IMMEDIATE EFFECTS AND OUTCOMES OF RESPIRATORY PHYSICAL THERAPY ON CRITICALLY ILL PATIENTS IN KENYATTA NATIONAL HOSPITAL INTENSIVE CARE UNIT

Dr. Mercy Wanjiku Kamau (Mbchb)

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DECLARATION

Principal Investigator

I declare that this dissertation is my original work and has not been presented for a degree or any other purposes in this or any other institution. Sections copied from any other source are explicitly identified with detailed, complete and accurate referencing.

Dr. Mercy W. Kamau, MBCh.B.

Mmed Anaesthesia Student

University of Nairobi

Registration Number: H58/87372/2016

Signature……. Date…….

SUPERVISORS' APPROVAL

We hereby declare that we have approved the submission of this dissertation to the Kenyatta National hospital/University of Nairobi board of post graduate studies.

Dr. Timothy Mwiti
MbChB (Moi), Mmed Anaesthesia (UON)
Lecturer,
Department of Anaesthesia
University of Nairobi
Signed……. Date……

Dr. Thomas Chokwe
MbChB, Mmed Anaesthesia (UON)
Senior Lecturer,
Department of Anaesthesia
University of Nairobi
Signed……. Date……

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LIST OF ABBREVIATIONS

ALI-	Acute lung injury
ANOVA-	Analysis of variance
ARDS-	Acute respiratory distress syndrome
CCU-	Critical care unit
COPD-	Chronic obstructive pulmonary disease
CRT-	Continuous rotational therapy
ECG-	Electrocardiogram
ETT-	Endotracheal tube
FLACC scale-	Faces Legs Activity Cry Consolability Pain scale
FRC-	Functional residual capacity
ICU-	Intensive Care Unit
ICP-	Intracranial pressure
KNH-	Kenyatta National Hospital
MHI-	Manual hyperinflation
NRS-	Numerical rating scale
PEEP-	Positive End Expiratory Pressure
RASS-	Richmond Agitation and Sedation Scale
SVO_2-	mixed venous oxygen saturation
UoN-	University of Nairobi
VAS-	Visual analogue scale
V/Q-	Ventilation perfusion ratio
VCO_2-	Carbon dioxide elimination
VO_2-	Oxygen consumption

ABSTRACT

Background

Respiratory physical therapy is an integral treatment intervention and is part of the multidisciplinary approach to the management of critically ill patients in intensive care units all over the world. It is prescribed by medical practitioners, and performed by attendant physiotherapists and nurses. Different techniques - their indications and benefits - have been described in literature. This treatment has adverse effects, therefore, careful assessment and monitoring is recommended to ensure safety.

Study Question

What were the immediate effects and outcomes of respiratory physical therapy treatment on critically ill patients in KNH ICUs?

Study Objectives

The main objective of this study was to describe the effects and outcomes of respiratory physical therapy on critically ill patients admitted to KNH ICUs.

Methodology

This was a prospective observational study, carried out at the KNH main intensive care units. It included critically ill endo-tracheally intubated patients undergoing respiratory physiotherapy. Written consent was sought from the next of kin of the recruited patients. 74 patients were studied.

Results

78.4% of the study subjects were male. Tracheal suctioning was the most common treatment modality applied, followed by vibrations and compressions. 16.2% of the patients received manual hyperinflation and only one patient received ventilator hyperinflation. 71.6% of the patients were sedated. There was an increase in blood pressure (SBP, DBP, and MAP) and heart rate from the baseline immediately after treatment. These changes were not statistically or clinically significant. There was slight elevation of respiratory rates and the tidal volumes immediately after treatment; and at 5, 10 and 15 minutes. The pain scores increased significantly immediately following treatment and declined with time up to 15 minutes.

Conclusion

Multimodal respiratory physiotherapy was applied to critically ill patients and it was not associated with significant adverse physiological events. Pain was associated with respiratory physiotherapy and it was undertreated.

CHAPTER ONE: INTRODUCTION

Physical therapy is beneficial and forms part of the multidisciplinary treatment approach of managing ICU patients. The treatment modalities in physical therapy in ICU/CCU are broadly classified into two: respiratory physiotherapy and rehabilitation. [1, 2, 3, 4]

The main goals of respiratory physical therapy are to promote ventilation by secretions' clearance, recruitment and maintenance of lung volume, optimization of oxygenation, improvement of lung and thoracic compliance and prevention of respiratory complications in the critically ill patient. [5]

Physiotherapy can result in clinically significant changes in haemodynamic, cardiovascular, intracranial, metabolic and oxidative parameters. These changes are detrimental to the critically ill patient. Other reported adverse effects include: falls during positioning and exercises, accidental extubation / tube displacement, incorrect reconnection of equipment, and inconsistent ventilator settings after the procedure [6,7,8,9,]

The knowledge of the effects and outcomes of respiratory physiotherapy is of great importance to the practitioner offering critical care. This knowledge enables a patient-tailored approach to the prescription of this intervention (with resultant favorable outcomes).

CHAPTER TWO: LITERATURE REVIEW

2.1 Effects of Endotracheal Intubation and Critical Illness on the Respiratory System

Endotracheal intubation diminishes the mucociliary escalator function and interferes with the cough reflex. Opioids, commonly used in the ICU, are antitussives, and neuromuscular blockers completely inhibit the cough reflex. The impaired innate airway clearing mechanism causes accumulation of secretions in the airway, with detrimental effects on the lung function and potential for colonization by microorganisms. This also predisposes to the development of Ventilator Associated Pneumonia. (10)

Immobilization of the critically ill patient and the use of neuromuscular blockers and steroids contribute to ICU neuromyopathy. This decreases the function of the respiratory pump, and is implicated in prolonged endotracheal intubation and failed weaning from mechanical ventilation. Malnutrition and biochemical abnormalities associated with critical illness also worsen ICU neuromyopathy. (10)

Nursing ICU patients in the supine position reduces lung compliance, because of the lung compression from the chest wall and the abdomen. There is also increased pulmonary blood volume. The functional residual capacity is reduced leading to atelectasis in the dependent regions of the lung. All these factors contribute to ventilation perfusion mismatch and increased work of breathing. (10)

2.2 Aims of Respiratory Physical Therapy

The aims of respiratory physical therapy in critical care are: to optimize oxygenation and ventilation; reduce and clear airway secretions; prevent pneumonia; recruit or maintain lung volume; improve ventilation perfusion mismatch; reduce the work of breathing; improve respiratory muscle strength; reduce ventilator dependency and promote weaning; and reduce post-operative complications. (10)

The European Respiratory Society and European Society of Intensive Care Medicine Task Force on Physiotherapy for Critically ill Patients recommend careful assessment of the patient before treatment. This enables accurate prescription of physiotherapy interventions and appropriate patient monitoring to ensure safety. (11)

2.3 Respiratory Physical Therapy Interventions and Their Effects

Different physiotherapy techniques have been described.

2.3.1 Retained Airway Secretions and Airway Clearance

Airway clearance is one of the main goals of respiratory physiotherapy. Secretions increase airway resistance and reduce pulmonary compliance and oxygenation. The treatment modalities used are described below.

2.3.1.1 Increasing inspiratory volume

Interventions used to increase inspiratory volume influence lung expansion and ventilation, the resistance of the airway and lung compliance. These include manual/ventilator hyperinflation, mobilization, positioning, breathing exercises, incentive spirometry, and use of non-invasive ventilator insufflator.

a. **Manual hyperinflation (MHI)**

MHI is also known as 'bagging' or 'bag squeezing'. This manouvre is widely used in ICU in intubated patients who are mechanically ventilated. It is carried out after disconnecting the patient from the mechanical ventilator temporarily then ventilating with a manual ventilator bag. This technique is thought to act by mimicking a cough by the application of tidal volume that is higher than normal at a low inspiratory flow, followed by an inspiratory pause, then expiration at a high flow. This forces airway secretions to move from the smaller peripheral airways towards the trachea to allow for removal with tracheal suctioning. MHI therefore could prevent plugging of the airway and promote recruitment of alveolar. [1, 12]

Frederique Paulus et al did a systematic review on benefits and risks of MHI and concluded that studies failed to show that MHI benefits the intubated mechanically ventilated patients and it may result in adverse effects. Volutrauma and barotrauma are likely to occur with MHI. Disconnecting the patient from the mechanical ventilator could be unsafe as the basic adapted ventilator settings are not be maintained. MHI also causes short-term hyperinflation. This can be detrimental in haemodynamically unstable patients due to the acute increase in intra-thoracic pressure which causes a decrease in the venous return to the heart.

MHI also poses a risk to patients with acute respiratory distress syndrome or acute lung injury. The pressure in the airway at the end of this intervention is often lower than the positive end-expiratory pressure applied by the mechanical ventilator, which, together with airway suctioning, may cause atelectasis. But, there exists manual hyperinflation bags with valves for PEEP inbuilt in the circuit for maintenance of PEEP and prevention of de-recruitment. [10, 12, 13, 14]

b. Ventilator hyperinflation

Ventilator hyperinflation involves manipulating the settings of the ventilator so as to deliver tidal volumes larger than the set baseline, without disconnection of the patient from the ventilator. There are a number of contraindications for MHI where the use of ventilator hyperinflation may be desirable. For example in patients with a baseline PEEP greater than 10cmH20, agitated or delirious patients who are intolerant of manipulation of their artificial airway , and in patients who require close monitoring and control of ventilator parameters (such as in patients with cardiovascular instability and labile intracranial pressures). Ventilator hyperinflation may also prevent transmission of infection caused by disconnecting the circuit to both the patient and attending practitioners. [10]

Several studies have demonstrated that ventilator hyperinflation is has the same effectiveness as manual hyperinflation in terms of clearing airway secretions. [1, 15]

2.3.2 Body Positioning and Mobilization

Positioning for critically ill patients can be employed to optimize transport of oxygen through effects of improved V/Q matching, increase in lung volume, reduction in the work of breathing, reducing the work of the heart, and enhancing airway clearance.

Postural drainage is considered as an example of positioning which uses gravity to promote secretion clearance. Head down tilt positioning when used with MHI significantly increases sputum yield in intubated patients and improves peak expiratory flows. [16]

Upright positioning has been shown to improve lung volume and reduce the work of breathing in patients who are being liberated from mechanical ventilation.

Positioning patients in prone improves V/Q matching, redistributes oedema, and increases FRC for patients with acute lung injury or acute respiratory distress syndrome (ARDS) [17, 18]
Patients with single lung disease positioned with the affected lung non-dependent benefit from improved lung volume and function and reduced atelectasis. [17]

Continuous rotational therapy (CRT) utilizes specialized beds which turn patients up to 60 degrees along the longitudinal axis on either side. The speed of rotation and degree of recline is preset. This treatment has been proven to reduce atelectasis, reduce the incidence of pneumonia, intubation duration and the hospital stay. [19]

Mobilization intervention techniques that are used for intubated mechanically ventilated patients are limb exercises, patient actively turning or moving in bed, sitting on the bed, standing from bed to sitting in a chair and finally walking. Mobilization that involves erect positioning has the beneficial effects of standing. Mobilization also provides a gravitational stimulus that helps maintain and restore physiological fluid distribution in the patient and also to reduce the known adverse effects of bed rest and immobility. Long term, mobilization optimizes the work capacity in patients and improve cardiopulmonary fitness and functional independence and. [17]

2.3.3 Increasing Expiratory Flow

Cough aids in the removal of secretions. There are three phases of cough: The first phase is the inspiratory phase, consisting of greater than resting inspiratory volume followed by the compressive phase that is defined by glottis closure and expiratory muscle contraction to increase intra-thoracic pressure. Then the expulsive phase results from sudden glottis opening. Any pulmonary disorder interfering with any of the three phases causes ineffective coughing that leads to accumulation of bronchial secretions. Neuromuscular disorders can impair any of the three phases. It has been postulated that thick bronchial secretions, as seen in some pulmonary disorders such as bronchitis and dynamic airway compression seen in emphysema reduce expiratory flow and contribute to ineffective cough. [20]

Methods used to assist the expulsive phase of cough are therefore aimed at increasing the expiratory flow.

Interventions that are carried out with an aim to increase expiratory flow consist of passive expiration and forced active expiration. These are carried out with an open glottis generating a huff and a closed glottis generating a cough. Manually assisted cough is done by compressing the thorax or abdomen and is indicated in patients with respiratory muscle weakness and/or fatigue as seen in patients with a neuromuscular disorder. These techniques however rely on adequate inspiratory volumes and are often be accompanied by techniques that increase inspiratory volume, if the patient has an ineffective cough due to reduced inspiratory volume. [20]

The mechanical in-exsufflator is a device that promotes excessive mucus removal by inflating the airways with a large volume of air that is then rapidly exsufflated by use of a negative pressure, therefore mimicking a cough. This causes an increase in the tidal volume and also improves expiratory flow and as such is beneficial in patients who are unable to sufficiently clear their airway secretions. It is not widely used, but it has been applied with success in patients with respiratory muscle weakness, without tracheal intubation. [21]

2.3.4 Percussion and Vibrations

These are intervention techniques that increase clearance of secretions through the transmission of energy waves across the chest wall, thought to dislodge secretions from the walls of the bronchi. Both techniques are performed manually or using mechanical devices. Percussion is performed during both the inspiratory and expiratory phases, manually done by clapping the chest wall over the affected zone of the lung. The optimal force and frequency for percussion is not known. Frequencies from 100 up to 480 cycles per minute producing up to 58-65N of force have been reported. [17]

The addition of vibrations to a combined chest physiotherapy treatment has not been shown to significantly improve arterial blood gases or lung compliance. However Ntoumenopoulos et al in a study demonstrated a direct relationship between combined respiratory physiotherapy treatment and a reduction in the incidence of ventilator associated pneumonia by 31%. [22]

Vibrations can be applied either manually by shaking, compressing or vibrating the chest wall at expiration.

2.3.5 Tracheal Suctioning

Tracheal suctioning forms an important component of respiratory physiotherapy for the critically ill patient with an artificial airway and it is widely applied. Patients unable to mobilize secretions to the proximal part of the tracheal tube through coughing require deep tracheal suctioning. The potential adverse effects associated with tracheal suctioning include atelectasis and de-recruitment due to loss of PEEP, hypoxia, traumatic injury to the airway, bronchospasms, spread of microbials to the lower airways, increased cerebral blood flow and intracranial pressure, hypo/hypertension, dysrhythmias especially due to vagal stimulation and anxiety. [10]

Tracheal suctioning is an invasive procedure to an essentially sterile/ clean environment and should therefore be done aseptically. Open and closed suction systems are used. The main advantage of using a closed system is avoidance of disconnecting the patient from the mechanical ventilator and thus maintenance of PEEP. This system is therefore recommended for use in patients with ALI/ARDS at risk of hypoxemia and atelectasis. Studies done to determine the effectiveness of either system on secretions yield have however had different outcomes. A bench study done by Lindgrel et al in 2004 showed that the secretions yield from a closed suction system was significantly lower than when an open system is used, when using same suction pressure and catheter size, and this was thought to be because the high inspiratory flows from the ventilator could push secretions lower down the lower/distal respiratory tree. However, in a different study by Witmer et al, there was no significant difference in the quantity of secretions removed from the closed and open systems [23, 24, 25]

Endotracheal suctioning should be done only when indicated as opposed to being a routine care intervention. The indications of tracheal suctioning include cough, audible/ visible secretions, course or reduced breath sounds, increased pressure in the airway, drop in oxygen saturation levels and increasing work of breathing.

A prospective randomized study of 383 showed that endotracheal suctioning only when indicated has less adverse effects and bears no significant difference in the incidence of pneumonia, ICU mortality, intubation duration, and stay in ICU in the patients who had routine suctioning or those suctioned when necessary. Therefore, assessment of the patient's need for suctioning should be done clinically as well as using the ventilator parameters. [26]

Appropriate catheter size selection is important. The catheter should be large enough to facilitate suction of thick secretions, but small enough to allow air entry around it during the procedure, to

minimize the risk of a significant drop in lung volume (FRC) and atelectasis. There is no consensus on the formula used to calculate catheter size. Generally, the recommendation is that the external diameter of the suction catheter in use should measure as a half of the internal diameter of the ETT. This recommendation is from Rosen and Hillard, who demonstrated using a model, that when a larger suction catheter is used it could increase the negative pressure that is applied to the lungs [27]

Mathematically, the lumen of the ETT is calculated as: pi×r2×length, therefore when the diameter is doubled the tube lumen is quadrupled. It is therefore logical to use the internal lumen, rather than the diameter of the ETT. This has been supported by a lung model test, which showed that the negative pressure transmitted to the lungs is reduced when a suction catheter occludes less than half the lumen of the ETT. From this, the suggested formula for determining the size of the catheter is:

Catheter size [in French gauge] = (ETT internal diameter in mm −1) ×2

The level of suction pressure used has an implication on hypoxia, atelectasis and damage to tracheal mucosa. It is difficult to reliably assess the actual negative pressure transmitted to the patients' lungs on the manometer/pressure dial on the suction machine because it's dependent on several factors: the catheter-ETT ratio, the total time taken to suction the patient and the viscosity and volume of the patients' secretions. However, no clinical study supports an exact limit. To reduce the complications associated with suctioning, it is recommended that the procedure takes a total of 15s.

Suctioning for the haemodynamically stable and well oxygenated patient has relatively few contraindications, but the benefit versus the risks of hypoxemia and arrhythmias must be evaluated for the unstable patient.

2.3.6 Saline Instillation during Tracheal Suctioning

Saline instillation before to tracheal suctioning is common in ICU, but its role has been questioned. It is done by introducing normal saline into the ETT just before suctioning. The volume of saline introduced is variable, ranging from 2-10 cc. Some practitioners manually hyperventilate the patients after introducing the saline and before suctioning. No study has demonstrated a significant increase in sputum weight when saline is instilled before tracheal suctioning.

Endotracheal saline instillation poses potential adverse effects on oxygenation. Kinloch carried out an observational study to investigate the effects of saline instillation on mixed venous oxygen saturation (SvO2) levels in post-operative bypass surgery patients. One group of the patients had instillation of 5cc normal saline before suctioning while the other did not. The time that was required for Sv02 to return to the baseline was significantly longer, with a mean of 3.7 minutes in the group that got saline instilled. [28]

A study comparing the physiological effect of suctioning with and without normal saline, Gray et al concluded that there was no variation in respiratory mechanics, airway pressure or even gas exchange. Although not backed by science, authors agree that the primary goal of saline installation should be to moisten thick secretions, but humidification of inhaled gases and hydrating the critically ill patient appear to be better and safer options. [29]

2.3.7 Inspiratory Muscle Training

Respiratory muscle weakness is implicated in weaning failure of intubated critically ill patients on mechanical ventilation. Mechanical ventilation has been shown to have a direct effect on the muscles of respiration, particularly the diaphragm. There is evidence that atrophy of the diaphragm occurs during mechanical ventilation, demonstrated by reduction in the area of Type one and Type two muscle fibres, decrease in the antioxidant glutathione and increased proteolytic enzymes. This causes an imbalance between the load imposed on the respiratory system and the capacity to overcome it. Inspiratory muscle training is one strategy employed to prevent or reduce respiratory muscle weakness. It uses resistance to progressively provide loading on the inspiratory muscles with an aim of strengthening the muscles. The devices used in this treatment commonly consist of a threshold valve which is adjusted to provide the required resistance. The device is attached to the endotracheal tube of the intubated patient after the patient is briefly disconnected from the ventilator. For the non-ventilated patient it is used with a mouth piece and nose clip. [30]

There is evidence that this treatment technique results in improved inspiratory muscle strength and improves weaning in ventilated patients. In one study Cader et al performed 5 minute sessions twice a day on intubated ventilated patients, starting at 30% of maximum inspiratory pressure and subsequently increased the intensity by 10% daily. There was a significant increase in inspiratory muscle strength with a mean difference in maximum inspiratory pressure of 7.60 cmH_20 and a decrease/improvement in the weaning time with a mean difference of 1.7 days. [30]

Weiner et al also demonstrated that respiratory muscle training spares the inotropy of inspiratory muscles from the damage caused by corticosteroids. [31]

2.4 Undesirable Effects of Respiratory Physiotherapy

Individual or combined respiratory physiotherapy techniques, like any other clinical intervention, can cause significant adverse effects to the ICU patient.

a. Hypoxemia

Although one of the primary end goals of chest physiotherapy is to improve oxygenation, hypoxemia during the procedure is common. The technique most implicated is tracheal suctioning. Application of negative pressure during suctioning induces de-recruitment, atelectasis and reduces lung volume, all contributing to hypoxemia. This is especially dangerous to patients with ALI or ARDS. Closed suctioning systems induce less hypoxemia compared to open systems. Alveolar recruitment maneuvers and hyper-oxygenation can help reduce hypoxemia. [25]

Cereda et al studied the changes in lung volumes, oxygenation, airway pressures and haemodynamics during endotracheal suctioning with open and closed systems on patients with ALI undergoing mechanical ventilation. The researchers observed a significant drop in lung volume immediately suctioning was initiated; with the drop being significantly higher when open system was used. Peripheral oxygen saturation also decreased significantly during the procedure; although the change was marked when open systems were used. [45]

Salvatore et al did a study on the prevention of suctioning induced derecruitment of alveolar in ALI. In this study, the effects of tracheal suctioning on lung volumes and peripheral oxygen saturation were similar to the findings of Cereda et al. Salvatore et al went further to perform a recruitment manouvre by triggering pressure-supported breaths during closed system suctioning and they observed that this fully prevented a drop in lung volume. [25]

b. Metabolic and hemodynamic changes

Weisman et al and Klein et al demonstrated that chest physiotherapy in the intubated ICU patient significantly increases blood pressure, heart rate, oxygen consumption and carbon dioxide production. This poses a risk of reduction of coronary blood flow, increased myocardial work and has the potential to cause myocardial ischaemia. [8, 32]

Berney S and Deheny L in 2003 carried out a study on the metabolic and haemodynamic changes with and without physiotherapy in haemodynamically stable intubated and mechanically ventilated ICU patients. Ten patients were selected, with each undergoing 2 different treatments. The first treatment involved 20 minutes of gravity associated drainage, ventilator hyperinflation and suctioning while the second treatment involved turning the patient to the side and leaving undisturbed for 2 minutes. They observed a transient increase in mean oxygen consumption (VO_2) on all patients, but there was no significant variation in the changes in the two treatment techniques. Suctioning, however, produced the highest peaks in VO_2 of up to 56% from the baseline. The time it took to recover to 5% of baseline $V0_2$ was achieved within 7 minutes for all the patients with no significant variation in the 2 groups. Also, no significant difference in the mean arterial pressure and cardiac index in the two treatment techniques 15 minutes after the end of the interventions was noted. [33]

Mariya P and Akishta P in 2018 carried out a study on cardiorespiratory response to chest physiotherapy in an intensive respiratory care unit. 40 patients were selected, 24 of which were on ventilator support and 16 spontaneously breathing. Heart rate, blood pressure, ECG, oxygen saturation and respiratory rate were monitored immediately post intervention and up to 30 minutes. From this study, chest physiotherapy caused an immediate significant increase in blood pressure and heart rate but the parameters returned to baseline by 15 minutes. [34]

A different study was done by Rafael S Don Santos et al in 2014, assessing the changes in metabolic, haemodynamic, oxidative stress variables, and inflammatory variables of 30 ICU patients in septic shock following respiratory physiotherapy. Of note, all the patients were not only intubated and mechanically ventilated but sedated as well. This study concluded that chest physiotherapy improves oxygenation, reduces lactate and also reduces oxidative damage in patients with septic shock without causing significant changes in inflammatory or haemodynamic variables. [35]

Zeng et al also demonstrated that combined chest physiotherapy significantly reduces blood lactate and improves the oxygenation index as well as the peripheral oxygen saturation without significantly altering the vital signs, respiratory rate, the tidal volume and the peak and mean airway pressures. [36]

A different study that observed an increase in VO_2 and metabolic demand after chest physiotherapy also demonstrated that administration of a muscle relaxant (vecuronium) prior to chest physiotherapy suppressed VO_2 and thus metabolic demand although it did not suppress blood pressure and cardiac output. [9]

c. Effect on intracranial pressure

Chest physiotherapy, in particular endotracheal suctioning can cause increased intracranial pressure (ICP) and impair cerebral perfusion pressure, particularly in patients whose cerebral auto regulation has already been disturbed as in head trauma. The increase in ICP following endotracheal suctioning is thought to be secondary to vasodilatation and an increase cerebral blood flow. The increase however has been shown to be small and clinically insignificant in patients who do not experience cough, agitation and movement during suctioning. Sedatives, lidocaine and muscle relaxants have been used to prevent this. [37, 38]

d. Other adverse effects

Other adverse effects associated with chest physiotherapy include new onset arrhythmias, bradycardia, agitation, anxiety, direct trauma to the airway and disconnection of equipment including self extubation. [34, 39]

e. Definition of adverse cardiorespiratory outcomes and other adverse events

A large observational study of 12,281 physiotherapy interventions reported an adverse event rate of 0.2%. The commonest adverse events were alterations in blood pressure, desaturation and arrhythmias, mostly bradycardia. Patients were more likely to suffer adverse events if they were already haemodynamically unstable and on inotropic or vasopressor support. Ninety six percent of the patients who had adverse events had documented cardiac comorbidities and 78% had abnormal baseline vital signs.

The definition of adverse outcomes from this large study is as listed below. [7]

i. Change in blood pressure more or less than 20% of baseline values.
ii. Change in heart rate more or less than 20% of baseline values.
iii. New arrhythmias on electrocardiogram (e.g., atrial fibrillation, ventricular tachyarrhythmia, increase in ectopic beats per minute, asystole).
iv. Drop in oxygen saturation more than 10% of resting value.
v. Agitation that results in detachment of lines or equipment.
vi. Incorrect settings or procedures (e.g., incorrect connection of equipment, level of inspired oxygen)
vii. Falls.

Mariya P and Akishta P in 2018 in the study mentioned above on cardiorespiratory response to chest physiotherapy in an intensive respiratory care unit also used the above listed definition of adverse outcomes in their study. [34]

2.5 Analgesia, Sedation and Neuromuscular Blockade during Chest Physiotherapy

Procedural pain in ICU is commonly unrecognized or undertreated. Pain in critically ill patients interferes with cardiovascular and respiratory physiology, negatively impacting recovery. It can also cause adverse psychological effects, including agitation, anxiety, delirium and post-traumatic stress disorder. Potential physical manifestations of pain include tachypnoea, patient-ventilatory dysynchrony, tachycardia, and hypertension, pupillary dilatation, sweating and crying. [40]

Maneuvers carried out during chest physiotherapy can cause pain, with some interventions causing more pain intensity than others. In one study, compared with mobilization, the risk of increased pain intensity was 20–67% greater with turning, endotracheal suctioning and other procedures not related to physiotherapy such as arterial line insertion, peripheral blood drawing, intravenous line insertion and wound drain removal. The intensity of the procedural pain has been related to the intensity of the background or baseline pain intensity, the analgesics administered including the dosages and the timeline. [41]

Pain recognition and assessment in ICU patients is often challenging. Self-reporting, considered the gold standard of pain assessment, may be impossible in patients with a depressed level of consciousness, sedated and intubated patients and children. The numerical rating scale (NRS) and the visual analogue scales (VAS) are used for pain assessment in conscious patients. These scales have been modified for the paediatric age group, for example in the Wong-Baker FACES rating scale. In the sedated or unconscious ICU patient, there are validated tools used to assess pain. These include the behavioral pain score, the critical care pain observation tool, the nonverbal pain assessment tool, nonverbal pain scale, the pain behavioral assessment tool, the Face, Legs, Activity, Cry, Consolability (FLACC) tool. The behavioral pain score has been found to be particularly useful for assessing pain related to procedures in critically ill patients. [40, 42, 43]

Similarly the Richmond Agitation and Sedation Scale (RASS) is a useful validated tool for determining level of sedation and agitation in critically ill paediatric and adult populations. [44]

Analgesics and sedatives are used to blunt the physiological effects of chest physiotherapy. Short acting opioids like Alfentanil, fentanyl, benzodiazepines and propofol have been used effectively. For example, Cohen et al observed that propofol in low dose attenuates, and in high dose blunts the increases in oxygen uptake, carbon dioxide elimination, heart rate and systolic blood pressure associated with chest physiotherapy even though this effect is inherent in the pharmacological action of the drugs otherwise.[8,9]

Muscle relaxants suppress the increases of $V0_2$ and VCO_2 observed with chest physiotherapy but do not appear to have an effect on blood pressure. [9]

2.6 Summary of the management of undesirable effects of respiratory physiotherapy

Management of undesirable effects of respiratory physiotherapy begins with careful patient selection for specific physiotherapeutic maneuvers. The stability of the patient is evaluated before treatment is prescribed.

To prevent and manage an acute drop in lung volume and hypoxemia, hyper-oxygenation therapy, closed suction system, careful selection of suctioning catheter and lung recruitment maneuvers are used. [25]

The management of significant hypertension resulting from respiratory physiotherapy is patient specific, depending on the primary diagnosis of the patient. If resulting from pain and agitation, analgesics and/or sedatives are administered and close monitoring continued. Persistent hypertension is treated using anti-hypertensive drugs, or altering dosages of cardioactive drugs if in use. Hypotension is managed using positive inotropic drugs, vasopressors or fluid therapy, depending on the primary pathology of the patient.

Muscle relaxants can be used to suppress increases in VO_2 and VCO_2 occurring as a result of respiratory physiotherapy. [9]

Cardiac arrhythmias including bradycardia, tachycardia and cardiac arrest are managed according to the cardiac life support guidelines. The most commonly used being the American Heart Association algorithms for advanced cardiac life support.

2.7 Study Justification

Respiratory physical therapy is a common intervention in the KNH ICUs. All intubated patients are subjected to this intervention. It is prescribed by ICU doctors and facilitated by attendant nurses and physiotherapists, who are part of the multidisciplinary team in ICU. The treatment modalities used are often modified for some group of patients, for example those who have undergone thoracic surgeries and those with acute head trauma.

Although its benefits and risks have been globally documented as discussed in the literature above, no local studies have been carried out to evaluate this therapy/intervention

There is no special chart at KNH ICUs to document the immediate haemodynamic and ventilatory changes that occur during respiratory physiotherapy. This study revealed how the treatment is carried out in our setup and assessed the associated effects. The study provides crucial information to ICU practitioners on how to improve patient care and outcomes.

2.7.1 Research Question

What were the immediate effects and outcomes of respiratory physical therapy treatment on endo-tracheally intubated patients in KNH ICUs?

2.7.2 Study Objectives

2.7.2.1 Broad Objective

To describe the effects and outcomes of respiratory physical therapy in critically ill patients in KNH ICUs

2.7.2.2 Specific Objectives

i. To describe the respiratory physical therapy modalities in critically ill endo-tracheally intubated patients in KNH ICUs.
ii. To determine the immediate haemodynamic and ventilatory outcomes of respiratory physical therapy on critically ill endo-tracheally intubated patients.
iii. To determine the sedation and pain scores of critically ill patients during respiratory physical therapy

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study Design

This was a prospective observational study of ICU patients

3.2 Study Site

The study was carried out in the main ICU. The main ICU in KNH primarily admits critically ill paediatric and adult surgical patients, although patients with medical illnesses are admitted as well. It is primarily run by anesthesiologists/intensivists. All patients in KNH main ICU are under continuous haemodynamic and respiratory monitoring.

3.3 Study Population

Endo-tracheally intubated mechanically ventilated patients undergoing respiratory physiotherapy in KNH-intensive care units

3.3.1 Inclusion Criteria

Endo-tracheally intubated mechanically ventilated critically ill patients whose next of kin consented to the study were eligible for recruitment into the study.

3.3.2 Exclusion Criteria

Patients with tracheostomy tubes, those younger than two years of age and those whose next of kin did not consent to the study were not be eligible and were excluded from the study.

3.4 Sampling

3.4.1 Sampling Method

Convenient sampling was employed until desired sample size was achieved.

3.4.2 Sample Size Determination

Sample size was calculated using the formula;

$$n = \frac{Z^2 x\ SD^2}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

SD = standard deviation (estimated at 18 i.e. average of 19 and 17 from a study conducted by Rafael S. et al (2014) looking at the Immediate Effects of Chest Physiotherapy on Hemodynamic and other factors, found Clinical and Hemodynamic Data Before and After Chest for Heart rate (beats/min) to be 94±19 and 97±17.)

d = desired difference for the means is estimated to be 4

$$n_0 = \frac{1.96^2 x\ 18^2}{4^2} = 78$$

A Sample size of 78 patients was recruited for the study.

3.5 Recruitment and Study Procedure

Patients were recruited in the ICU. The study objectives were explained in detail to the next of kin of the patient and a written consent obtained before the start of the data collection. Before physiotherapy, the bio data of the patient, including the weight (as per the treatment sheet) were extracted from the patient charts. Details of all analgesics, sedatives and neuromuscular blockers, including dosages were also recorded. The size of the endotracheal tube was indicated. The level of sedation was assessed according to the Richmond agitation and sedation scale. The pain score were also assessed using the behavioral pain score for patients 8 years or older and the FLACC tool for patients below 8 years. The primary caregiver(s) were required to state the indication of the physiotherapy intervention. The mode of ventilation, ventilator parameters of peak and plateau airway pressures, PEEP, inspired oxygen fraction and end tidal volumes were recorded for patients on mechanical ventilation. The blood pressure, peripheral oxygen saturation and heart rate and respiratory rate were also recorded. When the physiotherapy intervention commenced, the treatment modalities used were documented. After the intervention, the ventilator data, the vital signs, pain and sedation scores were monitored and recorded every 5 minutes for 15 minutes.

3.6 Outcome

The primary outcome was to assess the immediate outcomes of respiratory physical therapy. Blood pressure, heart rate, peripheral oxygen saturation, ventilation parameters, pain and sedation scores were measured before the treatment was applied and up to 15 minutes after treatment - at every 5 minutes interval. Because sedatives, analgesics and neuromuscular blockers have an effect on pain and hemodynamics during physiotherapy, we also studied their use. Practitioners were immediately informed if and when an adverse effect was noted, and any intervention carried out was recorded in the data collection form.

Thresholds for adverse cardiorespiratory outcomes and other adverse effects were:

a. Change in blood pressure more or less than 20% of baseline values.
b. Change in heart rate more or less than 20% of baseline values.
c. New arrhythmias on electrocardiogram (e.g., atrial fibrillation, ventricular tachyarrhythmia, increase in ectopic beats per minute, asystole)
d. Drop in oxygen saturation more than 10% of baseline.
e. Agitation that results in detachment of lines or equipment.
f. Incorrect settings or procedures (e.g., incorrect connection of equipment, level of inspired oxygen)
g. Falls.
h. Accidental extubation.

3.7 Data Management and Analysis

The data collection tools were each be coded and entered into a Microsoft Access document designed for the study. Data was continuously cleaned and then exported to SPSS version 21.0 for statistical analysis. Data forms were reviewed for completeness and accuracy of the recorded information. All electronic data was stored in password protected computers with only PI having the access rights. The paper data was stored in lockable study cabinets during the study period and will be handed over to the research office for storage at the end of the study. The data will be stored for a period specified in the university manual on storage of study materials before being discarded.

To ensure data was accurately entered, there were quality check/verifications of at least 10% of the already entered forms which involved comparing the electronic data with the hardcopy of the questionnaire.

Data Analysis

Data analysis was conducted as per the objectives

Objective 1: To describe the treatment modalities of respiratory physical therapy in critically ill endo-tracheally intubated patients in KNH ICUs.

Descriptive analysis measures of means (standard deviations) or median (interquartile range) were used to summarize treatment modalities variables e.g. suction catheter size or duration of tracheal suctioning. Variables such as positional change, tracheal suctioning, which were categorical were summarized using frequency and percentages.

Objective 2: To determine the immediate haemodynamic and ventilatory outcomes of respiratory physical therapy on critically ill endo-tracheally intubated patients.

Haemodynamic and ventilation outcomes were collected for 15 minutes at every 5 minutes intervals and one at baseline resulting into 5 data points for each individual. Observations from individual patients over time tend to be correlated. The change in each of the outcome measures over time was explored using Pearson correlation analysis in order to determine the right correlation structure of the significant outcome measures. Summary measures of mean and standard deviation were calculated at each time point for each of the outcomes to show the

variability in measurements over time. Repeated Analysis of variance (ANOVA) were conducted to determine possible mean difference between the measurement of baseline, time 0, 5 minutes, 10 minutes and 15 minutes for each of the outcome. The outcomes with significant difference were adjusted for multiple hypotheses testing using Bonferroni correction to determine which of the time point pairwise comparison is statistically different. The analysis of hemodynamic parameters was stratified by different age groups. All statistical tests were conducted at 5% level of significance (p value less or equal to 0.05). Tables and graphs were used to present the findings.

Objective 3: To determine the sedation and pain scores of critically ill patients during respiratory physical therapy

Sedation and pain scores were analyzed using appropriate measures of central tendency (modes and medians) at baseline, immediately after treatment intervention (time 0) and 5 minutes intervals up to 15 minutes and presented in graphs and box plots.

3.9 Ethical Considerations

In relation to the provision of informed consents, several conditions may hamper the decision making capacity of critically ill patients. These includes the medical condition for which the patients was admitted to ICU, the level of consciousness, pain, ICU associated anxiety and delirium and sedation. For this reasons, consent was sought from the next of kin of the patient as the surrogate decision maker for this study. Those who did not have consent for enrollment into the study were excluded (without any victimization or compromise to treatment).

A few ethical issues relating to consent from next of kin (as the surrogate decision maker) in this study are recognized. The patient's wishes may not have coincided with the next of kin's decision to exclude or include the patient in the study. Furthermore, the next of kin may have incorrectly interpreted study participation to equate with opportunity for better care for their patient (therapeutic misconception). The next of kin may have been under significant psychological or emotional stress, due to the patient's critical condition. This may have influenced decision making. For this study, the nature of intervention and purpose of study was fully explained to the next of kin, and their questions and concerns were addressed. The planned treatment interventions were carried out regardless of whether the patient was enrolled into the study or not.

Permission to conduct the study was obtained from KNH/UoN Ethics and Research committee prior to commencement of the study.

No additional costs were incurred by the study participants.

All findings from the study shall be availed to UoN and KNH.

3.10 Study Limitations

There were two limitations in this study. First, adverse events in critically ill patients are common and can occur spontaneously, including during the period of study. Secondly, respiratory physiotherapy may be associated with significantly different outcomes in patients with primary lung disease, who may have altered lung physiology and lung mechanics.

CHAPTER FOUR

4.1 Results

4.1.1 Demographic characteristics

A total of 74 participants were recruited into the study, males were the majority of the participants, mean age of the patients was 37.3(SD: 18.6) years. (Table 1, figures 1 & 2).

Table 1: Demographic characteristics of the patients recruited into the study (N=74)

Mean(SD) age in years	37.3(18.6)
Mean(SD) weight in Kgs	62.5(19.1)
Male n (%)	58(78.4)

Figure 1: Age distribution of patients

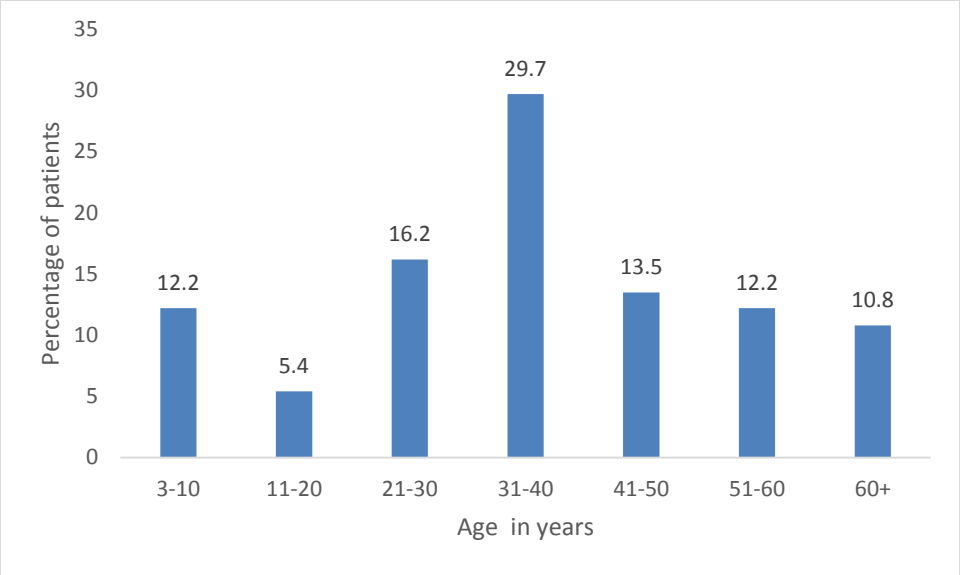
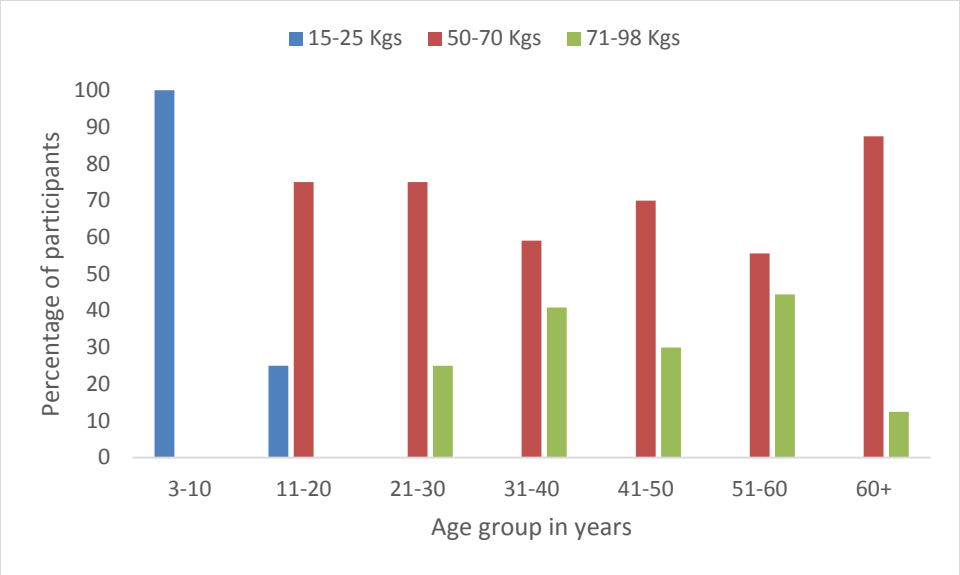


Figure 2: Distribution of patients' weights in Kilograms



4.1.2 Treatment modalities

16.2% of the study participants had bagging as a method of physiotherapy treatment. Vibration and compressions were applied to most of the patients. Only 6.8% had positional change applied as a treatment modality. All the participants had tracheal suctioning done, with a mean duration of the procedure being 37 (with a SD: 32.4) seconds, 61(82.4) with aseptic technique and sixty nine used catheter with mean size of 13.1(SD: 1.7). The number of participants that had saline instillation was 14(18.9%) with a volume of 12.8 ml (SD: 8.9) (Table 2)

Table 2: Treatment modalities of respiratory physical therapy patients in ICU KNH

Bagging, n (%)	12(16.2)
Ventilator hyperinflation, n (%)	1(1.4)
Vibrations/compression, n (%)	62(83.8)
Position change (Supine to lateral) n (%)	5(6.8)

Tracheal suctioning, n (%)	74(100.0)
Technique aseptic, n (%)	61(82.4)
Mean(SD) Catheter size(n=69)	13.1(1.7)
Saline instillation, n (%)	14(18.9)
Mean(SD) volume of saline instilled(n=16)	12.8(8.9)
Mean(SD) duration of tracheal suction(n=64)	37.0(32.4)

4.1.3 Treatment Outcomes

Ventilation

There was an increase in tidal volume and respiratory rate immediately after treatment but these changes were not significant. Peak airway pressure increased immediately after treatment, but it returned to below baseline measurements by 15 minutes. FiO2 was increased from the baseline levels and maintained higher than the baseline all through treatment. There was a drop in SpO2 immediately after treatment but it returned to the baseline by minute 15. Plateau airway pressures did not change immediately after treatment but declined lower than baseline at 5 to 15 minutes. There was little change in the PEEP values over time. There was significant difference mean measurements at the different time points for Fio2, $F(4,350) = 6.2$, $p<0.0001$. The post hoc analysis with Bonferroni adjustment showed pairwise significant difference between baseline and 0 minutes (p-value=0.0009), 5 minutes and 10 minutes (p-value=0.0010), and 5 minutes and 15 minutes (p-value=0.0013).

Table 3: Means (standard deviations) of ventilation outcomes

Time in minutes	Outcome measures						
	Tidal volume	Respiratory rate	Peak airway pressure	Plateau airway pressure	Peep	Fio2	% spo2
Baseline	433.3(146.0)	18.2(6.4)	20.7(6.4)	15.1(5.3)	5.4(1.4)	46.7(14.0)	99.3(1.5)

0	455.1(145.4)	21.2(7.2)	21.9(7.0)	15.4(5.8)	5.4(1.3)	58.9(25.4)	98.6(4.6)
5	451.1(131.5)	19.9(6.5)	20.6(5.6)	14.0(4.9)	5.3(1.4)	53.3(21.7)	99.0(4.1)
10	449.4(128.0)	19.4(5.8)	19.5(4.7)	14.4(3.9)	5.3(1.3)	47.1(14.5)	99.3(3.6)
15	443.5(119.9)	19.3(6.8)	19.7(5.7)	14.2(5.3)	5.2(1.2)	47.1(14.5)	99.6(2.5)
p-value	0.904	0.164	0.156	0.579	0.950	< 0.0001	0.538

Hemodynamic parameters

The Heart rate, SBP and MAP increased immediately after treatment (time 0) and remained above the baseline values after 15 minutes. DBP and MAP decreased below the baseline values during the same time. None of the parameters showed significant difference in means between the time points.

Figure 3: Distribution of Heart Rate, SBP, DBP, and MAP over time

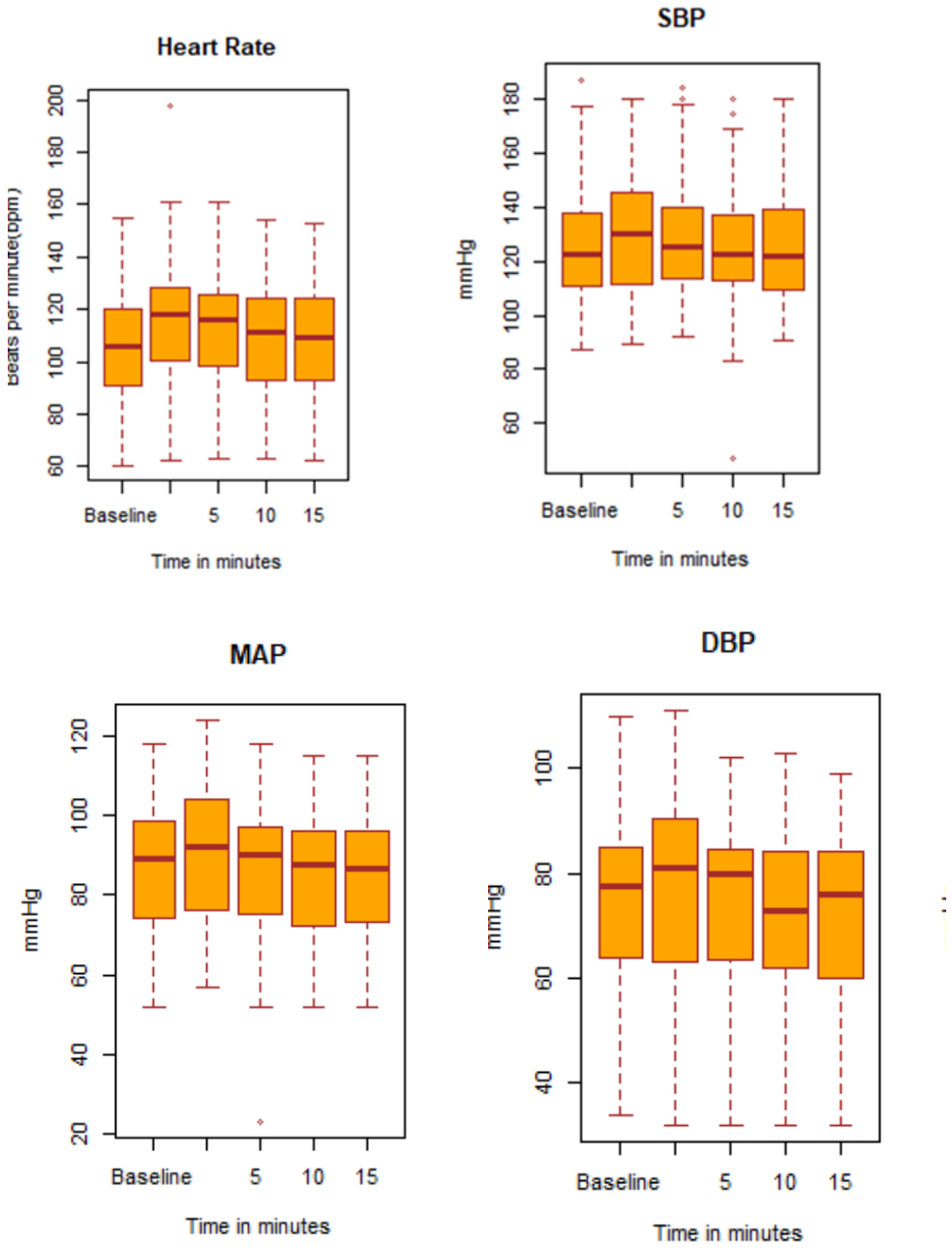


Figure 4: Graphs Showing Trends of blood pressure means for all patients

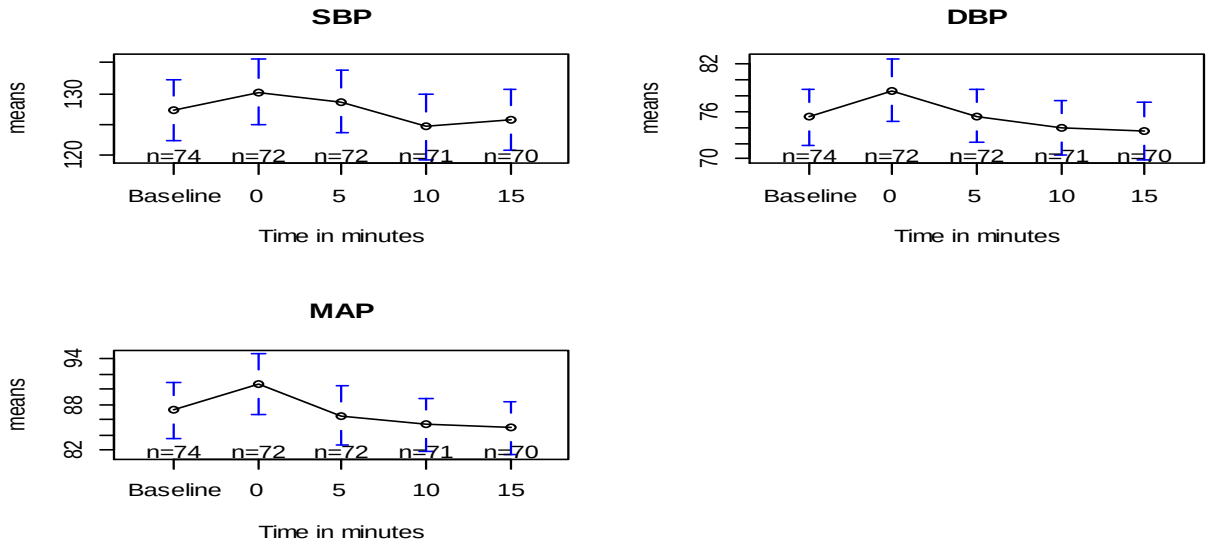


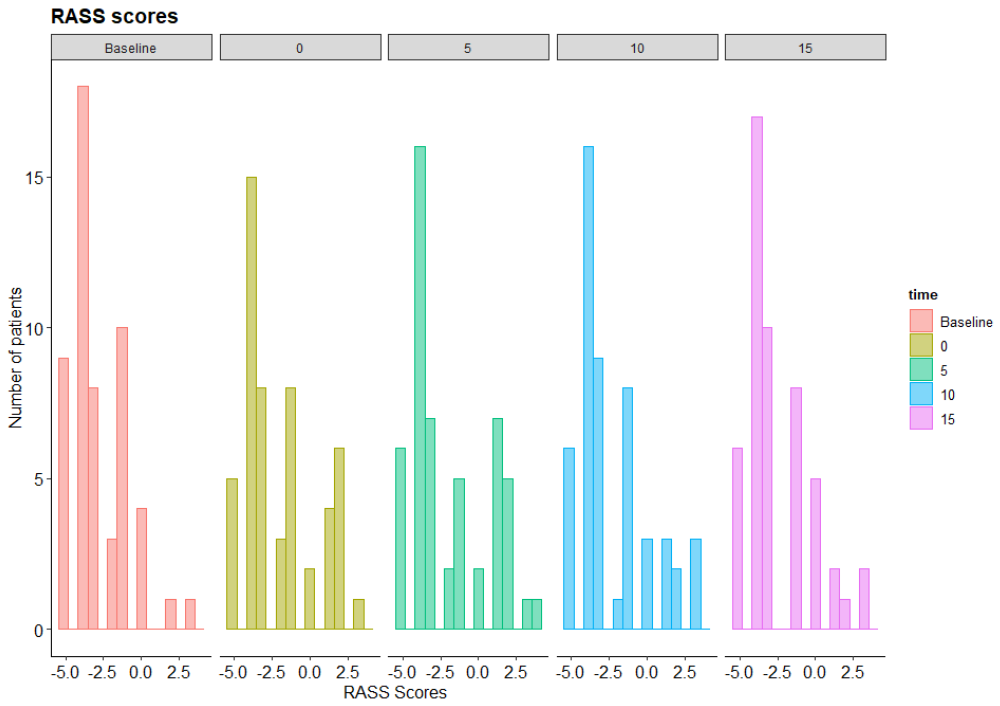
Table 4: Means of systolic blood pressure, Mean arterial pressure in sedated and unsedated patients

Time in minutes	Sedated		Not sedated	
	SBP	MAP	SBP	MAP
Baseline	124.2(19.2)	85.4(19.2)	134.9(25.6)	91.9(25.6)
0	127.0(20.9)	87.7(20.9)	138.3(25.7)	97.5(25.7)
5	125.6(19.8)	85.9(19.8)	136.1(25.6)	88.0(25.6)
10	121.6(20.1)	84.3(20.1)	131.9(26.8)	87.8(26.8)
15	122.6(17.3)	83.4(17.3)	133.5(26.1)	88.6(26.1)
p-value	0.327	0.277	0.599	0.165

Pain and sedation

The intensity of sedation as measured by RASS decreased immediately after treatment. This did not return to the baseline value at 15 minutes. Majority of the patients had a score of -4 at any point in time: 18 patients at baseline, 15, 16, 16, and 17 at minutes 0,5,10 and 15 respectively.

Figure 5: Distribution of RASS score at baseline, 0 minutes, 5 minutes, 10 minutes and 15 minutes



Distribution of pain scores

Distribution of pain scores for each of the time points is shown in figures 6 and 7. The pain score was highest immediately after treatment (Time 0) and declines with time up to 15 minutes. For patients 8 years and above using the BPS, the mode at baseline was 3, at time 0 it increased to 6, and declined to 3 at minutes 5, 10 and 15. For patients below 8 years (n=7), using the

FLACC scale the mode at the baseline was 0, immediately after it was bimodal, 2 and 4, at 5 minutes it was 0 and 4, at 10 and 15 minutes it was 0.

Figure 6: Distribution of pain scores at baseline, 0 minutes, 5 minutes, 10 minutes and 15 minutes for patients 8 years and above

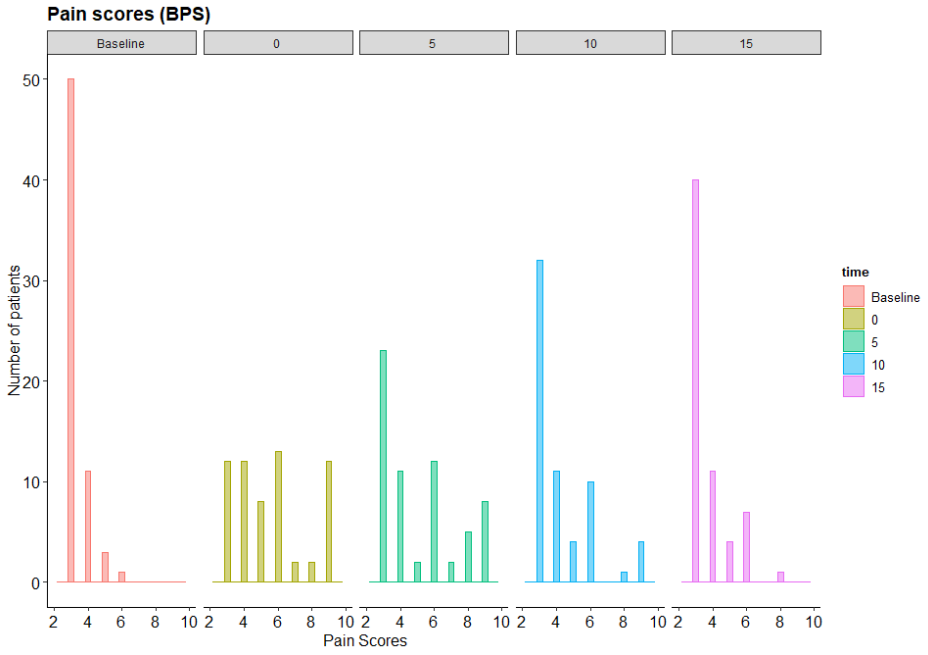
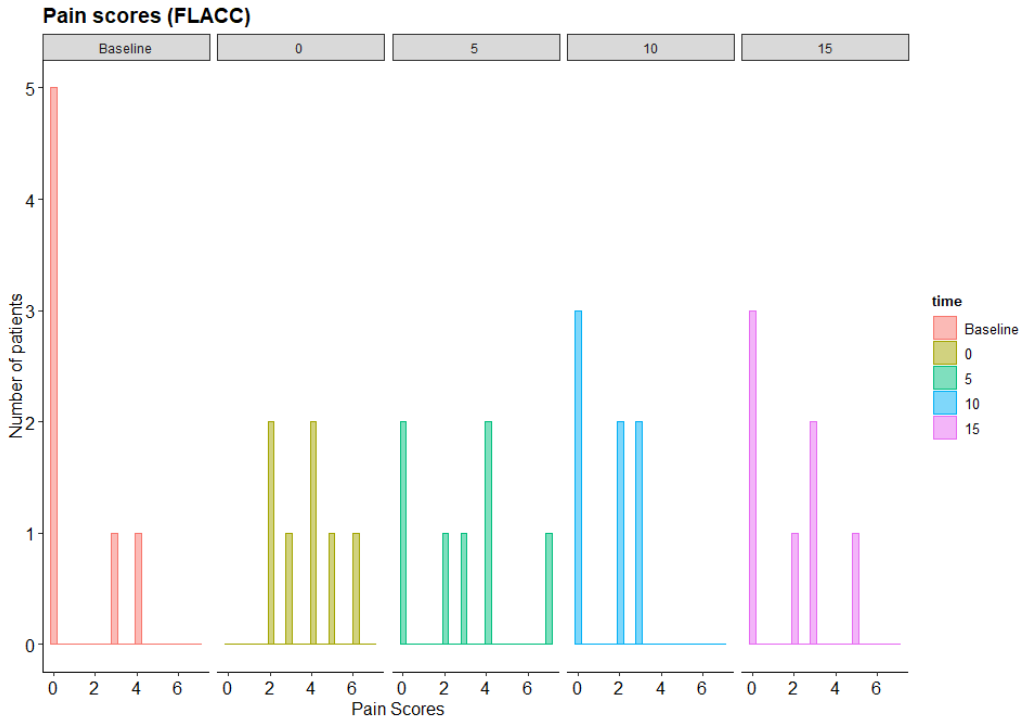


Figure 7: Distribution of pain scores at baseline, 0 minutes, 5 minutes, 10 minutes and 15 minutes for patients below 8 years


Pain scores (FLACC)
Baseline
0
5
10
15
Number of patients
Pain Scores
time
Baseline
0
5
10
15

Analgesia and sedation during respiratory physiotherapy

53(71.6%) of participants were sedated, of whom 4(7.5%) received procedural sedation, 38(71.7%) had background sedation, and 11(20.8%) had both. For most patients morphine (77.4%, n=41) or midazolam (32.1%, n=17) was used. Muscle relaxants were used in only two patients and the drug used was atracurium (Table 5).

Table 5: Current practice in peri-procedural analgesia and sedation during respiratory physical therapy in critically ill patients

Sedated, n(%)	53(71.6)
Type of Sedation, n(%)	
Procedural	4(7.5)
Background	38(71.7)
Both	11(20.8)
Analgesic/Sedative used, n(%)	
Morphine	41(77.4)
Fentanyl	5(9.4)
Midazolam	17(32.1)
Propofol	1(1.9)
Dexmedetomidine	5(9.4)
Ketamine	4(7.5)
Sodium thiopental	1(1.9)
Paracetamol	60(81.1)
Muscle relaxant use, n (%)	2(3.8)
Type of muscle relaxant used, n(%)	
Atracurium	2(100.0)

4.2 DISCUSSION

Our study examined the treatment modalities of respiratory physical therapy in critically ill patients, the immediate haemodynamic and ventilation outcomes and pain and sedation during respiratory physical therapy in KNH main ICU.

We observed the use of multimodal respiratory physical therapy in ICU, common techniques being tracheal suctioning and manual chest vibrations and compressions, manual and ventilator hyperinflation and mobilization being less common. A study done in South Africa by M Lottering et al also had similar outcomes, with manual clearance techniques and tracheal suctioning being common modalities of treatment. This may indicate that these techniques are the mainstay of airway clearance in intubated patients. Manual/ventilator hyperinflation is associated with side-effects such as increased intracranial pressure in traumatic brain injury patients. Since our study was carried out in an ICU that commonly admits patients with acute head trauma (who are intubated in the acute phase), this may explain the low use of this technique. Positioning and mobilization as part of respiratory physiotherapy were uncommon in our study compared to the practice documented elsewhere. Positions like proning have specific indications such as ARDS. [5, 46]

We recorded increases in blood pressure (SBP, DBP, and MAP) and heart rate from the baseline immediately after treatment: These changes were not statistically and clinically significant and remained within physiological ranges. Mariya et al demonstrated a similar trend in increase of blood pressure and heart rate immediately post treatment, and those were statistically significance. Their study was controlled, employed more treatment modalities, and the duration of treatment was longer. This could explain the difference between this and our study.

Muscular activity during compressions and vibrations increases metabolic demand which results in an increase in stroke volume as well as cardiac output to meet the rise in oxygen demand. Suctioning directly stimulates the excitatory sympathetic receptors located in the

airways increasing sympathetic activity, which induces peripheral vasoconstriction and increases the mean arterial pressure [9]. Major hemodynamic changes in our study may have been attenuated by use of analgesics and/or sedatives. There is existing evidence that short acting opioids like fentanyl, benzodiazepines and propofol blunt the metabolic and hemodynamic effects of chest physiotherapy. [8, 9] Our results build on the existing evidence that show that respiratory physical therapy does not cause significant haemodynamic changes in this patient population. [33, 34]

We found that respiratory physiotherapy increases respiratory rate and tidal volume although these changes are not significant. There was a rise in the mean peak airway pressure immediately after treatment which dropped to lower than pretreatment values 15 minutes after the intervention. The changes in oxygen saturation were not significant. This is consistent with previous studies. Airway clearance techniques such as compressions and vibrations cause increased muscular activity which results in an increase in the respiratory rate. Tracheal suctioning aids in the clearance of airway secretions reducing airway resistance, improving ventilation, lung volumes and oxygen saturation. Improved airflow reduces the work of breathing eliminating the use of accessory muscles and reducing dyspnea. This explains why the respiratory rate remains close to the physiological range. [34]

Our study recorded only one adverse event during the process of respiratory physiotherapy. This was an accidental extubation. Manual ventilation via bag-mask ventilation was commenced followed shortly by re intubation, exposing the patient to risks such as pulmonary aspiration. This is similar to previous studies that have evaluated the safety of physiotherapy in critically ill patients. [39]

We demonstrated that ICU patients experience pain during respiratory physiotherapy. This is consistent with literature that recognizes respiratory physiotherapy and more specifically tracheal suctioning as a painful ICU procedure. Majority of our patients were on analgesics/sedatives but they still experienced pain. This supports the existing literature that pain in ICU is difficult to predict and treat. Pain in critically ill patients is multifactorial and conditions like acute confusional states or sleep deprivation associated with the ICU environment may worsen the

pain experience during procedures. [40] Several other studies that have evaluated procedural pain in various ICU populations found that patients who had a surgical history, diagnosis or trauma had worse pain during procedures, and that the pre procedural pain intensity influenced the intensity of the procedural pain. The society of critical care medicine recommends that preemptive analgesia be provided to critically ill patients before painful procedures are performed. [47] There is therefore the need to recognize, closely monitor and treat pain during respiratory physiotherapy.

4.3 CONCLUSION

a. Multimodal respiratory physiotherapy is applied to critically ill patients in KNH main ICU.
b. It does not cause significant changes in heart rate, blood pressure, respiratory rate, tidal volume or oxygen saturation.
c. It is also not commonly associated with other major significant adverse physiological events.
d. Our study demonstrated that it increases pain, even in patients who are sedated.

4.4 RECOMMENDATIONS

a. We recommend incorporation of physiotherapy treatment techniques which have been shown to be beneficial to the critically ill patient but are underutilized in our setup, e.g. positioning and mobilization.

b. We recommend the use procedural analgesia (over and above background analgesia) during physiotherapy.

c. Further reviews and research on the approach to the management of pain during respiratory physiotherapy.

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WORK PLAN

TIME	DETAILS
December 2018-July 2019	Proposal preparation
August-September 2019	Department Approval
October 2019-January2020	Ethics approval
Februay-March2020	Data collection
April 2020	Data Analysis and compilation
April/May 2020	Results presentation

BUDGET ESTIMATE

ITEM	**AMOUNT (KES)**
Research assistant	30000
Statistician	40000
Stationary	8000
Printing and binding	10000
Ethics & research committee fee	2000
Miscellaneous	5000
Total	90000

APPENDICES

Appendix I: Data Collection Tool

Data Collection Tool

TITLE: IMMEDIATE EFFECTS AND OUTCOMES OF RESPIRATORY PHYSICAL THERAPY ON CRITICALLY ILL PATIENTS

Participant Number _____

1. Gender: Female ☐ Male ☐

2. Age _____

3. Weight (estimated) _____

4. Diagnosis _____

_____

5. Indication for Treatment_____

6. Team performing the physiotherapy treatment

7. Type of treatment modality prescribed _____

8. Endotracheal Tube (ETT) Size (Internal Diameter in mm) _____

9 a) Is the patient sedated? YES ☐ NO ☐

If yes: Procedural ☐

Background ☐

b. Sedative used and dose:

Morphine	☐	Fentanyl	☐
Remifentanyl	☐	Dexmedetomidine	☐
Midazolam	☐	Ketamine	☐
Propofol	☐	Sodium thiopental	☐

Others indicate_____

c. Pre procedural Sedation (RASS) score: _____

10 . Muscle relaxant use Yes ☐ No ☐

If yes indicate the agent and dose administered:

a) Atracurium ☐

b) Cisatracurium ☐

c) Rocuronium ☐

d) Other (Indicate) ☐

11. i) Indicate all background analgesics including dosages/regional blocks/continuous spinal or epidural analgesia

a) _____ d)_____

b) _____ e)_____

c) _____ f)_____

ii) Pre procedural Pain score _____

12. Treatment modality:

a. Bagging ☐ MHI ☐

Volume of self- inflating bag used (ml) _____

b. Ventilator hyperinflation ☐

c. Vibrations /compression ☐

d. Positional change: Yes ☐ No ☐

If yes Indicate positions _____

e. Tracheal Suctioning: Yes ☐ No ☐

If suctioning is done: Is the technique aseptic? Yes ☐ No ☐

Catheter size (French gauge)_____

Saline instillation during tracheal suctioning: Yes ☐ No ☐

If yes what volume was used ___ (milliliters)

Other fluids instilled (indicate) _____

Duration of suctioning _____ (seconds)

f. Other treatment techniques _____

13. Outcome

Time		**Baseline**	**Minute 0**	**Minute:5**	**Minute:10**	**Minute:15**
Mode of ventilation						
Ventilation data	**Peak airway pressure**					
	Plateau airway pressure					
	Peep					
	Fio2					
	Tidal volume					
Heart rate/min						
BP (mmhg)	**S.B.P**					
	D.B.P					
	M.A.P					

% spo_2						
Respiratory rate (total)						
RASS score						
Pain score						

14: Other adverse events
a. Extubation
b. Falls
c. Other drugs administered during the procedure _____
d. Any other _____

Appendix II: Explanation and Consent for the Next of Kin

AN OBSERVATIONAL STUDY ON THE EFFECTS AND OUTCOMES OF RESPIRATORY PHYSICAL THERAPY ON CRITICALLY ILL PATIENTS IN KENYATTA NATIONAL HOSPITAL INTENSIVE CARE UNIT

Study site

Kenyatta National Hospital Intensive Care units

Background

My name is Mercy Wanjiku Kamau, a postgraduate student studying anaesthesia at the University of Nairobi. I am conducting a study on the immediate effects and outcomes of respiratory physiotherapy in critically ill patients in KNH ICUs.

Purpose

The purpose of this study is to describe the treatment modalities of respiratory physiotherapy in KNH and the peri-procedural practices around it as well as identify the benefits and adverse effects that occur during respiratory physiotherapy. This will help improve the quality of care of our critically ill patients.

Participation

Participation is voluntary. You are free to withdraw from the study at any point. You will not incur any extra cost due to this study other than the usual cost of care at Kenyatta National Hospital. There will be no financial benefits from participation. Participation will not affect or delay your planned treatment.

Risks of participation

We will not alter your planned treatment.

Confidentiality

All the information obtained will be handled with utmost confidentiality. The patients name will not appear in any document

Sharing of results

The results obtained from this study will be shared with other experts through formal platforms.

Consent form

I…… next of kin to…….. of …… hereby give written consent for the participation in the prospective observational study on the immediate effects and outcomes of respiratory physical therapy on critically ill patients in Kenyatta National Hospital intensive care unit.

I have read this consent form or had the information read to me. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding the patient's identity confidential.

I have the right to withdraw consent at any point

Name: ……..

Signature/Thumb stamp……..

Date…….

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the next of kin of participant as named above and believe that s/he has understood and has willingly and freely given his/her consent.

Researcher's name……..Date……

Signature …….

Role in the study: …… (study staff who explained informed consent form.)

For more information contact Mercy Wanjiku Kamau at telephone number 0721984773 any time of day or night.

FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI

Fomu hii ya utafiti ni ya wale wagonjwa ambao wanahudumiwa katika hospitali kuu ya Kenyatta na wamealikwa kujiunga na utafiti.

AN OBSERVATIONAL STUDY ON THE IMMEDIATE EFFECTS AND OUTCOMES OF RESPIRATORY PHYSICAL THERAPY ON CRITICALLY ILL PATIENTS IN KENYATTA NATIONAL HOSPITAL INTENSIVE CARE UNIT

Jina langu ni Mercy Wanjiku Kamau. Nafanya utafiti wa shahada ya juu katika anaesthesia katika Chuo Kikuu cha Nairobi.

Utafiti huu unalenga kuchunguza jinsi ambavyo matibabu ya mazoezi ya kifua yanavyotekelezwa na jinsi yanavyofaidi au kudhuru wagonjwa mahututi katika chumba cha kuhudumia wagonjwa mahututi

Utafiti huu utaweza kuboresha matibabu haya kwa wagonjwa mahututi. Kusajiliwa kwa jamaa wako kwa utafiti huu ni kwa hiari yako. Hautahitajika kulipa malipo zaidi ya yale malipo ya kawaida ya hospitali. Hakuna pesa utakayo pewa kwa kushiriki. Hakuna hatari inayotokana na kushiriki katika utafiti huu. Uko na ruhusa kumuondoa jamaa wako kwa utafiti wakati wowote. Majina yako wala ya jamaa wako hayatatumika katika utafiti na usiri mkubwa utatumiwa katika utafiti. Kama jamaa wa mgonjwa utahitajika kuelewa kuhusu utafiti na kutia sahihi kubalio ili jamaa asajiliwe katika utafiti.

Baada ya utafiti, uchambuzi wa takwimu utafanywa na habari itachapishwa katika kitabu kitkachowekwa kwa maktaba ya Chuo Kikuu Cha Nairobi. Usiri mkubwa utatumika kwa kuziweka taarifa hizi.

Sasa nakupa nafasi ya kuuliza masawali yoyote uliyo nayo kuhusu utafiti huu. Ikiwa umekubali kushiriki katika utafiti huu, tia sahihi yako kwenye nafasi iliyotolewa.

FOMU YA IDHINI

Nambari ya Usajili……..

Mimi ni……..Kutoka……..

Ni jamaa wa karibu wa…….

Kutoka……..

Nimekubali kushiriksha jamaa wangu katika utafiti wa:

An observational study on the effects and outcomes of respiratory physical therapy on critically ill patients in Kenyatta national hospital intensive care unit

Nimesoma au kusomewa maelezo ya idhini na nikaelewa. Maswali yangu yote yamejibiwa kwa lugha ninayoelewa.

Ninaelewa ya kwamba uchunguzi utafanyika bila madhara yoyote kwa mgonjwa.

Nina uhuru wa kuuzulu kutoka kwa utafiti huu wakati wowote.

Jina……. Tarehe……..

Sahihi au alama ya kidole cha gumba…….

Mtafiti:

Nina thibitisha kwamba nimemwelezea jamaa wa mgonjwa wa karibu kwa ukamilifu kuhusu utafiti huu na amekubali bila kushurutiushwa

Jina……. Tarehe……..

Sahihi……..

Jukumu Kwa utafiti……..

Kwa habari zaidi unaweza kupiga simu Kwa Mercy Wanjiku Kamau kupitia Nambari 0721984773 wakati wowote usiku au mchana.

Appendix III: Behavioral Pain Scale

Behavioral pain scale		
ITEM	**DESCRIPTION**	**SCORE**
Facial expression	Relaxed	1
	Partially tightened e.g. brow lowering	2
	Fully tightened e.g. Eyelid closing	3
	Grimacing	4
Upper limbs	No movement	1
	Partially bent	2
	Fully bent with finger flexion	3
	Permanent retracted	4
Compliance with ventilation	Tolerating movement	1
	Coughing but tolerating ventilation most of the time	2
	Fighting ventilator	3
	Unable to control ventilation	4
BPS SCORE 3: NO PAIN TO 12: MAXIMUM PAIN		

Appendix IV: Faces Legs Activity Cry Consolability Pain Scale (FLACC Scale)

FLACC SCALE			
CATEGORIES	0	1	2
FACE	No particular expression/disinterested	Occasional grimace/frown, withdrawn	Frequent/constant frown, clenched jaw, quivering chin
LEGS	No position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
ACTIVITY	Lying quietly, normal position moves easily	Squirming, shifting back and forth, tense	Arched, rigid or jerking
CRY	No cry, awake or asleep	Moans or whimpers	Crying steadily
CONSOLABILITY	Content, relaxed	Reassured by occasional touching, hugging, or talking to. Distractable	Difficult to console or comfort

Appendix V: Richmond Agitation And Sedation Scale

Richmond Agitation and sedation scale (RASS)		
+4	Combative	Violent, immediate danger to self/staff
+3	Very agitated	Pulls or removes tubes/catheters. Aggressive
+2	Agitated	Frequent non purposeful movements, fights ventilator
+1	Restless	Anxious, apprehensive but movements not aggressive or vigorous
0	Alert and calm	
-1	Drowsy	Not fully alert, sustained awakening to voice (Eye opening and contact >/=10sec)
-2	Light sedation	Briefly awakens to voice (Eye opening and contact <10sec)
-3	Moderate sedation	Movement or eye opening to voice. No eye contact
-4	Deep sedation	No response to voice, but movement or eye opening to physical stimulation
-5	Unarousable	No response to voice or physical stimulation