ESTIMATION OF ENDOTRACHEAL TUBE CUFF PRESSURES AT KENYATTA NATIONAL HOSPITAL (KNH).

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN ANAESTHESIA OF THE UNIVERSITY OF NAIROBI

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2006
DECLARATION

This dissertation is my original work and has not to my knowledge been submitted for a degree in any other university.

Dr Stephen Wakaba Wangaka

Date

This dissertation has been submitted for examination with my approval as university supervisor.

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Date

Nov 29th 2006
DEDICATION

To Ruguru, my wife, and a source of inspiration during my Mmed programme.

To Edgar, my wonderful son who “helped” in my computer work

To all people who have made all of our lives better and more abundant today
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# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Contents</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>I</td>
</tr>
<tr>
<td>Declaration</td>
<td>II</td>
</tr>
<tr>
<td>Dedication</td>
<td>III</td>
</tr>
<tr>
<td>Acknowledgement</td>
<td>IV</td>
</tr>
<tr>
<td>Table of contents</td>
<td>V</td>
</tr>
<tr>
<td>List of tables and figures</td>
<td>VI</td>
</tr>
<tr>
<td>Abbreviations</td>
<td>VII</td>
</tr>
<tr>
<td>Abstract</td>
<td>VIII</td>
</tr>
<tr>
<td>Summary</td>
<td>1</td>
</tr>
<tr>
<td>Introduction and Literature review</td>
<td>2</td>
</tr>
<tr>
<td>Rationale/Justification of the study</td>
<td>20</td>
</tr>
<tr>
<td>Hypothesis</td>
<td>22</td>
</tr>
<tr>
<td>Objectives of the study</td>
<td>22</td>
</tr>
<tr>
<td>Methodology</td>
<td>23</td>
</tr>
<tr>
<td>Ethical consideration</td>
<td>27</td>
</tr>
<tr>
<td>Results</td>
<td>28</td>
</tr>
<tr>
<td>Discussion</td>
<td>31</td>
</tr>
<tr>
<td>Conclusions</td>
<td>34</td>
</tr>
<tr>
<td>Limitation of the study</td>
<td>34</td>
</tr>
<tr>
<td>Recommendation</td>
<td>34</td>
</tr>
<tr>
<td>References</td>
<td>35</td>
</tr>
<tr>
<td>Appendix</td>
<td></td>
</tr>
<tr>
<td>i. Data capture instrument</td>
<td>44</td>
</tr>
<tr>
<td>ii. Consent explanation</td>
<td>45</td>
</tr>
<tr>
<td>iii. Consent form</td>
<td>46</td>
</tr>
</tbody>
</table>

- Ethical approval letter
LIST OF FIGURES AND TABLES

Figure 1  Endotracheal tube
Figure 2  Inflation of ETTc (low/normal/high)
Figure 3  Ability to detect pressures correctly
ABBREVIATIONS

ETT ..................... Endotracheal tube
ETTc ..................... Endotracheal tube cuff
C.O ....................... Clinical Officer
ICU ....................... Intensive Care Unit
KNH ....................... Kenyatta National Hospital
ABSTRACT

Objective: To determine the ability of Intensive Care givers to accurately inflate endotracheal tube cuffs using standard syringe technique and estimate endotracheal tube cuff pressure by finger palpation of the pilot balloon.

Design: Cross-sectional descriptive/observational study

Setting: Kenyatta National Hospital

Methods: This descriptive survey of intensive care givers at KNH used a size 7.5 ETT with a large volume low pressure cuff (portex) in a 2 cm diameter rigid tube as a tracheal simulator. Using their choice of a 5 or 10ml syringe, participants inflated the ETTc by standard methods of injecting air and palpating the pilot balloon to estimate ETTc pressure. ETTc pressure was measured using a highly sensitive and accurate manometer (UBV, Suiz Germany). Participants then palpated 9 different ETTc previously inflated to pressures ranging from extremely low to extremely high, and reported their assessment of inflated as low, normal or high.

Results: Participants had 6.1% probability of inflating ETTc accurately. Majority, 94.7% inflated ETTc cuff to high pressures. We sampled 149 participants among them ICU nurses, physician anaesthetists, CO anaesthetists, Registrars in anaesthesia and clinical officer anaesthesia students. Only 6.1% inflated the ETTc to a safe pressure. The average ETTc pressure produced was greater than 91 cmH20. The true mean could not be determined because 31% inflated to pressures greater than the upper limit of manometer sensitivity (120cmH20). Using palpation, only 4.1% of participants were able to accurately detect inappropriately inflated ETTc.

Conclusions: Participants had little ability to inflate ETTc to safe pressure or to estimate pressure of a previously inflated cuff using standard technique, and most inflated to dangerously high pressures. Clinicians should consider using devices to facilitate safe inflation and accurate measurement of ETTc pressure rather than relying solely on standard techniques.
One of the main responsibilities of the anesthesiologist is to provide adequate respiration for the patient. The most vital element in providing functional respiration is the airway. Good diligent efforts are devoted to maintaining an intact functional airway.

Artificial airways and airway devices have been developed to assist in maintaining a patient’s airway during surgery and in intensive care to facilitate ventilation and oxygenation, and protect the airway from aspiration of foreign material. Cuffed endotracheal tubes have obvious advantages over pharyngeal airways in this regard.

A critical function of the endotracheal tube cuff is to seal the airway, thus preventing aspiration of pharyngeal contents into the trachea and ensuring that no leaks pass the cuff during positive pressure ventilation. Complications have been associated with insufficient inflation. Also, pressure exerted by the inflated cuff on the tracheal mucosa is responsible for a range of adverse consequences. Maintaining of adequate cuff pressures is therefore of paramount importance.

A prospective descriptive analytical study to determine the ability of intensive care providers in KNH to adequately determine ETTe by finger palpation of the pilot balloon was carried out. 149 intensive care givers were tested in the study. A data capture instrument was used to gather information regarding category of participant, inflated cuff pressure and detection of previously inflated ETTe as low, normal or high. Majority of the participants were ICU nurses (50.4%). 12.2% were physician anaesthetists. 10% CO anaesthetists. 15.1% were registrars, while the rest (12.2%) were CO student anaesthetists.
INTRODUCTION AND LITERATURE REVIEW

Management of the airway is central to the practice of anesthesia. This service is critically important in the safe conduct of anesthesia and care of critically ill patients outside the operating room environment (1). In order to understand airway management fully, the anesthesiologist must be fully conversant with the anatomy of the region and its variants, with its innervations, its possible pathological conditions and its physiology, and with the consequences and complications of airway management.

Knowledge of the use of artificial airway devices and their complications is vital in the practice of anesthesia. In this regard, tracheal intubation (translaryngeal intubation) is a safe and common practice in patients undergoing general anesthesia and in the critical care environment.

The history of airway control and importance of breathing for the maintenance of life dates back many thousands of years (2). Tracheal insufflation in animals was first described in the 1600s, although the development of tracheal intubation as we know it today dates from about 1900 (3).

Anatomy of the upper airway

The nose

This may be divided anatomically into two parts: the external nose and the internal nasal cavity (4). The nasal septum divides the latter into two. The nasal cavity is also separated into two parts by the backward continuation of the nasal septum. Each side has a roof, floor and a medial wall, and opening anteriorly through the external nares and posteriorly into
the nasopharynx. Majority of adults have a deviated nasal septum, which may be important in the context of airway management. This is because air flow through one side (nostril) will be better than the other (5). The function of the nose is to warm, filter and humidify incoming gases subserved well by the presence of three turbinates on each side that increase the mucosal air contact surface area.

Innervations come from the mucocilliary and maxillary branches of the trigeminal nerve, with olfactory fibers derived directly from the first cranial nerve. Openings exist from the various ethmoid and maxillary, air cells and the paranasal sinuses into the nasal cavity and tears drain into the nose via the nasolachrymal duct (5).

**The mouth**

The mouth opens via the lips and just within lie the gums and teeth with the cheek at the sides (4). The upper boundary is the alveolar arch, the hard palate, and the soft palate, with the anterior two-thirds of the tongue forming the floor of the mouth (6).

The hard palate separates the mouth below from the nasal cavity above. The mouth is opened by movement of the mandible, which pivots on the temporomandibular joints. These joints are unusual in that they permit movement in a number of different directions, namely rotation (mouth opening), sliding forwards and backwards (protrusion of the jaw, and sliding side to side). The latter is necessary for the mastication of food. The tongue is almost entirely muscle and can be moved in all directions. Its bulk prevents direct vision of the larynx, which is why it has to be displaced or depressed in order to perform a direct laryngoscopy (4). The motor supply to the tongue is from the facial nerves (cranial nerve
VII): whereas sensation of the posterior one-third is supplied by the glossopharyngeal nerves (cranial nerve IX).

**The larynx**

The larynx lies at the level of the 3rd and the 6th cervical vertebra in the adult. The larynx has a triple function, that of an open valve in respiration, that of a partially closed valve in phonation, and that of a closed valve protecting the trachea and bronchial tree during deglutition. Coughing is only possible when the larynx can be closed effectively.

It has cartilaginous framework formed by the epiglottis, thyroid cartilage, cricoids and the arytenoids. The larynx is slung from the U-shaped hyoid bone by thyrohyoid membrane and thyrohyoid muscle.

The laryngeal cavity extends from the epiglottis to the lower level of the cricoid cartilage. The inlet is formed by the epiglottis, which joins to the apex of the arytenoids cartilages on each side of the aryepiglottic folds. Inside the laryngeal cavity are the vestibular folds. These extend from the antero lateral surface of each arytenoid to the angle of the thyroid. These folds are referred to as false vocal cords and are separated from the true vocal cords by the laryngeal sinus or vestibule. The true vocal cords are pale, white, ligamentous structures that attach to the angles of the thyroid interiorly and to the arytenoids posteriorly. The triangular fissure between these vocal cords is the glottic opening, which represents the narrowest segment of the laryngeal opening in adults. In children younger than ten years, the narrowest segment lies just below the cords at the level of the cricoid ring.
The mean length of the relaxed open glottis is about 23mm in males and 17mm in females. The glottis width is 6-9mm but can be stretched to 11-12mm (9) the cross sectional area of the relaxed glottis is 60 to 100 mm squared.

The entire motor innervation to the muscles and the sensory supply to the larynx are supplied by two branches of the vagus nerve: the superior and recurrent laryngeal branch nerves (10).

The larynx receives a superior and an inferior laryngeal from the superior and inferior thyroid artery respectively. The vessels accompany the superior and recurrent laryngeal nerves.

The pharynx, epiglottis and vocal cords play a role in protecting the lower airway from aspiration of foreign bodies and secretions. Most vital in this protection function is the glottis closure reflex, which produces protective laryngeal closure during deglutition.

**The Trachea**

The trachea is a tubular structure that begins opposite the sixth cervical vertebra at the level of the thyroid cartilage. It is flattened posteriorly and supported along its 10-15 cm length by 16 to 20 horse shoe shaped cartilaginous rings until bifurcating into right and left main bronchi at the level of the fifth thoracic vertebra. The cross sectional area of the trachea is considerably larger than that of the glottis and may be more than 150mm$^2$ and as large as 300 mm$^2$ (9).

Several types of receptors in the trachea are sensitive to mechanical and chemical stimuli. Slowly adapting stretch receptors are located in trachealis muscle of the posterior wall.
These are involved in regulating the rate and depth of breathing but they also produce
dilatation of upper airways and the bronchi by decreasing vagal efferent activity (8).

MANAGEMENT OF THE AIRWAY

In the awake patient the airway is maintained by the tone of the muscles of the neck,
pharynx and tongue. Loss of consciousness results in loss of this muscular tone and the
tongue falls back to obstruct the airway. If the patient is supine, this obstruction can be
complete and without intervention potentially fatal hypoxia will ensue (10).

Simple elevation of the chin and extending the head and the neck may be all that is required
to produce a patent airway. Placing a small pillow behind the occiput and or a roll under the
shoulders may help. If these simple movements are not effective, an upward thrust on the
jaw is attempted. This is affected by placing fingers or thumb behind the angle of the
mandible and lifting it forwards. The mechanism by which this maneuver clears the airways
is by displacing the tongue in an anterior direction and pulling it away from the posterior
pharyngeal wall. It is tiring to maintain this position and so the use of an artificial airway is
commonplace (11).
**Artificial Airways**

**The Face Mask**

The face mask allows administration of gases from the breathing system without introducing any apparatus into the patient. The face mask is designed to fit the face of the ideal patient and the usual pattern fits over the mouth and nose with the lower part between the lower lip and chin. In a patient who is anaesthetized or in coma, chin lift and jaw thrust maneuver may still be required to maintain a patent airway in the presence of the mask. The mask’s primary function is an oxygen enriching device.

**The Pharyngeal Airway Device**

The oral airway is a curved rigid plastic tube, which was originally described by Guedel (13).

A nasal airway may be used instead of an oral airway. This is indicated for patients with fragile teeth, crowns, bridges, or when an oral airway canal is inserted. Nasal airways are better tolerated than oral airways at light levels of sedation and even in the awake patient (13).

Mucosal damage is relatively common, and trauma to the posterior pharyngeal wall can result in the development of a pharyngeal abscess. Nasal airways are avoided in patients with bleeding disorders or with a base-of-the-skull fracture (13).
**The laryngeal mask (LM)**

The laryngeal mask is a relatively new airway device that is inserted through the mouth and comes to lie at the back of the pharynx with its opening sitting anteriorly over the entrance of the larynx.

Easy insertion requires the patient to be deeply anesthetized with a relaxed mouth and pharyngeal muscles. The laryngeal mask has proved to be a very useful alternative in airway management. Many healthcare professionals find a laryngeal mask to be just as satisfying as, and sometimes easier to use than, a tracheal tube in cardiac arrest management (13).

**The combitube**

The combitube is a device with two lumens and two inflatable cuffs. One cuff seal within the oesophagus and the other within the larynx. It is possible to isolate the oesophagus from the trachea using this device and any regurgitated gastric material is vented to the exterior through the oesophageal lumen (12,13).

**Tracheostomy**

The airway may be managed following direct insertion of a tube into the trachea, bypassing the mouth and larynx. This is usually a surgical procedure.

Indications for a tracheostomy include major head and neck injury, malignant tumors of the head and neck, long term ventilation, and secretion control.
Complications include haemorrhage, infection, damage to structures in the anterior neck, damage to the larynx, and erosion of major blood vessels (13).

**The Endotracheal Tube (ETT)**

The endotracheal (tracheal tube, intratracheal tube and catheter) is inserted into the trachea and is used to conduct gases and vapours to and from the lungs (16). An ETT places a mechanical burden on the spontaneously breathing patient (17-21). It adds more resistance and is a more important factor in determining the work of breathing than the breathing system (22-24).

Resistance to gas flow through the tube is determined by internal diameter (25) tube length (26) tube configuration (27) and gas density (28).

The American Society for Testing and Materials (ASTM) standard (27) contains requirements and recommendations for tracheal tubes, including the material from which the tube is constructed, the inside diameter, length, inflation system, cuff, radius of curvature, markings, Murphy eye, packaging and labeling. A separate standard (28) covers the testing of the shafts of tracheal tubes for laser resistance.

The ASTM standard specifies a radius of curvature of 140-20mm. The internal and external walls should be circular. The machine (proximal) end receives the connector and projects from the patient. The patient (tracheal and distal) end is inserted into the trachea. It usually has a slanted portion called the bevel. The angle of the bevel is the acute angle
between the bevel and the longitudinal axis of the tracheal tube. The tracheal tube standard specifies a bevel angle of $38^\circ \pm 10^\circ$ (27). The opening of the bevel faces left when viewing the tube from the concave aspect. Having the bevel facing left facilitates visualization of the larynx as the tube is being inserted.

Figure 1 shows a standard, cuffed endotracheal tube. It has a hole through the tube wall on the side opposite to the bevel. This is the Murphy-type tube (29). The purpose of the eye is to provide an alternate pathway for gas flow if the bevel is occluded.

Tracheal tube lacking the Murphy eye is known as Magill or Magill-type tubes. Lack of a Murphy eye allows the cuff to be placed close to the tip. This may decrease the chances of inadvertent bronchial intubation and may reduce injury to the trachea. However herniation of the cuff and complete obstruction may still occur (29).
Fig. 1. A standard, cuffed, Murphy-type endotracheal tube, with specified standard components labeled.
The ASTM standard requires that a radiopaque marker be placed at the patient's mouth and along the entire length of the tube to aid in determination of the tube position after intubation. The barium sulfate stripe significantly lowers the temperature at which ignition occurs and thus increases the risk of fire in the presence of laser (31).

Other kinds of endotracheal tubes are designed for special purposes. They include preformed tubes, like the Ring – Adair-Ehvin (RAE) tube, spiral embolus tube, RAE-Flex tube, Carden bronchoscopy tube, carden laryngoscopy tube, Itui Endotrol tracheal tube, tubes with extra lumens, laser shield II tracheal tube, lasertubal and EMG reinforced tubes among others (16).
ETT CUFF SYSTEM

A cuff system consists of the cuff itself plus an inflation system in the wall of the tube, an external inflation tube, and a pilot balloon and inflation valve Fig

The purpose of the cuff system is to provide a seal between the tube and the tracheal wall to prevent passage of pharyngeal contents into the trachea and ensure that no gas leaks past the cuff during positive pressure ventilation (16).

The cuff also serves to centre the tube so that its tip is less likely to traumatize the mucosa. The cuff is an inflatable sleeve near the patient end of the tube. The cuffs material should be strong and less resistant but thin, soft, and pliable. Cuffs are usually made of the same material as the tracheal tube. Cuff materials are subject to the same tissue testing requirements as the tube itself (21).

The ASTM standard (21) specifies the maximum distance from the tip of the tube to the machine end of the cuff. This varies with the tube size. If this distance is too long, the tip should rest on the carina while the cuff impinged on the vocal cords. The standard also requires that the bonded edge at the cuff not encroach on the Murphy eye if present, that the cuff not herniate over the tip under normal conditions of use; and that the cuff inflate symmetrically.
Cuff Pressures

Intracuff pressure and pressure on the trachea wall.

A high cuff pressure prevents aspiration, ventilatory leaks, and eccentric positioning of the tube in the trachea but can cause damage to the trachea. The perfusion characteristics of tracheal mucosa, which is formed by the ciliated pseudostratified epithelium, make it very sensitive to the endotracheal cuff pressures (32, 35, 36, 37, 38, 39). In the presence of an ETT, perfusion of the tracheal mucosa is dependent on the balance between mucosal perfusion pressure and the pressure exerted on the tracheal mucosa by the ETT cuff. Then if the ETT cuff pressure exceeds tracheal mucosal perfusion pressure, induction of ischaemic and/or necrosis will just be a question of time (39).

It is thus desirable that the cuff seal the airway without exerting excessive pressure on the trachea that its circulation is compromised or the trachea is dilated. Most authors recommend that the pressure on the lateral tracheal wall measured at the end of expiration be between 25 and 30 cm H2O (41-45). If the pressure exceeds 25 cmH2O, aspiration should not occur, provided the density of the material above the cuff is not greater than that of water (41-46). Studies show impaired tracheal blood flow at 30 cm H2O (43). It may be necessary to use higher pressures when inflating to “just seal” under conditions requiring high ventilatory pressures over short periods of time (40). The use of high pressure, low compliance cuffs during surgery is associated with development of extremely high cuff pressures because of the diffusion of nitrous oxide into the cuff (45). The magnitude of this...
problem is related to the concentration of nitrous oxide and the duration of the anaesthetic. The true tracheal pressure is not easy to estimate when these cuffs are used, since most of the cuff pressure is dissipated in expanding the cuff itself (45).

**Low volume, High Pressure Cuff**

The low volume, high pressure (small resting diameter, low residual volume, low volume, small standard conventional, low compliance, high pressure) cuff has a small diameter at rest and a low residual volume (the amount of air that can be withdrawn from the cuff after it has been allowed to assume its normal shape with inflation tube exposed to atmospheric pressure (48). It requires a high intra cuff pressure to achieve a seal with the trachea and distends and deforms the trachea to a circular shape.

Most of the pressure inside this type of the cuff is used to overcome cuff wall compliance so that the pressure exerted laterally on the trachea wall will be less than the intra cuff pressure. The pressure exerted on the wall however is well above mucosal perfusion pressure (41, 49, and 50) intra cuff pressure and the lateral wall pressure increase sharply as increments of air are added to the cuff (51).

These cuffs offer advantage over low pressure cuffs. Because they can be reused and are less expensive. They offer better protection against aspiration and better visibility during intubation. Some investigators have reported a lower incidence of sore throat with their use.
than with high volume, low pressure cuffs (52, 53). Their use has been recommended in
adolescent patients to reduce trauma (54).

High volume, Low pressure cuff

A high volume, low pressure (large resting diameter: large residual volume, high volume,
high compliance: low pressure: floppy) cuff has a large resting volume and diameter and a
thin compliant wall that allows a seal with the trachea to be achieved without stretching its
wall. This type of wall is floppy and easily deformed. As it is inflated, it first contacts the
trachea at its narrowest point at that level. As cuff inflation continues, the area of contact
becomes larger and the cuff adapts itself to the surface. If cuff inflation is continued, the
areas in contact will be subjected to increasing pressure, and the trachea will be distorted to
a circular shape, similar to a high-pressure cuff (56). A significant advantage of these cuffs
is that provided the cuff wall is not stretched, the intracuff pressure closely approximates
that on the tracheal wall (57, 58).

The intra cuff pressure varies during the ventilation cycle (56). During spontaneous
breathing, airway (and cuff) pressure will be negative during inspiration and positive during
exhalation. The main advantage of high volume, low pressure cuffs is that the risk of
significant cuff-induced complications following pro-longed intubation is reduced with their
use (57, 58). However tracheal injury can occur even when these cuffs are used properly
(59, 60). A tendency toward tracheal dilatation has been reported.
Tubes with these cuffs may be more difficult to insert, as the cuff may obscure the view of the tube tip and larynx so that trauma to the airway may be more common (61, 62). The cuff is more friable and thus more likely to be torn during intubation, especially if forceps are used (63).

The incidence of sore throat is greater than with high pressure cuffs unless the cuff is specially designed so that the tracheal contact area is small (52, 53). Severe post extubation stridor has been reported with their use (62). Aspiration can occur past low pressure cuffs with folds or wrinkles (64, 65) and is more in spontaneously breathing while it is reduced by continuous positive airway pressure (66).

It is relatively easy to pass devices such as esophageal stethoscopes, around low pressure cuffs (67). There may be a greater likelihood of dislodgement (including extubation) with these cuffs, especially oral intubation and positive pressure ventilation (68). One of the biggest problems with the use of low pressure cuffs stems from a lack of understanding on the user. There is a widespread belief that simply using this type of cuff will prevent high pressures from being exerted by the wall of the trachea. Any cuff even a so called low pressure cuffs can be over filled or the volume and pressure can increase during use resulting in high intracuff and tracheal wall pressures (69, 70).
Estimation of endotracheal tube cuff pressures

The volume necessary to raise the cuff pressure from a point of a seal to an unsafe pressure is only 2-3 ml (71). Catastrophic consequences of endotracheal tube over inflation such as rupture of trachea (72), tracheal-carotid artery erosion (73), and innominate artery fistulas are rare now that low-pressure, high volume cuffs are used routinely. However, the most common aetiology of non-malignant secondary tracheoesophageal fistula remains cuff-related injury (74). Acquired laryngeal stenosis may be caused by mechanical abrasion or pressure necrosis of the laryngeal mucosa secondary to high cuff-pressure (75). and finally, post intubation sore throat remains common and is thought to result, at least in part, from ischaemia of the oropharyngeal and tracheal mucosa (76). Appropriate inflation of endotracheal tube cuffs is thus important.

Previous studies suggest that the cuff pressure is usually underestimated by manual palpation. For example, Braz et al. (77) observed cuff pressure exceeding 40 cmH2O in 91% of patients after anaesthesia with nitrous oxide, 55% of ICU patients, and of 45% of patients after anaesthesia without nitrous oxide. Cuff pressures were thus less likely to be within the recommended range (20-30 cmH2O). Determination of adequacy of cuff pressure is therefore mandatory and should be a routine procedure.

In a previous study by Parwani et al (78), experienced emergency physicians ability to accurately inflate endotracheal tube cuff (ETTc) or estimate ETTc pressure using standard technique, was tested. Using palpation, participants were only 22% sensitive in detecting inappropriately inflated ETTc. They had little ability to inflate ETTc to safe pressure or to
estimate pressure of a previously inflated cuff using standard technique and most inflated to dangerously high levels. Clinicians should therefore consider using devices to facilitate safe and accurate measurement of ETTc pressure rather than relying solely on standard techniques.

ETTc pressure can be easily measured with a small aneroid manometer (79) that is connected to the pilot balloon of the endotracheal tube via a three-way stopcock. This type of aneroid manometer is nearly as accurate as a mercury manometer, but easier to use (79).
RATIONALE /JUSTIFICATION

KNH is a 2000 bed referral and teaching hospital with an ICU capable of handling 22 patients and a total of 22 operating theatres with an average of 50 operations per day. On average 60-70 patients are intubated everyday. Care in the ICU is provided by a team of physician anaesthetists, residents in anaesthesia and nurses trained in intensive care.

Being a referral hospital, patients are admitted from all over the country. There is a high demand for ICU beds and only the critically ill patients often requiring intubation for ventilatory support are admitted.

Anaesthesia in the operating rooms is provided by a team of physician anaesthetists, clinical officer anaesthetists, residents in anaesthesia and student clinical officers distributed as follows. Twenty three physician anaesthetists 19 clinical officer (CO) anaesthetists, 26 residents in anaesthesia and 20 CO student anaesthetists. There are 105 ICU nurses.

Determination of ETTc pressure at KNH is routinely determined by finger palpation of the pilot balloon. Establishing a secure airway via endotracheal intubation is a critical clinical skill and lifesaving technique. The procedure, however, can cause complications even long after the ETT is placed past the vocal cords and secured. This study sought to determine the ability of anaesthetists, anaesthesia students and ICU nurses at KNH to appropriately inflate an ETTc accurately using standard syringe technique as well as assess pressure of previously inflated ETTc by palpation of the pilot balloon.
There is no locally published data in this important aspect of critical care. It is only after comprehensive review of the local practices that valid, practical and plausible recommendations can be advanced on improving ETTc inflation practice.
HYPOTHESIS

The maximal ETTc pressures generated by the study participants do not exceed 30cmH2O.

AIMS AND OBJECTIVES

BROAD OBJECTIVE

To determine the ability of intensive care givers to accurately inflate endotracheal tube cuffs and estimate endotracheal tube cuff pressures using standard syringe technique and finger palpation of the pilot balloon.

SPECIFIC OBJECTIVES

- To determine the ability of the study population to inflate an ETT cuff to safe pressure using standard syringe technique.
- To determine the ability of study population to identify adequately inflated ETT cuff by finger palpation of the pilot balloon.
- To determine the ability of study participants to identify under inflated ETT cuffs.
- To determine the ability of study participants to identify over inflated ETT cuffs.
METHODOLOGY

STUDY DESIGN

This was a cross sectional descriptive analytical survey

STUDY SITE

The study was conducted at Kenyatta National Hospital (KNH) theatre and ICU.

STUDY POPULATION

These were the intensive care providers at KNH including: physician anaesthetists, clinical officer anaesthetists, and residents in anaesthesia, clinical officer anaesthesia students and all nurses working in the intensive care unit (ICU)

DETERMINING SAMPLE SIZE

The total population of intensive care givers at KNH is currently at 203 (source; Officer in charge anaesthesia department at KNH)

Assuming the population proportion “p” of individuals who inflate ETT cuff to within normal limits is 0.5 and the population proportion “Q” or (1-P) inaccurately inflate ETT cuff pressure then the sample size is calculated by the formulae by Fisher et al (1995).

\[ S = \frac{X^2NP(1-P)}{D^2(N-1) + X^2P(1-P)} \]

In which:

- \( S \) = required sample size
- \( N \) = population size
\[ P = \text{population inflating ETT cuff to within normal limits} \]

\[ D = \text{degree of accuracy} = 0.05 \]

\[ X_2 = \text{table value for chi square for one degree of freedom that is 1.96 for confidence level of 95\%} \]

The calculated sample size is 133

**SAMPLING PROCEDURE**

Based on the nature of this study, the study population is stratified into five categories namely physician anaesthetists, clinical officer anaesthetists, residents in anaesthesia, clinical officer student anaesthetists and ICU nurses.

At KNH, there are 23 physician anaesthetists, 19 clinical officer anaesthetists, 26 residents in anaesthesia, 20 clinical officer student anaesthetists and 105 nurses working in ICU. In each category, random sampling was applied using the formula by Fisher et al (1995)

\[ Z = \frac{WS}{X} \]

Where: \( Z \) = number of participants needed from the selected category

\( W \) = population of the selected category

\( X \) = total population of intensive care providers in KNH

\( S \) = required sample size

Using the formula, the number of participants from each category was as follows:

- Physician anaesthetists = 15
- Clinical officer anaesthetists = 12
- Residents in anaesthesia = 17
Student clinical officer anaesthesia students = 13

ICU Nurses = 76

In this sampling technique the names of all intensive care providers were printed on identical pieces of paper cards. The pieces of cards bearing the names were placed in the various category baskets and vigorously agitated to ensure even mixing of cards. Facing the other side the researcher picked cards successfully until the number required from each category was achieved.

Once the study participants were identified successfully and consent obtained from them after purpose of the study was explained, data collection commenced.

DATA COLLECTION

A size 7.5 ETT with a high volume, low pressure cuff placed in a rigid plastic pipe 2.0cm in diameter and 5cm long was used to simulate the trachea. Using their choice of a 5- or 10-mL syringe, participants will be asked to inflated the ETTc by standard method of injecting air then palpating the pilot balloon to estimate ETTc pressure. ETTc pressure was measured using a highly sensitive and accurate analog manometer (UBM Suiz. Germany). Participants were then asked to palpate 9 ETTc previously inflated to pressures ranging from extremely low to extremely high and reported their assessment of inflation as appropriate, low, normal or high. The choice of 9 tubes reduces bias. The pressures in cm H2O. pre-inflated ETT was: 0. 5. 8, 10, 20, 30, 50, and 80,100.

Data of participants including age and sex; category and duration of experience was recorded.

Data was collected using a pre-designed data collection instrument (Appendix 1)
INCLUSION CRITERIA
All intensive care providers involved in taking care of intubated patient at KNH willing to participate in the study after an informed consent.

EXCLUSION CRITERIA
All workers in KNH not involved in direct care of intubated patients
All intensive care providers not willing to participate in the study after an informed consent.
ETHICAL CONSIDERATION

Verbal informed consent was sought from all willing participants. In addition approval was sought from the KNH Ethical and Scientific Review Committee, before embarking on the study.

The study did not compromise the care of patients either in the ICU or in theatre.

The study did not pose any harm to the participants.

All data obtained from this study was treated with utmost confidentiality and used only for the intended purposes.
RESULTS

We sampled 149 intensive care givers. Among them 54% were nurses, 11% were physician anaesthetists, 9% were CO anaesthetists. 14% were registrar anaesthetists while 12% were CO student anaesthetists. On average, each respondent had a work experience of five years.

Among ICU nurses 8% inflated ETTc to normal pressures of between 20-30cmH2O. 93% inflated to high pressures. None inflated to low pressures.

Among the physician anesthetists 8% inflated to normal pressures, while 92% inflated to high pressures. None inflated to low pressures.

14% of the CO anaesthetists inflated the ETTc to normal pressures, while 86% inflated to high pressures. and none inflated to low pressures.

Among the registrar students, 5% inflated to low pressures, 5% to normal pressures and the rest (90%) inflated to high pressures.
Among CO student anaesthetists, 6% inflated to normal pressures while 94% inflated to high pressures.

Only 9% of participants accurately inflated the ETTc to normal pressures (20-30cmH2O).

the average ETT cuff pressure produced could not be precisely determined because 33% of participants (n=149) inflated to pressures greater than the upper limit of manometer sensitivity (>120cmH2O). Using the available data however, the average pressure generated was >91cmH2O, range 32-120cmH2O.

Using a one-tailed hypothesis test width of 0.01, the null hypothesis that the mean pressure generated by study participants does not exceed 30cmH2O was rejected.

The calculated p-value among the various categories of care givers for inflation of ETTc was 0.6.
In detecting previously inflated ETTc all participants correctly detected low pressures as low. The sensitivity of detecting normal pressure was 4.1%. The sensitivity for detecting high pressure was also 4.1%.

Specificity (probability of detecting incorrect pressures when they are incorrect) was 52.1. The positive predictive value PPV (probability that pressures detected to be correct is actually correct) was 4.1%. The negative predictive value (probability that pressure detected to be incorrect is actually incorrect was 52.1%).

No participant correctly identified all over inflated ETT cuffs.
DISCUSSION

Catastrophic consequences of ETTc over-inflation such as rupture of the trachea (72), tracheal-carotid artery erosion (73), and tracheal-innominate artery fistulas are rare now that low pressure, high volume cuffs are used routinely. However, the most common aetiology of non-malignant tracheoesophageal fistula remains cuff-related tracheal injury (74).

Acquired laryngeal stenosis may be caused by mechanical abrasion or pressure necrosis of the laryngeal mucosa secondary to high cuff pressure (75). Recurrent laryngeal nerve palsy following interior neck surgery has been related to the high pressure in the ET tube pressing against the retractors in the neck wound (76). And finally, post intubation sore throat remains common and is thought to result at least in part from ischaemia of the oropharyngeal and tracheal mucosa (76). Appropriate inflation of ETT cuffs is thus important.

Previous studies suggest that the cuff pressure is usually under-estimated by manual palpation. For example, Braz et al. (77) observed cuff pressure exceeding 40cmH2O in 91% of PACU patients after anaesthesia with nitrous oxide, and 55% in ICU patients.

In an experimental study, Fernandez et al. (79) observed that when the cuff was inflated randomly to 10, 20 or 30cmH2O, 69% of the participating physicians and ICU nurses were able to identify high pressure cases, 58% were able to identify normal pressure cases and 73% correctly identified low pressure cases.

Our results are inconsistent in that inflated cuff pressure exceeded 30cmH2O in 94% of the cases, and were less than 20cmH2O in none of the cases. Cuff pressures were thus less
likely to be within recommended range (20-30cmH2O) than outside the range. It is discouraging that we observed extremely high values as reported in previous studies.

Interestingly, there was also no significant or important difference as a function of the provider—ICU nurses, physicians, anaesthetists, CO anaesthetists, registrars in anaesthesia and CO student anaesthetists inflated cuff pressures being virtually identical for each group. Our results thus failed to support the theory that increased training improves cuff management.

ICU nurses are involved in the continuous monitoring and care of critically ill patients in the unit. They assist physiotherapists during chest suctions and chest drainage sessions. This requires frequent deflation and inflation of endotracheal tube cuffs. They therefore need to accurately estimate ETTc pressures. In our study, their ability to adequately inflate the ETTc and estimate ETTc pressures via finger palpation of the pilot balloon is largely lacking. This leaves the helpless unconscious critically ill patients under the obvious complications of the trachea exposed to high ETTc pressures.

The physician anaesthetists and the clinical officer anaesthetists are involved in imparting knowledge to the anaesthesia students and registrars. It’s therefore mandatory that they be armed with the correct knowledge and skills. Our results showed no demonstrable difference in the practice among the various categories of intensive care providers as far as estimation of ETTc pressures are concerned.
Various devices can be used to accurately measure ETTc pressures. Microchip sensors placed in the anterior lateral, and posterior surfaces of the cuff have been used in studies to determine mucosal pressures exerted on the tracheal wall by the cuffs(80). Automatic cuff inflator devices are useful especially in theatre settings where nitrous oxide is in use with the prevailing dangers of over distention of ETTc following diffusion of nitrous oxide across the cuff walls. Use of cuff manometer as we used in the study is common practice in centers where proper cuff inflation practices are adhered to. After finding a direct relationship between increasing cuff volumes and mucosal pressures, Herbert Ulrich-Pur and colleague at The Medical University Vienna in Austria, advise: “Recommended volumes should be strictly followed because slight overextension exert high pressures.”(80)

Other cuffed airway devices exert similar pressures on the laryngotracheal mucosa as does the cuffed endotracheal tube. Some airway devices exert significantly higher pharyngeal pressures than others though the difference may not be clinically relevant due to their short intended use. At the cuff inflation volumes recommended by the manufacturer, the intubating laryngeal mask (ILMA) induced significantly higher pharyngeal pressures than other devices.

While recommending that manufacture guidelines are followed to avoid inducing excessive pressures the observed differences between the various devices (laryngeal mask airway, esophageal tracheal combitube, Proseal laryngeal mask airway and laryngeal tube) do not seem to be clinically relevant and do not preclude the use of any device clinically because the devices investigated are not intended for prolonged use (for more than 8 hours)(80).
CONCLUSIONS

1. Participants had little ability to inflate ETTc to safe pressures

2. Clinicians should consider using devices to facilitate safe inflation and accurate measurement of ETTc pressure rather than relying solely on standard finger palpation technique.

STUDY LIMITATIONS

• Estimation of many ETTc pressures within a short time may have resulted in confusion in estimating some pressures

• The rigid tube used may not adequately simulate a trachea

• The small sample size in some category of participants may have created bias in the results
RECOMMENDATIONS

Care givers need to be trained on the adequate pressures needed to inflate the ETTc accurately.

More accurate techniques e.g. manometers, should be used at all times to measure ETTc pressures;

Manufacturer guidelines should be followed to avoid inducing excessive pressures.
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APPENDIX 1

DATA COLLECTION INSTRUMENT

1. **INITIALS** _______________.

2. **CATEGORY**
   - PHYSICIAN ANESTHETIST
   - CLINICAL OFFICER ANESTHETIST
   - RESIDENT IN ANESTHESIA
   - CO ANESTHESIA STUDENT
   - ICU NURSE

3. **DURATION OF EXPERIENCE** ____________ YEARS IN ICU/THEATRE

4. **INFLATED CUFF PRESSURE** --------------------- CMH₂O

5. **ESTIMATED PRE-INFLATED ETT CUFF PRESSURE**

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<thead>
<tr>
<th>TUBE NO.</th>
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APPENDIX II

CONSENT EXPLANATION

1. Dr Stephen W. Wangaka MBChB (Nbi), a final year Anaesthesia registrar will give you, the participant, a full explanation of my intended study before you sign the consent form.

The study

The study aims to seek the ability of intensive care givers at Kenyatta National Hospital to inflate endotracheal tube cuff accurately and the ability to estimate inflated endotracheal tube cuff using standard finger palpation technique.

Confidentiality

Your identity will be protected at all stages of the study. only initials will be used during the reference to the participants during the study.

Participation in the study

Your participation in the study will be voluntary and you can decide to withdraw from the study at any stage. The study is non invasive and will be carried at no cost to you.

No complications are expected to occur as a result of your participation in the study. The study will be carried out during your routine work and the whole process takes about one minute.
Participation consent

I.............of.....consent to participate in the study of endotracheal tube pressure estimation at the Kenyatta national hospital.

Am fully aware that the study does not entail the use of any invasive procedures. or pose any danger. I also understand that incase I need to get in touch with the researcher, Dr Stephen w. wangaka is available on mobile number 0722745791.

I have the freedom to decide to participate in the study at anytime.

Signed.......................... Date........................

I confirm that I have explained to the participant the nature of the study.

Signed..........................date...........................
Dear Dr. Wakaba

RESEARCH PROPOSAL: "ESTIMATION OF ENDOTRACHEAL TUBE CUFF PRESSURES AT KENYATTA N. HOSPITAL" (P129/6/2006)

This is to inform you that the Kenyatta National Hospital Ethics and Research Committee has reviewed and approved your above cited research proposal for the period 3rd August 2006 – 2nd August 2007.

You will be required to request for a renewal of the approval if you intend to continue with the study beyond the deadline given.

On behalf of the Committee, I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of database that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Yours sincerely

[Signature]

PROF AN GUANTAI
SECRETARY, KNH-ERC

C.C. Prof. K.M.Bhatt, Chairperson, KNH-ERC
The Deputy Director CS, KNH
The Dean, Faculty of Medicine, UON
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