extubation among surgical and medical patients were equal 45%. These findings differed from a study done by (de Groot et al.,2001) which

reported the rate to be higher among surgical patients 2%.(4) . However the rate of unplanned extubation in our ICU is still high compared to other studies and this may be explained by delayed weaning from mechanical ventilation and limited knowledge of critical care services among many ICU nurses.

Tube blockades were observed more in medical patients 15.1% compared to surgical ones 6.1% (p=0.02). This may be due to unequal distribution of nurses among these ICUs since they were working independently during study period. However long intubation time among medical patients and less adheherence of ICU protocol by less experienced nurses contributed to this. More studies with large sample size therefore long study period need to be done as 50% of tube blockade were due to tracheostomy of which their total numbers were just 11 cases.

Tube fixation

Endotracheal tube stabilization is necessary for avoiding displacement. The rate of unplanned extubation among those whose ETT was secured using medical tape only, used gauze only or both (medical tape and gauze) didn't differ significantly. This findings differs from study done by (Boulin et al,. 1998) which found an increased rate of tube movement which could lead into unplanned extubation among patients whose tubes were secured with medical tapes only(26). Clinical studies have not confirmed the superiority of any taping method used or of any single fixation material in preventing tube movement or accidental extubation(15).

This also was explained by the fact that during weaning period patients were not deeply sedated .Therefore were able to push the oral endotracheal tube by the tongue or during coughing and this lead into unplanned extubation. Tube marking through application of tape at the required depth made it easy to be noticed even by medical personnel in training and this led to low rate of events due to fixation. However more studies specifically looking at the effect of tube fixation technique on unplanned extubation should be done.

Nursing shifts

The rate of unplanned extubation was seen more during day shift compared to night time (p=0.03). This was also observed in one study done by(Bauza et,al 2001) (5) and may be explained by the fact that there are a lot of activities in the ICUs during day time such as patient change in position, physiotherapy and radiological activities which could put the intubated patients into risk of accidental extubation. The nurse patient ratio during day time was about 1:1 plus other medical personnel who are usually in daily activities in the ICUs. However the ratio at night was quite variable and usually less than that of daytime.

Tube blockade were observed more during night shift (p=0.03) which is explained by low number of nursing staff and therefore reduced surveillance , infrequency suctioning and lack of nebulization due to nurse fatigue. This was determined through failure to pass a catheter during suctioning, difficult on manual ventilation plus increased airway pressure on mechanical ventilation.

Sedation

Sedation depth is difficult to determine on the basis of administered doses of sedatives, because of simultaneous administration of multiple medications and considerable differences in drug metabolism among ICU patients(5) . Goal-directed sedation based on sedation-agitation and pain was used.

This study found that the rate of unplanned extubation among sedated patients were 23% compared to 10.2% in non sedated patients (p=0.09). the findings were high compared to a study done by (Bouza etal., 2007) which was reported to be lower(5). However their ICU settings which included involvement of relatives in taking care of these patients in the ICU are quite different from ours. ICUs in East Africa which has the same settings as ours have never conducted such studies. High rate among sedated patients were contributed by accidental extubation by health workers and this mainly during routine activities. It occurred also during weaning period in patients who were less following nursing directions and therefore were prone to getting self extubation. Unlike the sedated patients, most non sedated patients were

able to follow commands and this could explain why they were associated with low frequency of unplanned extubation.

All tube blocked occurred in non sedated patients which was found to be (p=0.76). This may be inadequate rate of suctioning and the non use of HMEs.

Use of physical restraints

The rate of unplanned extubation among patients with use physical restraints was 19.6% compared to 10.6% in patients without restraints. These findings were supported by other studies that have shown that physical restraints don't reduce the rate of unplanned extubation(26,29). This is due to the fact fixation of the wrists and legs does not prevent movement of head, tongue and coughing which plays a big role on leading to unplanned extubation.

Type of Airway devices

The rate of blocked tube among tracheostomy patients was found to be 42% compared to endotracheal tube patients3.3% (p=0.04) .This increased rate among tracheostomy patients was also reported by Kapadia., 2001)(6). This may be due non routine use of HMEs among tracheostomy patients and non strict adheherence to ICU protocols due to presence of inexperienced ICU staffs. Strict ICU protocols need to be followed up even to junior/inexperienced staffs so as to reduce this rate in the future.

ETT size and use of HMEs

The rate of unplanned extubation was seen more in patients with endotracheal tube size 5mm ID and below 42.9% compared to bigger sizes 13% (p=0.03) . This may be explained by the fact that these were pediatrics patients who are less likely to follow directions from ICU staff due to anxiety. There were no significance findings in terms of tube blockade among patients using HMEs and those who did not. This may be due to lower number of HMEs users due to their inadequacy and therefore were not used continually.

4.4 Outcome of the airway events

Of the 22 cases of airway adverse events, only one case 4.5% was regarded as severe after sustaining cardiac arrest following unplanned estuation**.** CPR was done on this patient and was able to recover into stable cardiopulmonary clinical paramaeters. The remaining cases did not get any serious complications. This low rate of serious complication was also supported by two studies(5,9). Availability of two intensivist in these ICU recently and ease accessibility of anesthetists for airway care in case of any emergency has played role on avoiding catastrophic effects of these adverse events.

The rate of reintubation after these airway adverse events was 36.4% such findings were also reported by other studies which reported it to be between 28·5% and 74·7%(5,15,26). The rate of re intubation among tracheostomy patients was 50% compared to 31.3% in patients with endotracheal tubes. This may be due to the fact that the non use of HME (due to unavailability) and lack of nebulization among these patients facilitated formation of thick secretions which could easily block the lumen. Because of airway adverse events from patient with tracheostomy are associated with severer outcome compared to endotracheal tube patients.

4.5 Study Limitations

1. Some airways adverse évents may not have been reported by nurses especially tube blocking due to reduced survaillance at night and therefore failure to notice them
2. During time of study total number of Ventilated enabed beds in the ICU were just 14 of which some patients were occupying them for a long time. This lead to low number of study participants.
3. At the beggining of the study there were no intensivists in both ICU, later on the hospital employed two of them during a study. They may have led into change in outcomes of airway adverse events.

CHAPTER FIVE

5.0 CONCULUSION AND RECOMMENDATIONS

5.1 Conclusion

The study concluded that rate of airway adverse events in intubated patients in ICU is high compared to other ICUs. This is contributed more by inadequate nurse staff especially at night shifts and handling of these patients by staff with low critical care training.

Non routine use of HMEs and less number of suctioning in patients with tracheostomy was associated with increase chance of developing tube blockade whereas ETT size less than 5mm was likely to end up with unplanned extubation.

Unplanned extubation and tube blocking were the only airway adverse events which were noted during this study .This was explained by tendency of correcting some critical care incidences without documenting them by critical care staff.

Severity of these airway adverse events is quite low and this may be explained by easily accessibility of airway management personnel from anesthesia emergency department.

5.2 Recommendations

Routine care of intubated patients with a nurse patient ratio of 1:1 should be observed all times. Nurses with critical care training should be the one involved caring of these patients.

ETT protocol should be adhered all times plus documentation of every procedure that takes place in ICU

Daily checking of endotracheal tube cuff pressure and routine use of HMEs should be included among other services which these patients receive during mechanical ventilation.

Introduction of capnography use is recommended in all ventilated patients among other monitoring tools.

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APPENDICES

Appendix I: Data Collecting Form

Baseline patient data	
What was a diagnosis of the patient?	
What was the reason for intubation?	
ASA grade of the patient	
Is the patient on anyinotropes? If yes which ones	
Factors relating to tube and ventilation	
Size of the ETT	
Depth of tube	
Type of ventilation	
Duration of intubation?	
Percentage of oxygen used at a time?	
ETT cuff pressure	
Risk factor of airway adverse events	
HME filter use	
Method of securing the tube Medical tape with/without gauze.	
Frequency of suctioning	
Use of physical restraints	
What sedations were used	
Ramsey sedation scale score when the event occurred	
Factors relating to the airway event	
Type of airway adverse event and frequency	

Self extubation Accidental extubation Blocked tube Tube kinking Endobronchial intubation	
How was the adverse event discovered?	
At which shift did the event occur? Day shift Knight shift	
How was the patient managed	
Who managed the patient(nurse, resident/registrar or a specialist?	
What were the consequences of the event?	
What happened to the patient? (no adverse effect, hypoxic brain damage, cardiac arrest or death?)	
How long has it taken to re intubate the patient	

Appendix II: Ramsay Sedation Scale

Ramsey Sedation Scale

If Awake

Ramsey 1
Anxious, agitated, restless

Ramsey 2
Cooperative, oriented, tranquil

Ramsey 3
Responsive to commands only

If Asleep

Ramsey 4
Brisk response to light glabellar tap or loud auditory stimulus

Ramsey 5
Sluggish response to light glabellar tap or loud auditory stimulus

Ramsey 6
No response to light glabellar tap or loud auditory stimulus

Appendix III: Severity of outcome scale: from National Patient Safety Agency

Grade of severity	Description
None	No harm(whether lack of harm was due to prevention or not)
Low	Minimal harm , but necessitating extra observation or minor treatment*
Moderate	Significant but not permanent harm or moderate increase in treatment**
Severe	Permanent harm due to incident***
Death	Death due to the incident

* first aid addition therapy or additional medication. Excludes extra stay in the hospital, return to surgery or re admission

**return to surgery, unplanned re admission, prolonged episode of care as in or out patient transfer to another area such as ICU

***permanent lessening of bodily functions, sensory, motor, physiologic or intellectual.

Appendix IV: Consent Form (English version)

CONSENT TO PARTICIPATE IN A RESEARCH ON STUDY TO OF AIRWAY ADVERSE EVENTS IN INTUBATED ICU PATIENTS AT MUHIMBILI NATIONAL HOSPITAL, DAR ES SALAAM,TANZANIA FROM MAY 2017 TO DECEMBER .

Hello

I am Dr. MAKUBULA Lukansola, student of Muhimbili University of Health and Allied Sciences. I am conducting a research to study the incidence and associated risk factors on adverse airway events in intubated ICU patients at Muhimbili National Hospital, Dar Es Salam Tanzania;

From May 2017 to December 2017.

Purpose of the Study

This study mainly three purposes;

1. To determine the incidence of airway adverse events in incubated ICU patients.
2. To determine the associated risk factors for these adverse events in these intubated ICU patients at Muhimbili National Hospital
3. To determine the patterns of airway adverse events in ICU patients.
4. To assess the outcome of these airway adverse events on the affected patients at Muhimbili National Hospital

Participation

If you agree to take part to the study, you will be required to respond to some questions about the patient and his family. If you are not able to respond your relative can answer for you.

Confidentiality

All information that will be collected from you will be treated confidential and will not

Be used for any other purpose other than this study.

Risks

We ensure you that no harm will happen to your relative because of joining in this study. Will not use any invasive device and we will not interfere in planned management by your physicians or surgeons.

Rights to withdraw and alternatives

Taking part in this study is entirely your choice. If you choose not to participate in the study or if you decide to stop participating in the study, your relative will continue to be treated normally. You can stop participating in this study at any time, even if you have already given your consent and if for any reason you would wish to come back into the study after withdrawal, we will be ready to accept you to continue with the study. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which your relative is otherwise entitled.

Benefits

Firstly participating in this study you will contribute to estimate the incidence of airway adverse events in intubated ICU patients at Muhimbili National hospital, Dar Es Salam Tanzania.

Secondly, you will contribute to the knowledge of the risk factors of adverse airway events in intubated ICU patients at Muhimbili National Hospital, Dar Es Salam Tanzania. This knowledge can be used to form protocols for reduction in incidence of these events and therefore reduction in their complications

Finally, you will contribute to know the outcome of airway adverse events and their management at Muhimbili National hospital, Dar es Salam Tanzania which will help to improve the safety in all intubated ICU patients.

Who to contact

If you ever have questions about this study, you should contact the following:

Dr. MAKUBULA Lukansola (Principal Investigator)
School of Medicine,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65001, Dar es Salaam.
Mobile phone: +255764 325 377
Dr FREDIRICK MBANGA. (Principal Study Supervisor)
School of Medicine,
Muhimbili University of Health and Allied Sciences,
P.O. Box 65013, Dar Es Salaam.
Mobile: +255 658 288 171

Also, if you will have questions about your rights as a participant, you may callcontact Professor Said Aboud, the chairman of the university senate research and publications,
P.O. Box 65001, Dar Es Salaam. Tel: 2150302-6.

Signature

Do you agree to participate? *Write the word 'Yes' if you agree……..*

I, _____ have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of investigator _____

Date of signed consent _____

Appendix V: Consent Form (Swahili Version)

Habari.

Naitwa DR. MAKUBULA Lukansola mwanafunzi kutoka chuo kikuu cha sayansi ya tiba MUHIMBILI.

Ninafanya utafiti juu ya kiwango ,vichochezi vyake na madhara yatokanayo na kutofanya vizuri mipira ya kupumulia iliyowekwa kooni mwa wagonjwa waliolazwa katika vyumba mahututikatikahospitaliyataifa MUHIMBILI.

Umuhimu wa utafiti huu.

1. Kutambua kiwango cha kutofanya kazi vizuri mipira ya kupumulia iliyowekwa kooni.
2. Kutambua visababishi vya kufanya kazi vizuri kwa hii mipirayakupumulia vya kooni.
3. Kutambua aina tofauti zinazofanya kwa nini hii mipira isifanye kazi yake vizuri.
4. Kutambua madhara yatokanayo na kutofanya kazi vizuri kwa hii mipira.

Kushiriki

Kama unakubali kushiriki katika utafiti huu unaweza kutakiwa kujibu maswali kwa niaba ya ndugu yako ambae tiyari ana huo mpira wa kooni na hawezi kuongea.

Usiri wa taharifa za mshiriki.

Nakuthibitishia kuwa taarifa zote zitakazopatikana kutoka kwako zitatumika kwa utafiti huu tunazitapewa usiri mkubwa sana .Hata jina lako halitatajwa kwenye taarifa wakati wote wa utafiti na hata baadaya utafiti. Kukuhakikishia hilo hata jina lako halitaonekana kwenye fomu ya kuchukulia taarifa zako.

Athari za utafiti huu kwa mshiriki

Hakuna athari au madhara yeyote yatakayo kupata kutokana na kushiriki katika utafiti huu.

Haki ya kushiriki au kuto shiriki katika utafiti huu

Ushiriki wako katika utafiti huu ni wa hiari kabisa .Unayo haki ya kushiriki au kutoshiriki bila kulazimika. Pia unayo haki ya kuhoji chochote, kukataa kuendelea kushiriki/kuacha wa kati wowote utakapo jisikia kufanya hivyo na hakuta kuwa na hatua yeyote itakayochukuliwa dhidi yako au kulaumiwa kwa kufanya hivyo.

Faida ya kushiriki katika utafiti huu.

Kwanza kwa kushiriki katika utafiti huu utakua umesaidia kutambua makadirio ya kiwango cha tatizo la mipira ya kupumulia kutofanya kazi kama ilivyotegemewa katika vyumba mahututi vya hospitali ya taifa ya MUHIMBILI.

Pili utakua umesaidia kuleta uelewa wa vichochezi vya kwa nini hii mipira ya kupumulia isifanye kazi kama ilivyotegemewa katika hospitali ya taifaya MUHIMBILI. Uelewa huu utasaidia kuweka mikakati ambayo itasiadia kupunga tatizo hili.

Mwisho utakua umesaidia kujua madhara yatokanayo na kushindwa kufanya kazi vizuri kwa mipira hii ya kupumulia inayowekwa kooni.

Mawasiliano:

Wasiliana na mtafiti mkuu, DktMAKUBULA lukansola, kwa simu namba -0764325377 au Dkt FREDERIC Mbanga - 255 658 288 171wakati wowote utakapokuwa na maswali au jambo lolote lenye kuhitaji ufafanuzi kuhusu utafiti huu.

Na endapo utakuwa na maswali kuhusu haki yako kama mshiriki unaweza pia kuwasiliana na Profesa Said Aboud, Mwenyekitiwa Baraza la UtafitinaUchapishajiwa Chuo Kikuu cha Sayansi yaTiba Muhimbili. S.L.P. 65001, Dar es Salaam. Simu namba 2150302-6

Mimi,_____, nimesoma/nimesomewa maelezo yote yaliyomo kwenye fomu hii na nimeelewa. Maswali yangu yamejibiwa na niko tayari kushiriki.

Kama unakubali kushiriki andika neno “Ndio” katika nafasi hapa chini_____

Sahihiyamshiriki _____ SahihiyaMtafiti _____

Tarehe _____