

**A PROSPECTIVE COMPARATIVE STUDY OF CONTINUOUS AND
INTERMITTENT ENDOTRACHEAL TUBE CUFF PRESSURE MEASUREMENT IN
AN ADULT INTENSIVE CARE UNIT**

By

Mduduzi Emmanuel Memela

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Submitted in fulfilment of the Master's degree in Clinical Technology

In the

Department of Biomedical and Clinical Technology

Faculty of Health Science

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Durban, South Africa

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Supervisors: **Dr P D Gopalan**

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This study was carried out at King Edward VIII Hospital' surgical ICU. The study represents original work done by the author and has not been submitted in any form to another University. In cases where use of the work by others, it has been duly acknowledged in the text.

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Abstract

Introduction: The aim of this study was to establish the most reliable standard method for monitoring endotracheal tube cuff pressure in an intensive care unit.

Methodology: The study was conducted at King Edward VIII Hospital ICU on adult patients undergoing prolonged intubation of more than 24 hours. Consent was obtained from the patient's next of kin. The patient's Pcuff for this study was recorded in two ways simultaneously for a period of 12 hours during the day. The principal investigator recorded the Pcuff thrice during the study period using the Posey cufflator[®]. Continuous recording was done using a pressure transducer connected to the Nihon Kohden BSM[®]. Factors causing changes in Pcuff were also documented.

Results: Thirty-five critically ill adult patients were enrolled into the study. Nineteen (54.3%) of the subjects were male. Seventeen out of 35 subjects were studied for the entire 720 minute period. The mean time of study of the group was 667 minutes with the lowest period being 135 minutes for one patient. The group mean \pm Standard deviation (SD) was 26.6 ± 8.7 with a 95% confidence index of 9.2 – 44.0 and the median value was 25 for continuous readings. For the entire group, 13% of the time was spent in the low pressure range ($< 20 \text{ cmH}_2\text{O}$), while 23% was spent in the high pressure ($> 30 \text{ cmH}_2\text{O}$). A mean of 64% of the time was spent in the normal pressure range. Overall, the most frequently encountered events that caused pressure changes were body movement, coughing, head movement and suctioning accounting for 26.2%, 20.1%, 19.2% and 9.4% respectively. For intermittent readings, the mean \pm SD of all patients for T_0 was 25.3 ± 6.9 ; for T_6 25.9 ± 8.7 and for T_{12} 24.8 ± 3.8 . The overall mean \pm SD for all readings was 25.6 ± 7.1 . For the entire group, 12% of the time was spent in the low pressure range ($< 20 \text{ cmH}_2\text{O}$), while 5% was spent in the high pressure ($> 30 \text{ cmH}_2\text{O}$). A mean of 83% of the time was spent in the normal pressure range. The correlation between intermittent pressure and the continuous reading at the same time was $r = 0.87$.

Discussion: Continuous monitoring of Pcuff indicated that the endotracheal cuff pressure varies extensively during mechanical ventilation in critically ill patients, such variation being noted both between patients and within an individual patient. In an attempt to compare intermittent and continuous monitoring of endotracheal cuff pressures, a good correlation between the two measurements was demonstrated. However, the variations in pressures noted for an individual patient would not have been detected if endotracheal cuff pressures were monitored intermittently. Hence, with continuous monitoring the pressure changes may be detected early.

Conclusion: Continuous monitoring of cuff pressure during mechanical ventilation in intensive care units is thus recommended for all patients. If intermittent monitoring is performed, it should be more frequently than eight-hourly. It is recommended that a pressure range of 20-30 cmH₂O still be used as the normal range. The role of self adjusting pressure devices, although needing further exploration, holds much promise.

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The journey that I have been through would not have been possible without the support and assistance of the following people. Therefore I would like take this opportunity to convey my sincere appreciation and salute them all.

To the Almighty God, without you I would not be breathing right now, I love you God.

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List of abbreviations

ABBREVIATION	DESCRIPTION
Pcuff	Cuff pressure
ETT	Endotracheal tube
BSM	Bed side monitor
ICU	Intensive care unit
PVC	Polyvinyl chloride
HVLP	High-volume, low-pressure
SIMV	Synchronised intermittent mandatory ventilation
CMV	Control mandatory ventilation
BiPAP	Biphasic positive airway pressure
PEEP	Positive end expiratory pressure
CPAP	Continuous positive airway pressure
ARDS	Acute respiratory distress syndrome
LVLP	Low-volume, low-pressure
VAP	Ventilator acquired pneumonia
TOF	Tracheo-oesophageal fistula
LCD	Liquid crystal display
NGT	Nasogastric tube

CHAPTER ONE: INTRODUCTION

Cuff pressure is the pressure generated by the inflated cuff of endotracheal or tracheostomy tubes. There are many types of endotracheal tubes with varying cuffs, various methods of inflating cuffs and a variety of “ideal ranges” for maintaining cuff pressure. Endotracheal tubes are used for intubation of the airway. This is done orally or nasally to facilitate the passage of gases into the lung, and to protect the airway. Most patients in intensive care units require endotracheal intubation, and some subsequently have tracheostomy tubes placed. Both tubes have cuffs that exert pressure against the tracheal mucosa. The purpose of these cuffed tubes is to form a seal against the tracheal wall to prevent air leaking around the tube, as well as to protect against aspiration of any secretions. Endotracheal Tube (ETT) cuff pressure (Pcuff) can change drastically by several effects exerted on the cuff (Wujtewicz, 2004). This may lead to side effects due to under-inflated or over-inflated cuffs. Over-inflation of the ETT cuff can cause changes in the tracheal mucosa. It may cause partial or total blockage of tracheal mucosal blood flow, granuloma, rupture of the trachea, formation of tracheo-oesophageal fistulae, or tracheal stenosis. Under-inflation may cause air leakage, risk of pulmonary aspiration and accidental extubation.

Research has shown that there is a need for precise measurement of Endotracheal Pcuff in prolonged intubation such that side effects may be prevented (Braz, Navarro, Takata, and Nascimento Junior, 1999). This may occur in patients undergoing intensive care therapy or prolonged anaesthesia. Several studies have been undertaken in order to determine the best techniques for cuff inflation, e.g., minimum occlusive volume and minimum leak technique. However, no common method has been widely accepted.

The ideal range for cuff pressure has differed with each study. Most studies have recommended cuff pressures around 20 cmH₂O. However, Akmal, Hameed, and Motasem (2008), argue that monitoring cuff pressure alone is insufficient because tracheal damage may occur even in ideal ranges. Ideally, cuff volumes should not exceed 6-8 ml; and the need to inflate the cuff to greater than 10 ml should raise concerns about tracheal injury (Make, Hill, Goldberg, Bach, Criner, and Dunne, 1998).

An international study has demonstrated high rates of ETT cuff overinflation in intensive care unit patients, ranging from 55% to 62% (Braz et al., 1999). When the Pcuff was maintained at less than 20 cmH₂O, the risk for ventilator-associated pneumonia was four times higher than when pressures were maintained at higher levels (Rello, Soñora, Jubert, Artigas, Rue, and Valles, 1996). However, according to the literature, no such studies have been undertaken in South Africa.

The aim of this study was to establish the most reliable standard method for monitoring endotracheal tube cuff pressure in an intensive care unit. The first objective was to identify the extent of Endotracheal cuff pressure changes during ventilation. The second objective was to identify the differences between continuous and intermittent monitoring of endotracheal cuff pressure during prolonged intubation in early detection of pressure changes within a set normal range.

This study used continuous monitoring of endotracheal Pcuff of patients in an intensive care unit (ICU) to investigate the degree and reasons for changes in Pcuff. In addition, a comparison was made with the currently employed technique of intermittent monitoring of Pcuff. The study was conducted at King Edward VIII Hospital ICU on adult patients undergoing prolonged

intubation of more than 24 hours. Currently, the Pcuff is recorded thrice in a 24 hour period using a mechanical manometer. After obtaining informed consent from the patient's next of kin, the patient's Pcuff for this study was recorded in two ways simultaneously for a period of 12 hours during the day. The principal investigator recorded the Pcuff thrice during the study period using a mechanical manometer called Posey cufflator[®] (Posey company, Arcadia, USA). In addition, a continuous recording was done using a pressure transducer connected to the Nihon Kohden BSM[®] (Nihon Kohden Corporation, Japan). Factors causing changes in Pcuff were also documented.

CHAPTER TWO: STUDY BACKGROUND AND LITERATURE REVIEW

2.1 STUDY BACKGROUND

2.1.1 Introduction

Critically ill patients and anaesthetized patients undergoing surgery may require intubation of their airway and mechanical ventilation. This involves the insertion of an endotracheal or tracheostomy tube with a cuff into the airway to facilitate the passage of gas into the lungs, as well as to protect against aspiration. There has been continuous development of these tracheal tubes to reduce the risk of injury to the tracheal wall (Dullenkopf, Gerber, and Weiss, 2003). Cuff pressure is the pressure generated by the inflated cuff of endotracheal or tracheostomy tubes. Endotracheal Tube (ETT) cuff pressure (Pcuff) can change drastically by several effects exerted on the cuff (Wujtewicz, 2004). This may lead to side effects due to under-inflated or over-inflated cuffs. Over-inflation of the ETT cuff can cause changes in the tracheal mucosa. It may cause partial or total blockage of tracheal mucosal blood flow, or it may cause tracheal stenosis, granulomata, rupture of the trachea, nerve palsy, or the formation of tracheo-oesophageal fistulae.

Under inflation may cause air leakage, increased risk of pulmonary aspiration and accidental extubation. Research has shown that there is a need for precise measurement of Endotracheal Pcuff in prolonged intubation (Braz et al., 1999). This may occur in patients undergoing intensive care therapy or prolonged anaesthesia. Endotracheal cuff pressure changes may also be affected by factors like coughing, suctioning and patient movement, which can only be monitored by a continuous dynamic monitoring device (Kao, 1991).

Despite the improvement of the endotracheal/tracheostomy tubes, the proper inflation methods need to be used for appropriate cuff pressure management. There are several methods of cuff inflation. Such methods include minimum occlusive volume, minimum leak technique, pre-determined volume technique, palpation technique and direct intra-cuff pressure measurement techniques using different mechanical devices (Stewart, Secrest, Norwood, and Zachary, 2003).

2.1.2 Respiratory anatomy and physiology

2.1.2.1 Upper airway anatomy and physiology

The upper airway includes the nose and nasal cavity, pharynx and larynx which are responsible for delivering air into the lungs. These structures are affected, or their functions are bypassed, due to intubation.

2.1.2.1.1 The nose and nasal cavity

The nose is the only structure that is externally visible as part of the respiratory tract. This is except for the mouth which acts as an alternative if there is nose blockage. The internal part of the nose called the nasal cavity lies in and posterior to the external nose as shown in figure 1 (Marrieb, 2004). The functions of the nose are to provide an airway for respiration, moisten and warm entering air, filter and clean inspired air, serve as a resonating chamber for speech and contribute to smelling (Sembulingam, 2005).

2.1.2.1.2 The Pharynx

The pharynx, which is about 12 to 15 centimetres long, extends from the base of the skull to the level of the cricoid cartilage anteriorly and the inferior

border of the sixth cervical vertebrae posteriorly (Heylings, Spence and Kelly, 2007). It is divided into three regions, the nasopharynx, oropharynx and laryngopharynx. Its main functions are to serve as a passage way for respiration, and to protect the airway against pathogens in inspired air.

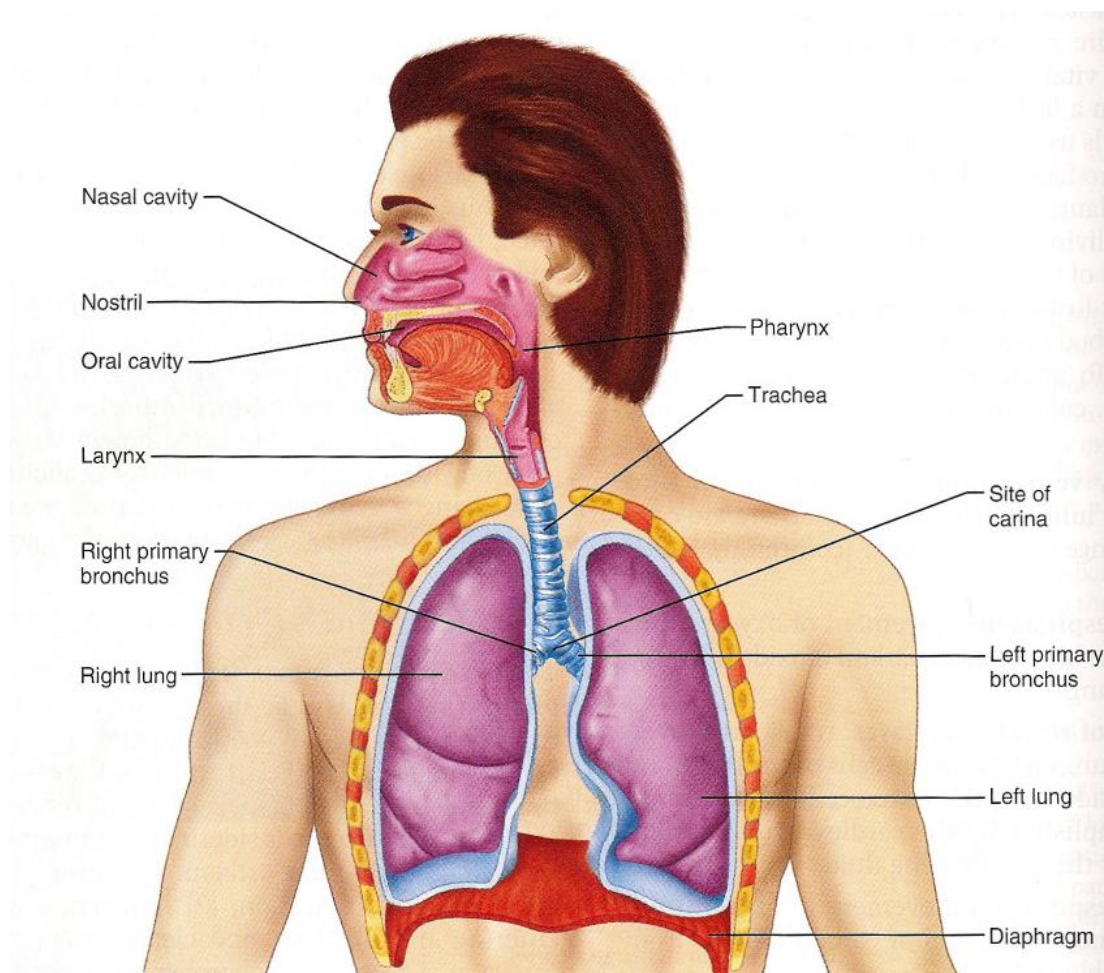


Figure 1 The major respiratory organs (Marrie, 2004).

The oropharynx and laryngopharynx also serve as a passageway for food. The laryngopharynx lies directly posterior to the upright epiglottis and extends to the larynx, where the respiratory and digestive pathways diverge. At this point the laryngopharynx is continuous with the oesophagus

posteriorly which conducts food and fluids to the stomach. Air enters the larynx anteriorly (Sembulingam, 2005).

2.1.2.1.3 The larynx

The larynx is about 5 centimetres long and positioned around the third to the sixth cervical vertebrae in the neck. It opens into the laryngopharynx superiorly and is continuous with the trachea inferiorly. The functions of the larynx are to provide a patent airway and to act as a switching mechanism to allow air and food into the correct channels. The vocal cords are situated in the larynx and these are responsible for voice production. The epiglottis is situated on the larynx, forming one of the nine cartilaginous structures of the larynx. The inlet to the larynx is open wide and the free edge of the epiglottis projects upward during the flow of air only into the larynx. When there is swallowing, the larynx is pulled superiorly and the epiglottis tilts to cover the laryngeal inlet (Guyton and Hall, 2006; Stanton and Koeppen, 2008).

2.1.2.2 Lower airway anatomy and physiology

2.1.2.2.1 The trachea

The trachea extends inferiorly from the larynx and descends down to the superior mediastinum. It ends by dividing into two main bronchi at the mid-thorax. This point of bifurcation is called the carina. Tracheal length is about 10 – 12 centimetres with a diameter of about 2.5 centimetres. The trachea is flexible and mobile. The tracheal wall consists of mucosal, submucosal and adventitial layers. The mucosa has goblet cells whose cilia continually propel debris-laden mucus towards the pharynx. The submucosa is made up of the connective tissue layer deep to the mucosa and contains seromucous glands. These glands help to produce the mucus within the trachea. The adventitia, the outermost layer, is a connective tissue layer reinforced

internally by 16 to 20 C-shaped rings of hyaline cartilage (Heylings et al., 2007). The trachea plays a very important role of keeping the airway patent even with changing pressures during respiration. This is achieved by the cartilage rings that prevent it from collapsing. The trachea has elastic elements which allow it to be flexible enough to stretch and move inferiorly during inspiration and recoil during expiration. The open posterior parts of the cartilage rings are joined by the smooth muscle fibres of the trachealis muscle and by soft connective tissue. This part of the tracheal wall is not rigid and therefore the oesophagus can expand anteriorly as swallowed food passes through it. When the trachealis muscle contracts, the diameter of the trachea decreases and it forces air outward. This action also helps to expel mucus from the trachea when we cough. The carina is the last tracheal cartilage that is expanded and it projects posteriorly marking the division of trachea into two primary bronchi. The carina's mucosa is highly innervated and aggressive coughing is elicited when foreign objects makes contact with it (Guyton and Hall, 2006).

2.1.2.2.2 The bronchi and it branches

This consists of the conducting zone and the respiratory zone. When the trachea divides, approximately at the level of the seventh thoracic vertebra on a standing person, it forms the left and right main bronchi. These bronchi run obliquely in the mediastinum before plunging into the hilus of the lung on the opposite sides. The gas reaching this point must be warm, not contaminated, and saturated with water vapour. The walls of the main bronchi are made of tissues that mimic that of the trachea but changes as conducting tubes become smaller. Primary bronchi then subdivide into secondary bronchi and further divisions to segmental bronchi until smaller bronchi, called bronchioles, are formed. Terminal bronchioles are less than 0.5 mm in diameter and this marks the end of the conducting zone and the beginning of the respiratory zone (Rhodes and Bell, 2009).

2.1.2.2.3 The respiratory bronchioles and alveoli

The respiratory zone begins as the terminal bronchioles supply into respiratory bronchioles within the lungs. The alveoli are the major part of the respiratory zone which protrudes from the smallest bronchioles. The respiratory bronchioles lead to winding alveolar ducts, whose walls consist of diffusely arranged rings of smooth muscle cells and connective tissue fibres. The alveolar ducts lead to terminal clusters of the alveolar called alveolar sacs. Heylings et al. (2007), claim that many people mistakenly equate alveoli, the site of gas exchange, with alveolar sacs, but they are not the same thing. The alveoli sac is analogous to a bunch of grapes, and the alveoli are the individual grapes. The 300 million or so gas-filled alveoli in the lungs account for most of the lung volume and provide a very large surface area for gas exchange. The walls of the alveoli are composed primarily of a single layer of squamous epithelial cells called type 1 cells, surrounded by a delicate basal lamina. The respiratory membrane is the combination of the alveolar and capillary walls, and their fused basal laminae. It is an air-blood barrier that has gas on one side and blood flowing past on the other side as shown on figure 2. There is also cuboidal type II cells forming the wall of the alveoli which secrete a fluid containing surfactant that coats the gas exposed alveolar surfaces.

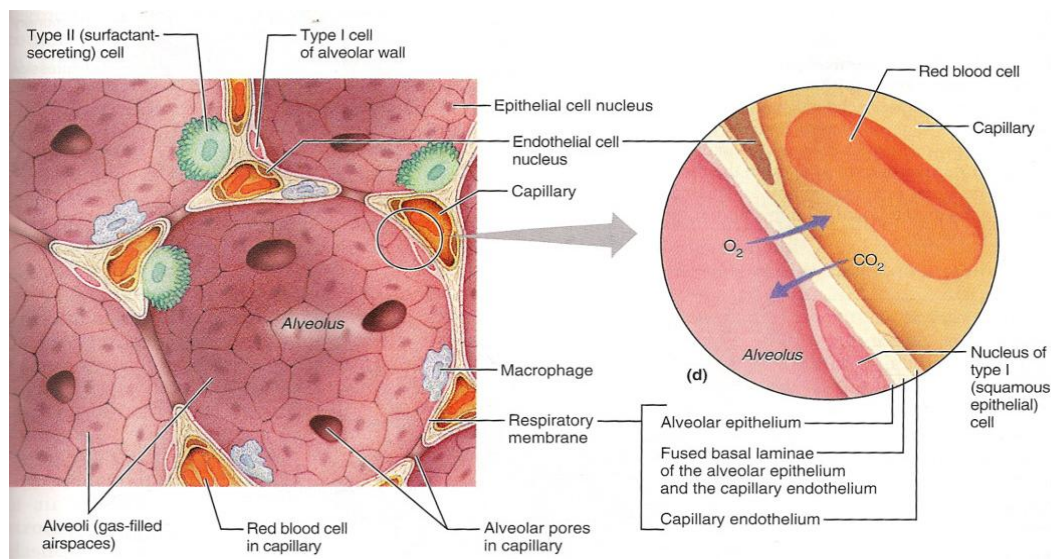


Figure 2 The structure of the respiratory membrane (Marieb, 2004).

2.1.3 Airway management

2.1.3.1 Endotracheal Intubation

Endotracheal intubation is a procedure that involves insertion of endotracheal tube (ETT) through the mouth into the trachea. Intubation can also be done through the nose using nasotracheal tubes. This procedure is performed by trained medical personnel usually under anaesthesia or sedation, and often the use of muscle relaxant is required.

An appropriate level of unconsciousness and muscle relaxation has to be achieved before insertion of the tube for a smooth intubation process to occur. The correct placement of the endotracheal tube is vital. The distal tip of the tube should end approximately 2 centimetres above the carina which is the point of bifurcation of trachea. At insertion and under vision, the tube should be passed until the cuff just disappears beyond the cords. At this point, distance markings on the tube at the level of the teeth should be noted. The position of the tube should be verified clinically by auscultation of equal

breath sounds bilaterally. The position can also be verified by chest X-ray examination.

2.1.3.2 Endotracheal tubes

Endotracheal tubes are hollow airway tubes that are usually made from polyvinyl chloride (PVC) as shown in figure 3 below. The tube may have a cuff, pilot tube and pilot balloon, Murphy eye and the permanent distance markings (Gary, 2005).

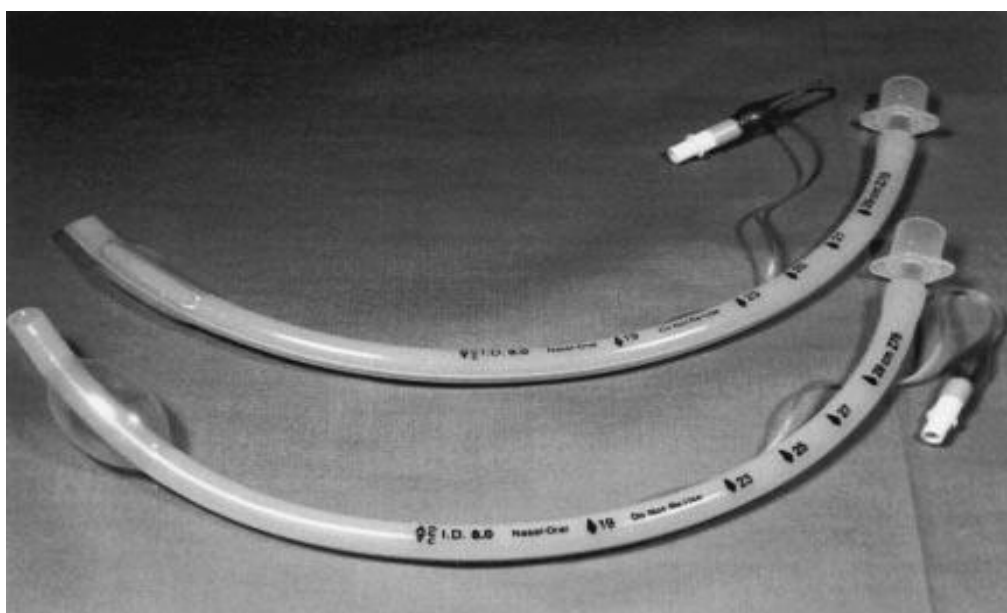


Figure 3, Two adult endotracheal tubes. On one tube (upper) the cuff is deflated and the other (lower) is inflated (Gary, 2005).

Endotracheal tubes may be cuffed or uncuffed. Uncuffed tubes are commonly used for neonates and young children. Cuffed tubes are used for older children and adults. There are different sizes of cuffed tubes available commercially ranging from 4.0 to 10.0 mm in internal diameter. The guidelines for choosing the correct size tube are as follows according to Morgan Jr and Mikhail, (2005): For a full-term infant use 3.5 mm; for a child

use the formula $(4 + \text{age}/4)$; and for adult the guidelines are to use 7.0 mm to 7.5 mm for adult females and 7.5 to 9.0 mm for adult males depending on the size of the individual. It is important to choose a correct size tube so that minimal pressure may be applied. If too small a tube is used, a higher volume and pressure will be needed to provide the seal against the tracheal wall. There are also various other specialized ETT used for specific purposes. For instance, reinforced endotracheal tubes used to prevent kinking and also used for difficult intubation, and the oral and nasal RAE[®] tubes (Rusch Inc, Duluth, Georgia) designed for removing the breathing circuits away from the head with its bending characteristic feature. Endobronchial tubes are especially designed for intubating either the left or the right mainstem bronchus selectively. The Carlens tube is used for intubating the left mainstem only. There are two Robertshaw tubes that are used selectively for insertion into the left bronchus only (Robertshaw left) or the right bronchus only (Robertshaw right).

For several years, there have been attempts to develop a safe cuffed ETT, which will minimise pressure exerted on the tracheal wall. Sixteen commercially cuffed tubes were tested and Shiley[®], Portex soft-seal[®], and Kamen-Wilkinson[®] (Bivone Fome) showed the lowest tracheal wall pressure (MacKenzie, Klose and Browne, 1976).

An observational study at the Queen Elizabeth Hospital has recently been conducted between high-volume, low-pressure and low-volume, low-pressure ETT. It showed that a low-volume, low-pressure tracheal tube cuff reduces pulmonary aspiration in the anaesthetised and critically ill patients (Young, Pakeerathan, Blunt and Subramanya, 2006).

2.1.3.2.1 Endotracheal tube cuff

The endotracheal tube cuff is a large inflatable balloon near the distal tip of the tube. It is inflated to seal against the tracheal wall to prevent air leaking around the tube and aspiration of oropharyngeal secretions as shown in figure 4.

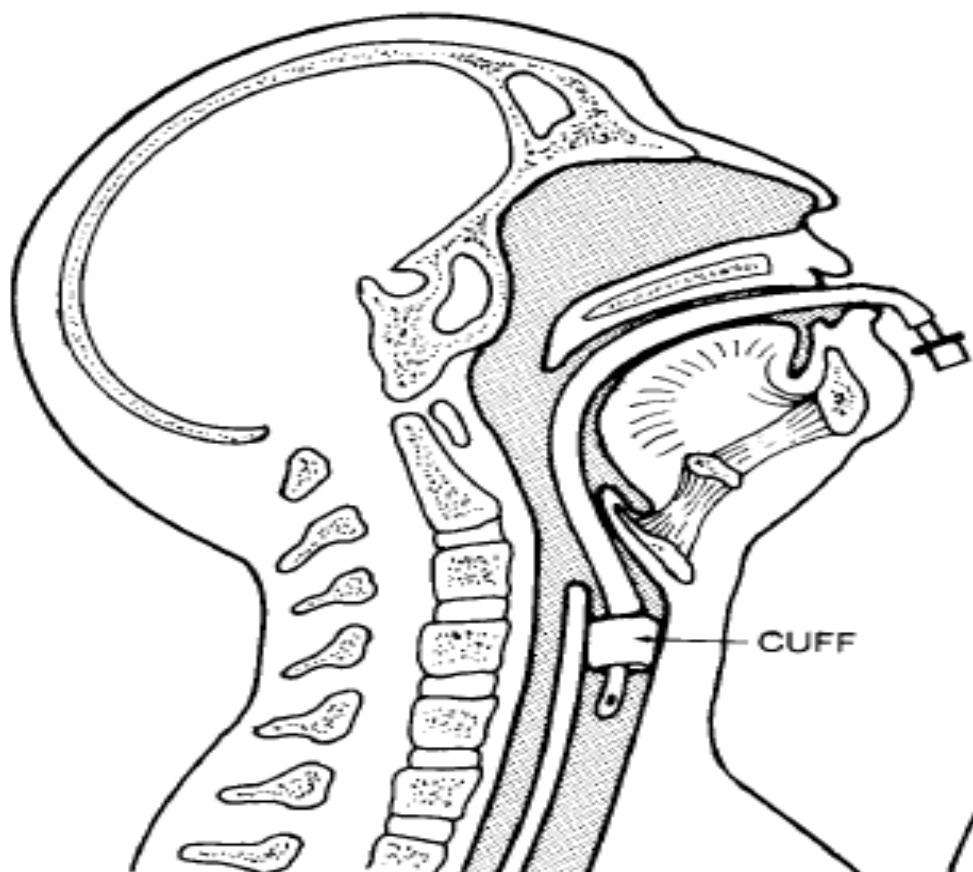


Figure 4 Schematic diagram of intubated model with inflated cuff (Gary, 2005).

Modern cuffs are designed to be high-volume, low-pressure cuffs (HVLP) to minimise pressure exerted on the tracheal wall. This is achieved because the pressure is distributed over a greater area which also helps to seal the cuff (Gary, 2005). A study was conducted on the Microcuff[®] ETT (Microcuff GmbH, Weinheim, Germany), high-volume low-pressure featuring an ultra thin polyurethane cuff membrane. This study, conducted at University Children Hospital, Department of Anaesthesia, Switzerland, showed that it

prevents fluid leakage at 25 – 30 cmH₂O (Dullenkopf et al., 2003). The different cuffs that were tested in this study are shown in figure 5. Cuffs marked a to e in Figure 5 represent the following: (a) Microcuff[®] HVLP; (b) Mallinckrodt HiLo[®] (Mallinckrodt Medical, Athlone, Ireland); (c) Portex profile soft seal[®] (SIMS Portex Ltd., Hythe, Kent, UK); (d) Rűsch Super Safety Clear[®] (Rűsch GmbH, Kernen, Germany); and (e) Sheridan CF[®] (Hudson Respiratory Care, Temecula, USA).

Another ETT that seems to minimise pressure exerted to the tracheal wall is the Lanz[®] tube (Covidien, Mansfield, England), Figure 6. This tube is designed in such a way that it is integrated with a regulating valve and a control balloon made of latex within the large pilot balloon. The principle by which it functions is that when extra volume is infused, the control balloon absorbs it without transmitting additional pressure to the cuff. This ETT was tested in a study that was conducted by Leigh and Maynard, (1979). Eight different tubes were compared to test pressures exerted by these cuffed tubes on the tracheal mucosa. The Portex[®] and Mallinckrodt[®] tubes exerted pressures close to the mean capillary perfusion pressure but resulted in very high pressures if overinflated. The Lanz[®] tube was the only tube that was able to maintain an optimal lateral wall pressure even if inflated beyond the seal point due to its over-pressure safety balloon. The regulation valve and balloon of the Lanz[®] tube limited cuff pressures between 16 and 18 millimetres of mercury (Gary, 2005).

Another study investigated the advantage provided by the Lanz[®] tube during nitrous oxide anaesthesia. This study conducted by Cuvas, Dokumaci, Yazar and Basar (2007), showed that the Lanz[®] tube works properly and it limits the increase in intracuff pressure. There were no advantages with respect to reduction in intensity and incidence of postoperative laryngotracheal complications after nitrous anaesthesia lasting approximately two hours.

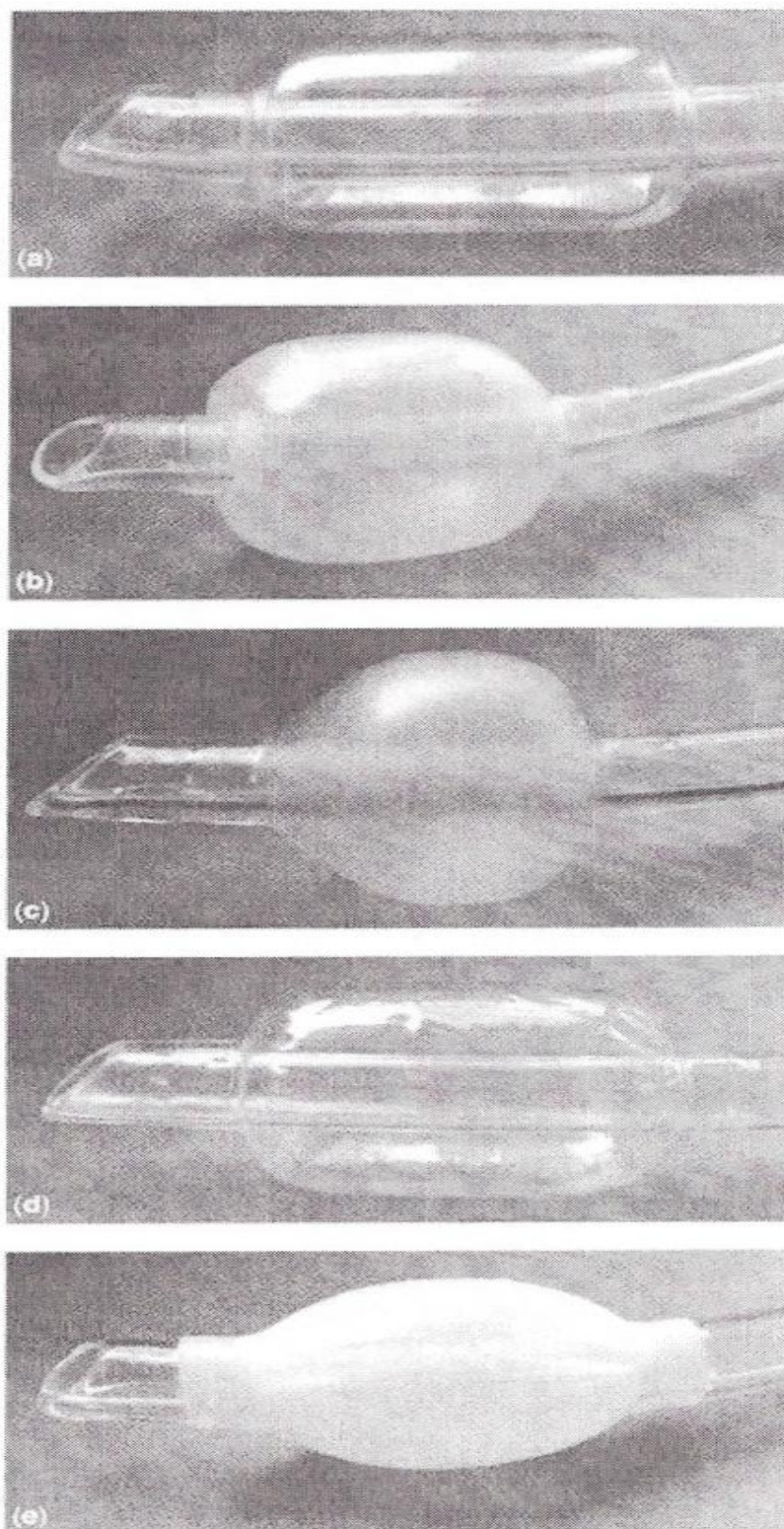


Figure 5 Different endotracheal tube cuffs (Dullenkopf et al., 2003)

Despite proposed advantages, the Lanz[®] tube has not achieved widespread popularity.

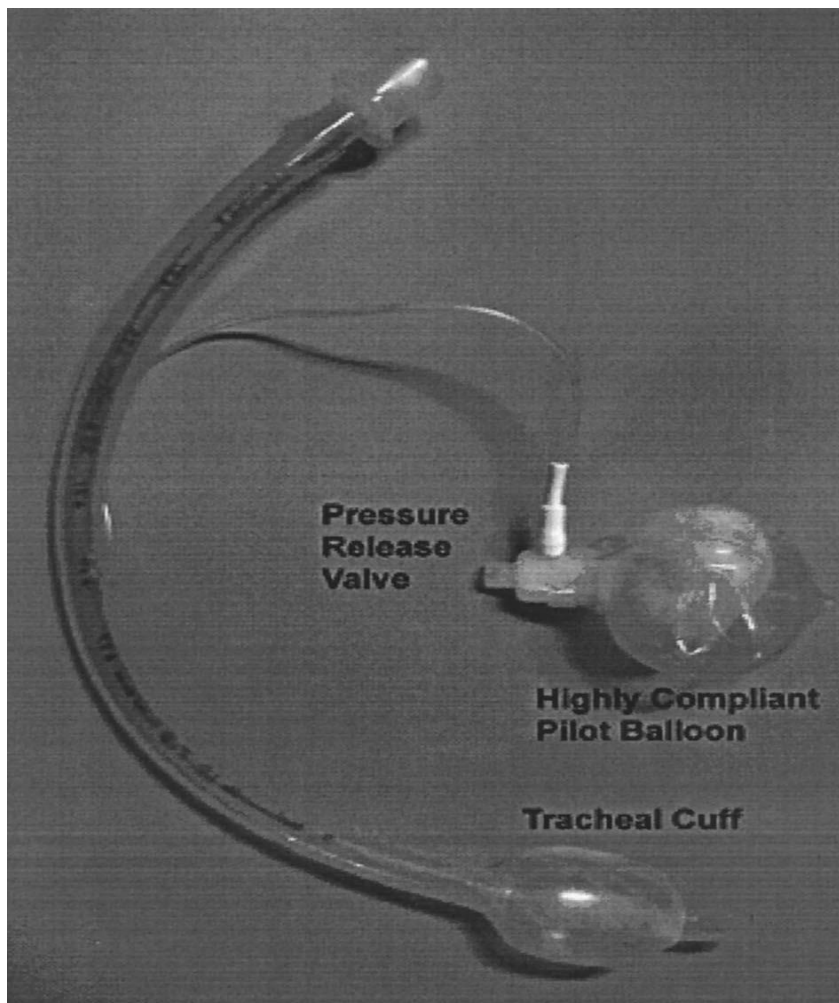


Figure 6 The Lanz[®] tube (Jaeger and Durbin, 1999)

A new development in ETT technology is the endotracheal tube with an integrated suction line. Examples of such tubes are the Unomedical ETT suction[®] manufactured by Unomedical A/S, Denmark and the Mallinckrodt[™] SealGuard Evac[™] ETT (Covidien, Mansfield, England). These tubes have an integrated suction line with a suction port above the cuff. Suctioning can easily be performed using a syringe, or by utilization of wall suction. The ETT

Suction tube enables removal of subglottic secretions in order to help reduce the incidence of ventilator-associated pneumonia (Unomedical ETT suction[®], 2010; Mallinckrodt™ SealGuard™ Evac ETT, 2010).

2.1.3.2.2 The pilot balloon and pilot tube

The pilot balloon and pilot tube are attached to the ETT as shown previously in figure 3. The pilot balloon is on the proximal end of the pilot tube. The pilot balloon expands when the cuff is inflated with air or water depending on the preference of the user. The pressure in the pilot balloon is a good indicator of cuff pressure. This may be done either by tactile or visual reference to see if the cuff is still inflated. The pilot tube is a small-diameter tube that serves as the passageway for air to be infused to the cuff.

2.1.3.2.3 The Murphy eye and the markings

The Murphy eye is an opening at the distal end of the ETT on the lateral side just below the cuff. It serves as an alternative pathway for gas flow if the tip of the ETT gets obstructed. This is useful in improving air flow dynamics at the distal end of the ETT. It has to, however, be noted that there will be resistance to flow due to the decreased airway diameter of the Murphy eye opening. The ETT has permanent markings to indicate various parameters (figure 3). This includes the inside and outside diameter, as well as the tube length. The inside and outside diameter is used to identify the size of the tube being manufactured which are available from size 2.5 to 10.0 mm with the internal diameter being the reference. This allows the appropriate size ETT to be chosen for each patient. The length of the tube from the distal tip is measured in centimetres and it serves as a guide as to how far the tube is inserted into the airway (Rhodes and Bell, 2009). Noting the length at, for example the teeth, is vital in ensuring that displacement of the ETT, either out or in, is readily detected.

2.1.3.3. Endotracheal Tube Management

Once the required ETT level at the patient's lips or incisors using the length in centimetres has been reached, this has to be documented. The ETT is then properly secured according to the unit's protocol e.g. using Harnes strapping (Morgan Jr and Mikhail, 2005). Another example for strapping ETT using adhesive tape is Lillehei method (Owen, Castle, Hann, Reeves, Naidoo R and Naidoo S, 2009). The level at the teeth is then checked to ensure the tube did not move in or out during strapping. The position of the tube is confirmed clinically by observing equal chest expansion on ventilation and by auscultating equal breath sounds on ventilation. A chest X-ray should be obtained to confirm the tube position. It is a common practice that documentation is done promptly so that it will serve as the reference guide in the event of the ETT advancing downward or is displayed outward of the airway (Gary, 2005). There is a radio-opaque strip that runs along the length of the ETT from the proximal tip to the end of the tube. This can be used to clearly identify the ETT on the chest X-ray.

2.1.3.3.1 Suctioning

Suctioning is the most important part of ETT tube management. If the ETT and patient's airway is not regularly suctioned, the tube may become blocked. Furthermore, repeated and prolonged suctioning may result in patient desaturation or tube dislodgement.

Suction apparatus are used to remove secretions, vomitus and blood in the ETT tube as these may interfere with gas exchange. The source for suctioning is either available from a wall supply or a portable vacuum apparatus. A flexible catheter and rigid tonsillar tip are available for

suctioning. This catheter is connected to the suction tubing from the suction source. The flexible catheter is more useful for decompressing the stomach and suctioning the oesophagus, pharynx, and ETT, whereas the tonsillar tip is for fast suctioning of large volumes of fluid from the oropharynx (Morgan Jr and Mikhail, 2005). Another new device used for suctioning is the closed suction system. This incorporates the control valve, suction catheter, plastic sheath and a modified aerosol T as shown in figure 7. This system has been found to be very useful as catheter can be used several time thus reducing costs. There is no increased risk of infection and oxygen saturation is minimally reduced (Gary, 2005).



Figure 7, An example of the closed system manufactured by Ballard Medical, Inc (Gary, 2005)

Although these devices are very useful in clearing the airway, care should be taken as it may cause some complications. Complications like laryngospasm, mucosal damage and bradycardia may be induced by suctioning (Finucane and Santora, 2003). Vandenberg and Vinson (1999), warned that the traditional suction equipment, such as the Yankauer tip suction, are not suitable enough to clear common particulate material in vomitus. They suggested that larger diameter suction tubing and tips should be available for the airway management.

2.1.3.4. Tracheostomy tubes

Tracheostomy tubes are tubes that are surgically inserted directly into the trachea bypassing the upper airway. Usually an incision is made through the 2, 3 and 4th tracheal rings to place the tube. Tracheostomy tubes are made in differing configurations including cuffed, cuffed with a disposable inner cannula, uncuffed fenestrated tubes, Hollinger tubes, and Communi-Trach tubes (Morgan Jr and Mikhail, 2005).

2.1.3.4.1 Cuffed tracheostomy tubes

This type of tube (figure 8) is the common tube that is used for tracheostomy. It is almost similar to the design of the endotracheal tubes in that it has a cuff, pilot tube and balloon as part of its design. It is made from PVC, providing a flexible, nontoxic appliance. This tube does not have a removable inner cannula and therefore it needs to be changed intermittently to maintain airway patency. The other types include cuffed tracheostomy tubes with a disposable inner cannula to maintain the airway patent and fenestrated tracheostomy tubes that are usually used for weaning from mechanical ventilation. This tube allows the patient to breathe through the fenestrations if the cuff is not inflated. A cuff tube in place and inflated is shown in figure 9.



Figure 8, A disposable adults tracheostomy tube (Gary, 2005).

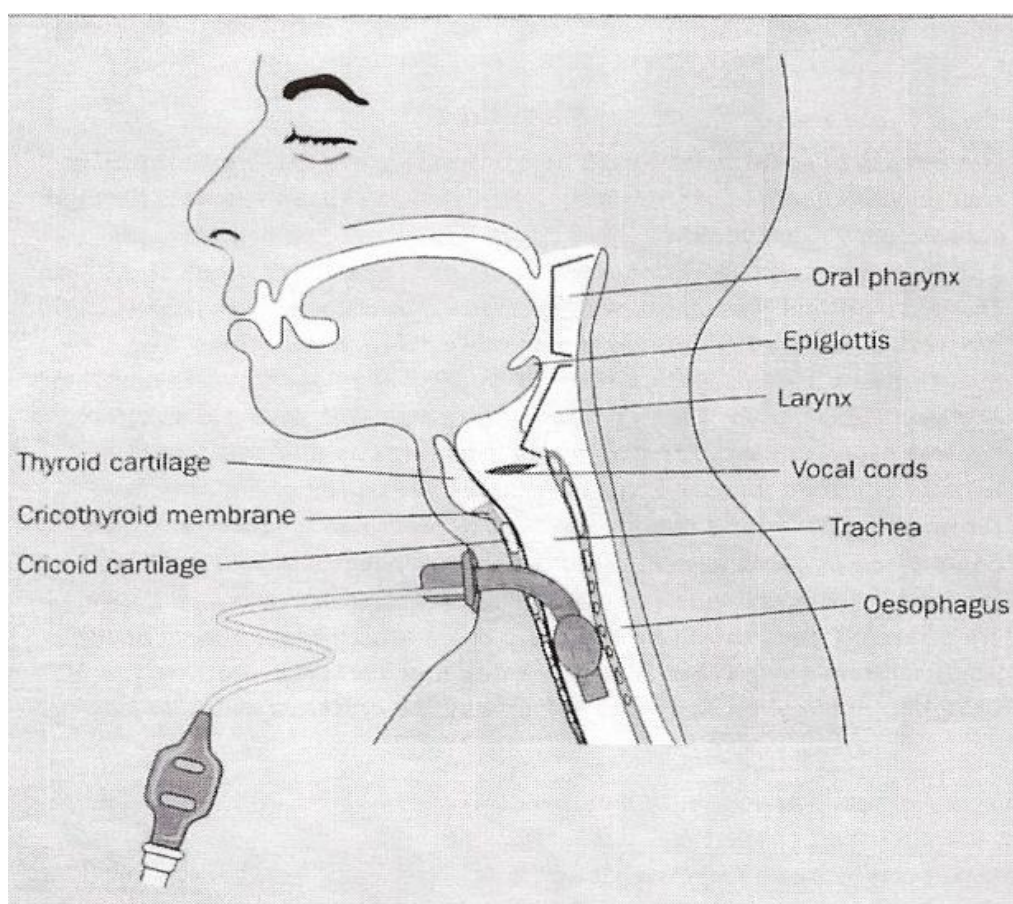


Figure 9 Tracheostomy tube in place and inflated (Ganner, 2001).

2.1.3.4.2 Uncuffed tracheostomy tubes

Uncuffed tracheostomy tubes are usually used permanently for patients with upper respiratory problems. The Silver Jackson (Hollinger) tracheostomy tube is frequently used and is made of sterling silver as shown in figure 10 below. This tube is more durable and easier to clean than PVC tubes (Gary, 2005).



Figure 10, A silver Jackson tracheostomy tube (Gary, 2005).

2.1.3.5. Indications for intubation

The main purpose for intubation is to provide ventilatory support which can be either assisted or mechanical. There are other reasons beside ventilatory support. These are the protection of the airway, ensuring airway patency, intubation for providing anaesthesia and surgery, and for suctioning purposes.

2.1.3.5.1 Ventilatory support

Endotracheal intubation is most commonly required for respiratory failure that requires mechanical ventilation and/or oxygen therapy. Once the patient has

been intubated, several modes of ventilation are available that can be used to mechanically ventilate the patient. Some of the modalities are synchronised intermittent mandatory ventilation (SIMV), Biphaseic positive airway pressure (BIPAP), control mandatory ventilation (CMV) and spontaneous/assisted ventilation. These modalities may be further divided into pressure or volume control ventilation. Other additional manoeuvres may be added like positive end-expiratory pressure (PEEP) or continuous positive airway pressure (CPAP). These help in improving oxygenation, increase the functional residual capacity, improve lung compliance, and decrease work of breathing (Morgan Jr and Mikhail, 2005). Positive pressure ventilation may affect cuff pressure. The pressure in the cuff is not solely a result of the amount of air used for ventilation but fluctuates with inspiration. If peak inflation pressure exceeds cuff pressure, a leak may ensue.

The most common condition that requires ventilatory support is hypoxia, an inadequate supply of oxygen to meet physiologic demands of the tissues (Ganong, 1985). According to Finucane and Santora (2003), hypoxia is classified into:

- Hypoxaemia (decreased partial pressure of oxygen in arterial blood, PaO_2),
- Anaemia (decreased oxygen carrying capacity);
- Impaired oxygen utilization (e.g., cyanide poisoning);
- Inadequate tissue perfusion (e.g., shock, cardiac failure, pulmonary embolus);
- Increased oxygen demand (e.g., shock, cardiac failure, pulmonary embolus) and;
- Interference with oxygen transport mechanisms (e.g., carbon monoxide poisoning).

2.1.3.5.2 Protection of the airway

The other most important reason for intubation is to protect the airway especially in patients that have lost their laryngeal reflexes. Impairment may be due to stupor and coma. Some the of the examples causing this are anaesthesia, encephalopathy, cerebrovascular accident, drug overdose, ethanol intoxication, cardiac arrest, seizures, airway burns, tracheoesophageal fistula, and partial paralysis of laryngeal musculature. There is a great risk of aspiration in these patients which may lead to aspiration pneumonitis (Jardins and Burton, 2002).

2.1.3.5.3 Ensuring airway patency

Loss of airway patency commonly occurs in patients with abnormal airway or depressed level of consciousness. This occurs in comatose patients who are unable to breathe properly due to airway obstruction by the tongue or by any violation of the airway from without or within. It may also occur if the patient has a tumour of the larynx, acute epiglottitis, airway burns, foreign body aspiration, vascular trauma to the neck and anaphylaxis (Rhodes and Bell, 2009). In such cases, the presence of the ETT provides a rigid strut to the airway.

2.1.3.5.4 Intubation for providing anaesthesia and surgery

Another common reason for intubating patients is to provide anaesthesia such that surgical operations may be performed. ETT's are placed when patients need to have muscular paralysis and mechanical ventilation. Endotracheal intubation may also be performed in operations where the anaesthetist may have difficulty in gaining easy access to the airway during operation. Such operations include procedures to the head and neck area. Another reason is that the patient may be at high risk of aspiration of blood or

other contents during surgery. This is the case in emergency operations where the patient is deemed to have a full stomach. The anaesthesiologist will then need to access the airway quickly in order to suction the patient. In addition, contamination of surgical field may occur if airway equipment lies close to the sterile area and the anaesthesiologist needs to handle such equipment (Morgan Jr and Mikhail, 2005).

Endotracheal intubation should be performed whenever muscle relaxants are used (with some exceptions), because the protective reflexes are significantly impaired during paralysis (Finucane and Santora, 2003).

More recently, laryngeal mask airways with mechanical ventilation have also been used in such situations.

Endotracheal intubation is also used to facilitate the delivery of oxygen and anaesthetic gases, and when there is a risk of aspiration during surgical operations that are expected to be prolonged. Positioning of the patient for surgery may also be an indication for ETT intubation. These include lateral, prone, sitting or head down positions in which it will be difficult to maintain the airway. Furthermore, some procedures may require ETT intubation occasionally for an adequate seal, especially if patient is edentulous, large or obese to perform mask anaesthesia. Suctioning is another indication for intubation for patients that produce a lot of secretions either intra-operatively or post-operatively especially in intensive care units (Gary, 2005).

2.2. LITERATURE REVIEW

2.2.1. Importance of endotracheal tube cuff pressure

Cuffed ETT's are important in preventing air leaks around the tube and also in preventing aspiration of fluid into the lungs. Although cuffs serve an important role, they create pressure on the tracheal wall that may be dangerous if not inflated correctly and monitored properly. Endotracheal Tube Pcuff can change drastically by several effects exerted on the cuff (Wujtewicz, 2004). This may lead to side effects due to under-inflation or over-inflation of the cuff.

2.2.1.1. Under-inflation of endotracheal tube cuff

Under inflation of ETT cuff is referred to as pressures reading below 25 cmH₂O or 18 mmHg. There is no single value to be used as different studies suggest otherwise (Stewart et al., 2003). When the ETT cuff is under-inflated, a complete seal is not achieved. Hence, under inflation may cause air leakage around the tube, an increased risk of pulmonary aspiration and accidental extubation.

2.2.1.1.1 Ventilation insufficiency

Ventilation is the process that is employed continuously or intermittently to improve breathing and gaseous exchange in the lungs. Its objective is specifically to deliver therapeutic gases at the set tidal volume or airway pressure. If the delivered therapeutic gases do not reach the respiratory zone, it is referred to as ventilation insufficiency. This occurs when there is inadequate Pcuff to seal against the tracheal wall allowing gases to escape through the mouth. It is usually detected by an audible sound through the mouth during mechanical ventilation. This will lead to lower volumes of gases reaching the lungs and inadequate pressure to open alveoli for gaseous

exchange. Such leaks are more commonly observed in predetermined volume technique of cuff inflation (Stewart et al., 2003).

2.2.1.1.2 Ventilator-associated pneumonia

Ventilator-associated pneumonia is an infective process of the lungs that occurs when patients are mechanically ventilated through endotracheal or tracheostomy tubes. Pneumonia or pneumonitis with consolidation is an inflammatory process that primarily affects the gas exchange area of the lung. In pneumonitis, inflammation of lung tissue occurs without an infection. Pneumonia occurs when an infective organism or microbe is present. In response to the inflammation, fluid and some red blood cells from adjacent pulmonary capillaries pour into the alveoli. Pneumonia can be caused by various organisms as outlined in the table 1.

Table 1. Causes of pneumonia

Bacterial causes	Viral causes	Other causes
It can be caused by gram-negative organisms such as <i>E coli</i> , <i>Klebsiella</i> , <i>Haemophilus influenza</i> , <i>Pseudomonas aeruginosa</i> , <i>pneumoniae</i> , etc.	These include <i>influenza</i> , <i>Parainfluenza</i> , <i>varicella</i> , <i>rubella</i> , and <i>adenovirus</i> .	Aspiration of gastric contents
It can also be gram-positive organisms such as <i>staphylococcus</i> and <i>streptococcus</i>		May include, fungal infections, rickettsial infections

2.2.1.1.2.1 Aspiration pneumonitis

Aspiration of gastric juice with pH of 2.5 or less causes a serious and often fatal pneumonitis (Jardins and Burton, 2002). It is commonly missed due to acute inflammatory reactions not beginning until several hours after aspiration of the gastric juice. It usually progresses to acute respiratory distress syndrome (ARDS). If there is no secondary bacterial infection within 72 hours, the inflammation usually then becomes clinically insignificant. If however the inflammation is very severe, it can continue causing clinical problems to the patient. Mendelson (1946), first described the clinical manifestations of tachycardia, dyspnoea, and cyanosis associated with the aspiration of acid stomach contents.

Jardins and Burton (2002), classified three distinctive types of aspiration pneumonitis according to the nature of aspirate, the clinical presentation, and management guidelines are as follows:

- Toxic injury to the lung (such that caused by gastric acid);
- Obstruction (by foreign body particles or fluids)
- Infection

They further explained that there is a difference between aspiration of gastric contents and food aspiration. Aspiration of gastric contents causes initial hypoxaemia regardless of the aspirate's pH. Thus, oximetry is a good measurement if aspiration is assumed. If the aspirate's pH is high (greater than 5.9), the initial injury is rapidly reversible. When the pH is low (unbuffered gastric contents normally range from pH 1 – 1.5), parenchymal damage may occur, with inflammation, oedema, and haemorrhage. If food is aspirated, eradicated bronchiolitis with subsequent granuloma formation occurs.

The following are studies that have been undertaken which involved pulmonary aspiration and the use of cuffed ETT. A study conducted by

Spray, Zuidema and Cameron (1976), investigated the hypothesis that aspiration is a source of pulmonary complication seen in patients with ETT. They demonstrated that the incidence of aspiration in patients with ETT can be decreased by modification of ETT cuff design. Subsequently, Young et al. (2006), reported that low-volume, low-pressure (LVLP) tracheal tube cuff reduces pulmonary aspiration compared to high-volume, low-pressure (HVLP) cuffs. This was based on the fact that leakage of fluid from the subglottic space occurs along longitudinal folds within an inflated HVLP cuff. The LVLP cuff does not have these folds and it allows for convenient and reliable control of tracheal wall pressure.

The use of special ETT with integrated suction line above the cuff can minimize the incidence of aspiration. The studies on continuous aspiration of subglottic secretions have shown that it can prevent VAP (Vallès, Artgas, Rello, Bonsoms, Fontanals, Blanch, Fernandez, Baigorri and Mestre, 1995; Smulders, van der Hoeven, Weers-Pothoff and Vandenbroucke-Grauls, 2002). Therefore, these new special tubes can be used continuously to suction subglottic secretions that are accumulating above the cuff of the ETT.

2.2.1.1.2 Accidental extubation

Failure to secure the ETT properly may lead to an untimely extubation. This has serious implications in anaesthetised patients undergoing surgery, especially if the patient is obese, a difficult intubation or in a position that makes access to the airway difficult e.g. prone.

2.2.1.2. Over-inflation of the endotracheal tube cuff pressure

Over-inflation of ETT cuff occurs when there is a greater volume of air/liquid in the cuff than is necessary to provide an adequate seal. This excess volume increases the pressure in the cuff and leads to untoward effects. The exact pressure defining over-inflation has not been clearly identified. A

pressure reading above 40 cmH₂O has been considered for the definition, though this has not been validated with other studies suggesting otherwise (Stewart et al., 2003). Over-inflation of cuff can cause changes in the tracheal mucosa by increasing the pressure exerted on the wall. It may cause total blockage of tracheal mucosal blood flow and tracheal stenosis, nerve palsy, granuloma, rupture of the trachea, formation of tracheo-oesophageal fistulae and hoarseness.

2.2.1.2.1 Tracheal wall damage

Endotracheal cuff inflation produces transmission of the pressure directly to the tracheal wall around the cuff. If P_{cuff} exceeds the perfusion pressure of tracheal mucosa and submucosa, it causes tracheal wall damage (Nordin, 1977).

The tracheal mucosa is made up of the epithelium which has a thick base membrane and the underlying layer of loose connective tissue (the lamina propria). This epithelium which lines the trachea is typically ciliated, pseudostratified and columnar and contains numerous goblet cells. The histological specialization of the trachea includes a vascular (venous) plexus which facilitates heat exchange to condition air before it reaches the delicate alveoli.

Damage as a result of cuff over-inflation may include loss of mucosal cilia, ulceration, bleeding and tracheal stenosis and tracheal rupture. The pressure within the cuff is transmitted to the tracheal mucosa. This transmitted pressure distorts the epithelial cells and the underlying tissue. Consequently, the mucosal cilia are damaged. Furthermore, the transmitted pressure to the vascular plexus results in occlusion of these fine vessels. This impairs the blood supply to the area.

The continual exertion of pressure to the mucosa will eventually result in mucosal ulceration as the area becomes ischaemic from the diminished blood supply. The ulceration may lead to bleeding if the vessels are eroded, and necrosis if the blood supply is totally stopped.

Tracheal stenosis is a severe, late complication of endotracheal intubation and tracheostomy. Tracheal stenosis usually occurs when there is damage to the mucous membrane and cartilaginous framework of the trachea. It is uncommon and has a high morbidity (Grunglingh, 1993). It is mostly associated with prolonged intubation with cuffed ETT (Finucane and Santora, 2003). Capillary pressure of the tracheal wall is approximately 25 mmHg in a healthy individual. If the pressure exerted by cuff exceeds this level, it may cause ischaemia to the mucous membrane. This can be minimised by using more compliant cuffs and infusing the minimal amount of air required to seal air leakage around the ETT. Patients may present with dyspnoea (shortness of breath), and stridor (wheezing). These symptoms may occur in a few days to weeks or months after extubation (Brouns, Jayaraju and Lacor, 2007).

Tracheal stenosis may occur at four sites, namely: above the tracheostoma, at the tracheostoma, just below the tracheostoma and at the end of the tracheostomy tube (Montgomery, 1989). Most patients require several techniques and repeated procedures. However, a high rate of success is reported in the literature (Grillo, Zannini and Michelassi, 1986; Anand, Alemar and Warren, 1992). A number of cases of membranous tracheal rupture following intubation have been reported (Marty-Anne, Picard, Jonquet and Mary, 1995). These seem to be caused by over-inflation of the ETT cuff. The diagnosis was suspected on the basis of the following signs: subcutaneous emphysema, respiratory distress, pneumomediastinum, and pneumothorax.

A case of a tracheal rupture was reported in a 34 year old patient who was primarily intubated following generalised seizures and loss of consciousness (Striebel, Pinkwart and Karavias, 1995). The patient developed high ventilator airway pressures. Subcutaneous and mediastinal emphysema were also noted. Endotracheal tube pcuff was measured and found to be greater than 120 cmH₂O. Tracheal rupture was diagnosed and confirmed with a fiberoptic bronchoscopy. Finucane and Santora (2003), reported that if high pressures are used, cuff should be deflated at intervals in all patients undergoing prolonged ventilation to allow perfusion of the mucous membrane at the cuff site. Powaser, Brown, Chezem, Woodburne, Rogenes and Hanson (1976), argued that hourly inflation and deflation of cuff pressure has not shown to reduce the risk of tracheal injury. It actually increases the risk of aspiration.

2.2.1.2.2. Granuloma

These are polypoid growths that occur on the vocal cords of some patients that have been intubated with cuffed ETT. They are usually due to trauma caused by the ETT during intubation and trauma of cuff against mucosa. Finucane and Santora (2003), reported the incidence to be between 1 per 1000 and 1 per 20 000 cases and was more common in women. Surgical intervention may be required to remove granulomas.

2.2.1.2.3. Tracheo-oesophageal fistula (TOF)

Tracheo-oesophageal fistula is an abnormal connection between the oesophagus and the trachea. It can be either congenital, which is due to failed fusion of the tracheoesophageal ridges during the third week of embryological development or it can occur due to pressure necrosis by an ETT or tracheotomy tube (Clark, 1999). Tracheo-oesophageal fistulae are severe lesions that lead to dangerous and often lethal pulmonary

complications. The lesions are predominantly iatrogenic, occurring in the course of tracheal intubation. They may also be of malignant origin with invasion of oesophageal and tracheal walls (Couraud, Ballester and Delaisement, 1996).

It has been suggested that tracheo-oesophageal fistula may occur when cuff pressure is over 40 cmH₂O (Stauffer, Olsen and Petty, 1981). In acquired TOF, clinical presentation includes increased secretions, pneumonia, and evidence of aspiration of gastric contents while the patient is on mechanical ventilation. There is often increased air in the nasogastric tube collection bag as well. When diagnosed after extubation, the most frequent sign of TOF is coughing after swallowing. The final diagnosis must be made by doing a chest radiograph and bronchoscopy. Acquired tracheoesophageal fistula is a rare complication which occurs in approximately 1% of patients (Harley, 1972; Akmal et al., 2008; Couraud et al., 1996; Wolf, Yellin, Talmi, Segal, Faibel and Kronenberg, 2000).

2.2.2. Endotracheal cuff pressure management

2.2.2.1. Methods of cuff inflation

The inflation method is an important factor in determining the adequate pressure in the ETT cuff. There is currently no agreement on the method of cuff inflation to be used, but there are currently several methods used in anaesthetic practice. The methods as outlined by Stewart et al. (2003), are as follows:

- Minimal occlusive volume technique

In this technique, a volume of air is injected slowly into the cuff until the audible leak with positive pressure ventilation is eliminated (Hess, 1999). When the cuff pressure is low, usually a leak can be heard at the patient's

mouth. More air is then added to the cuff to stop the leak. This technique has been shown to be insufficient. In the study undertaken by O'Donnell (1995), 12 out of 15 patients were considered to be at risk of aspiration from cuff pressures being too low. One patient was considered at risk of ischaemia from Pcuff over-inflation, and only 2 patients were considered to be in an ideal range. In this study, different cuff inflation techniques were observed. Minimum occlusive volume technique could not achieve the targeted range of 19 to 25 mmHg.

- Minimal leak technique

This technique is described as air being injected into the cuff allowing only a “small” leak to be auscultated at end-inspiration. “Small” is not clearly defined. Thus results and effects may differ greatly. When compared to the minimal occlusive technique described above, this method is associated with an increased risk of silent aspiration (Hess, 1999).

- Predetermined volume technique

In this technique, a randomly selected predetermined volume of air is used to inflate the endotracheal cuff (O'Donnell, 1995). This technique does not take into account factors such as tracheal diameter and thoracic pressure. Of the 20 patients recruited in this study, five (25%) were at risk of ischaemia damage (cuff over-inflation), and only three (15%) were in an ideal range. The cuffs in 60% of subjects were underinflated. This technique was thus criticized as being too inaccurate to be used for inflation of endotracheal tube cuffs.

- Palpation technique (finger estimation)

In this method, the ETT cuff is inflated with air whilst palpating the pilot balloon. The pilot balloon serves as an indicator of appropriate intra-cuff pressure (Morgan Jr and Mikhail, 2005). For practical reasons, this is the most used technique in clinical settings (Fernandez, Blanch, Mancebo, Bonsomy and Artigas, 1990). It is, however, reported to be unreliable for determining the adequacy of pcuff and was considered unacceptable (Morgan Jr and Mikhail, 2005). A small study of 9 patients found that two were at risk of aspiration, four at risk of ischaemia and only three were in an ideal range when compared with direct measurement method (Fernandez et al., 1990). This technique is also thus deemed inadequate for appropriate cuff inflation.

- Direct intracuff pressure measurement technique

The direct intracuff pressure measurement method is the most accurate method. This method involves the use of a manometer to directly assess the intracuff pressure via the pilot balloon (Stoelting and Miller, 2000). This technique is recommended as an effective technique to prevent over-inflation and under-inflation of ETT cuffs (Fernandez et al., 1990). This technique was also supported by a comparative study that was conducted at Siriraj hospital in India on the appropriate procedures for inflation of ETT cuff in intubated patients. This study was conducted on 34 patients divided into an experimental group and a control group. In the experimental group, the ETT cuff was inflated using a manometer as a guide every eight hours. In the control group it was inflated using conventional methods. The volume required to inflate to the intracuff pressure of 25 cmH₂O was a mean of 7.1 ml. The optimal Pcuff was achieved in 90.5% in the experimental group and 31.8% in the control group. It was thus concluded from this study that inflation of ETT cuff should be guided by manometer to achieve an ideal

range every eight hours (Sridermma, Limtangturakool, Wongsurakiat and Thamlikitkul, 2007).

Once the ETT has been inserted to a satisfactory level of estimated correct position, adequate cuff inflation is required. Usually most clinicians use a syringe to inflate air into the balloon cuff until there is no leak around the tube. Some clinicians connect the tube from the balloon cuff to the oxygen source and manually apply pressure to the reservoir bag until 20 cmH₂O registers on the airway monitor. This has been identified to be the best way to determine the cuff inflation pressure (Finucane and Santora, 2003). It is important to listen for a leak at the patient's mouth until none is audible but bearing in mind not to overinflate the cuff. If the leak persists even with large amount of air inserted into the cuff, there may be two possibilities for this as reported by Finucane and Santora, (2003): (1) the cuff may have been damaged during intubation, or (2) the tube may not be far enough down (i.e. the tip of the tube may be below the level of the vocal cords but a large portion of the cuff lies above it). If the first possibility is considered, a new ETT will need to be inserted. The second possibility can be excluded by the use of a laryngoscope to identify the inflated cuff.

Researchers have suggested that it is important to have a pressure gauge in line when inflating cuffs, especially with large volume cuffs (Stoelting and Miller, 2000; Fernandez et al., 1990; Sridermma et al., 2007). They observed that the accurate method of determining the exact seal point of the cuff in clinical practice is not constant. Therefore, the concept of fixed intracuff pressure in the range of 25 - 30 cmH₂O with variable volume to produce an optimal tracheal seal is recommended (Mehta, 1984).

Cuff inflators with pressure monitors are more precise in the inflation of cuff tubes (direct intracuff pressure measurement technique as discussed earlier) than using a syringe which is commonly used throughout the world. A recent study at King Hussien Medical Centre in Amman, Jordan, showed that using the cuff inflator called DHD Cuff Mate 2[®] (DHD/Diemolding Health care, New York, USA) to inflate cuffs until no air leak was detected, in addition to simultaneous monitoring of the Pcuff to prevent excessive Pcuff, decreases the ischaemic damage caused by over-inflation (Swaiss and Badran, 2003).

A pilot study was conducted by Duguet, D'Amico, Biondi, Prodanovic, Gonzalez-Bermejo and Similowski (2007), using a pneumatic device. They evaluated the efficacy of a simple mechanical device to maintain constant ETT cuff pressure during mechanical ventilation. The large encased inflatable cuff was connected to the ETT cuff and received a constant pressure from the heavy mass attached to an articulated arm. The tested device successfully controlled pressure cuff with minimal human resource consumption. Further prospective studies are required to assess its clinical impact.

2.2.2.2 Methods of measuring cuff pressure

There are various methods that are used to monitor Pcuff. A study on cuff palpation technique (finger estimation) and direct intra-cuff pressure measurement was conducted at Erlanger Medical Centre, USA. It showed that the finger estimation technique was inadequate and that the direct measurement is suggested (Stewart et al., 2003). To avoid tracheal wall damage or inadvertent falls of the ETT cuff pressure in intubated and mechanically-ventilated patients, a simple aquarium air pump with the conventional tubing connected to the ETT cuff was devised for automatic and continuous regulation of cuff pressure. This was first tested at the laboratory

when applied to an intubated and ventilated lung model. It was further tested in eight intubated patients for a 24 hour period. Researchers recommended that routine implementation of this may be useful for protecting the trachea from tissue damage and for reducing the risk of ventilator associated pneumonia (Farré, Rotger, Ferre, Torres and Navajas, 2002).

A study on a newly designed cuff pressure regulating device and comparison of postoperative complications was performed in adults undergoing anaesthesia. It demonstrated that the automatic cuff pressure and regulation device was useful and reliable in an adult population of intubated patients in the studied pressure range (20 – 30 cmH₂O), (Kunitz, Jansen, Ohnsorge, Haaf-vonBelow, Schulz-Stuibner and Rossaint, 2004). This newly designed cuff pressure control (figure 11) is an automatic cuff pressure monitoring device manufactured by TRACOE medical GmbH, Germany (Tracoe® cuff pressure controller 2010).



Figure 11 Tracoe® cuff pressure control

A continuous dynamic record of intracuff pressure in the endotracheal intubated patients was attempted using a PC polygraph. The aim was to record pressure changes occurring during sputum suction, cough, and struggle. This study was conducted by Kao (1991), at the Kaohsiung medical college, Taiwan. They suggested that continuous monitoring should be routinely conducted.

2.2.2.3. Frequency and importance of Cuff Pressure Monitoring

Several studies on the measurements of ETT cuff pressure have shown the importance of monitoring cuff pressures. These studies have shown that there is a need for precise measurement of ETT cuff pressure. The study conducted by Braz et al. (1999), suggested that Pcuff should be routinely measured to minimize tracheal trauma. Curiel Garcia, Guerrero-Romero and Rodriguez-Moran (2001), also conducted a study which concluded that high tube cuff pressure is a related factor to the tracheal pain. They also suggest routine monitoring of Pcuff to maintain it within the required range. Both these researchers do not specify how often cuff pressures should be measured.

Recent research conducted at Hospital Pedro Hispano, Portugal, suggested that monitoring of Pcuff three times a day seems to contribute to the prevention of ischaemic lesions and tracheal stenosis (Granja, Faraldo, Laguna and Gois, 2003). A recent study conducted at the University of the Free State, emphasised the use of current techniques by critical care nurses. The study discouraged routine cuff deflation and encouraged collaboration with ICU physicians on the standard of care (Mol, De Villiers, Claassen and Joubert, 2004). Other researchers also found that regular measurement of tracheal cuff pressure was not a routine procedure (Wujtewicz, 2004).

2.2.2.4. Cuff pressure manometers

There are different manometers that are being used to measure the P_{cuff} . Mechanical manometers record changes in pressure. This pressure is directly proportional to the changes of the diaphragm contained inside the manometer. Examples are the mechanical manometer with three-way stopcock and the Posey Cufflator[®]. A strain gauge type manometer also uses diaphragm changes as change in electrical resistance. Examples are the DHD Cuff-Mate2[®], the Respironics Pressure Easy[®] (Smith Medical Inc, St Paul, USA), Tracoe[®], VBM cuff controller[®] (VBM Medizintechnik GmbH, Sulz a.N., Germany).

The mechanical manometers records changes in pressure which is directly proportional to the expansion and contraction of the diaphragm contained inside of the manometer as illustrated in figure 12.

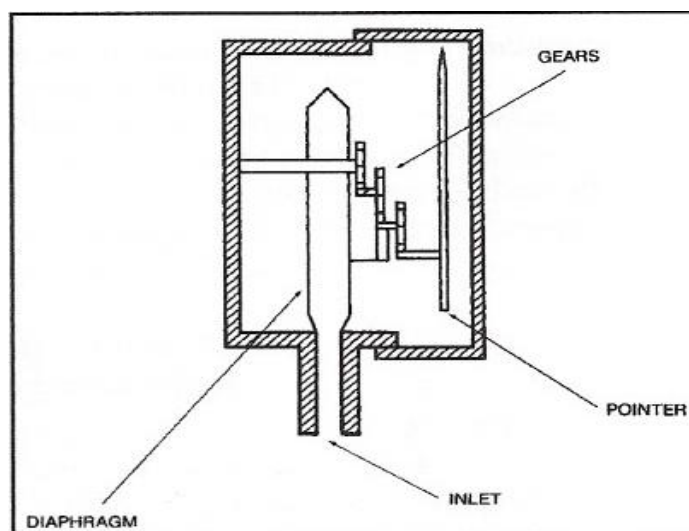


Figure 12 Mechanical manometer cross-section area (Gary, 2005)

The needle is connected to the diaphragm by a gear set, in such a way that the linear motion of the diaphragm is converted to a rotary motion. These manometers are calibrated so that atmospheric pressure reads zero on the

instrument scale (Gary, 2005). The other manometer uses the strain gauge with a diaphragm which changes shape as pressure changes. When the diaphragm moves, the strain gauge stretches or contracts proportionally with the movement of the diaphragm. The strain gauge transducer uses electrical resistance change as its indicator. As the length of the strain gauge changes, the electrical resistance increases or decreases. Thus, a change in resistance is proportional to the change in pressure. Pressure is usually recorded on a liquid crystal display (LCD). The schematic diagram of the strain gauge cuff manometer is shown as figure 13.

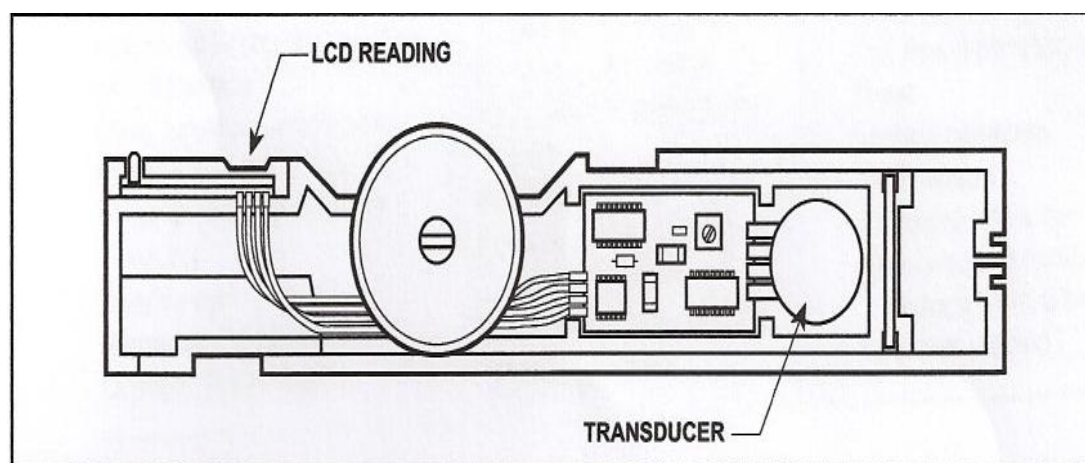


Figure 13, a schematic diagram of a strain gauge cuff manometer (Gary, 2005).

2.2.2.4.1. Mechanical manometer and Three-Way Stopcock

One of the effective ways to measure and record cuff pressure is to connect a mechanical manometer to a 3-way stopcock and a syringe as shown in figure 14. Understanding of the 3-way stopcock as it is rotated to various positions (open or close specific limbs) is vital for using this method effectively. If positions are not clearly known, a practitioner may cause loss of pressure to the cuff if it is already connected to the ETT. The syringe is filled with 5-10 ml of air and attached to the 3-way stopcock. The valve is rotated

so that it points to the distal tip of the 3-way stopcock connected to the pilot tube (where it is off). Air is added slowly to the system until the manometer reads the required pressure. The valve is rotated to a position opposite the syringe, opening all three ports so that the entire pressure can be observed.



Figure 14, the mechanical manometer, syringe and three-way stopcock (Gary, 2005).

2.2.2.4.2. DHD Cuff-Mate 2[®]

The DHD Cuff-Mate 2[®] based on the strain gauge principle is shown in Figure 15. It combines a syringe (piston) and a diaphragm strain gauge. Firstly, the piston is withdrawn by rotating the thumbwheel toward the digital display until the calibrated indicator reads between 0.0 and 5.0 cc. It is then connected to the patient's pilot tube and the power switch is depressed to put on the machine. The Pcuff will be displayed on the digital display. To adjust Pcuff, the thumbwheel is rotated until desired cuff pressure is reached on the digital display.

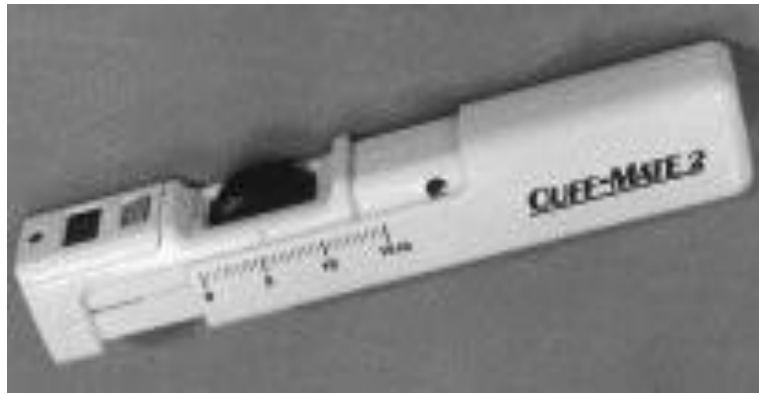


Figure 15, DHD Cuff-Mate2®, (Gary, 2005).

2.2.2.4.3. The Respironics® Pressure Easy system

This system consists of a diaphragm spring assembly with a line that is connected to the ETT via a T-piece assembly as shown in figure 16. The purpose is to maintain a low pressure in the ETT cuff during positive pressure ventilation. During inspiration when pressure increases in the patient's circuit, a greater pressure is applied to the cuff (through the pilot line on the T assembly). During expiration, that pressure is reduced. This system maintains P_{cuff} at less than 27 cmH_2O , while minimizing volume loss during inspiration (Gary, 2005).

The manufacturers claim the following advantages (Smiths medical's manual 2006):

- It monitors endotracheal cuff pressure between 20 – 30 cmH_2O ;
- It guards against aspiration and tracheal damage;
- The pressure feedback line is designed to eliminate cuff leaks at peak inspiratory pressure.



Figure 16, Pressure-easy, cuff pressure-controller®.

2.2.2.4.4. VBM Cuff Controller®

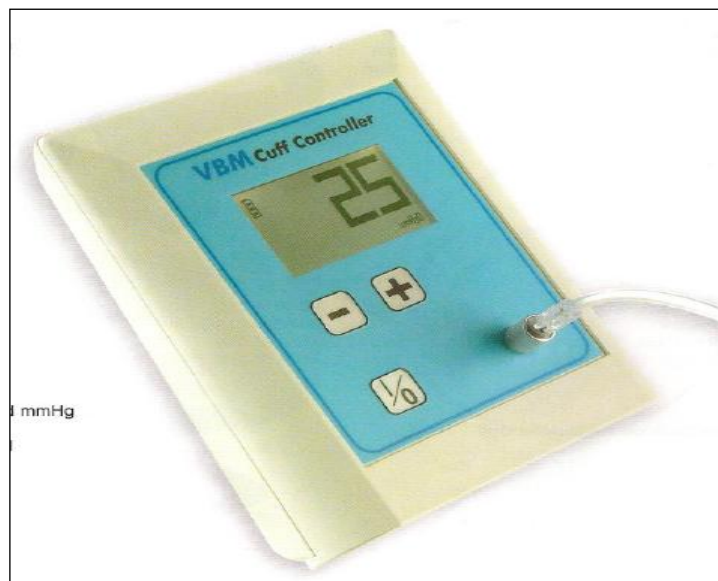


Figure 17, Automatic VBM cuff controller® (VBM manual 2008)

This is an electronic pneumatic device with microprocessor controlled pressure regulation to block and control Pcuff on the tracheal tubes with high volume low pressure cuffs. It comes with a back-up battery. It displays continuously the actual internal cuff pressure, and if the pressure increases or decreases by 2 cmH₂O for 5 seconds, an audible alarm is activated and a message appears on the LCD display.

An in-vitro laboratory model study was recently conducted by Weiss, Doell, Koepfer, Madjodpour, Woitzek and Bernet (2009). They investigated the effect of automated Pcuff controllers on tracheal sealing using the HVLP tubes. The study involved the manual cuff pressure controller, and two automated cuff pressure controllers i.e. VBM Cuff Controller® (Figure 17) and Tracoe® (Figure 11) discussed above. They concluded that automated cuff pressure controllers with rapid pressure correlation interfere with the self-sealing mechanism of high HVLP tube cuffs and reduce its improved sealing characteristics.

Thus, although these automated cuff controllers are effective in early detection of pressure changes and are able to constantly regulate the pressures, they may alter the sealing characteristics of the ETT cuff negatively.

In the present study the mechanical manometer (Posey cufflator[®] manometer) was used for recording intermittent Pcuff. For the continuous recording, a pressure transducer connected to a Nihon Kohden bedside monitor[®] was used. Both these devices are currently being utilised at the King Edward VIII hospital ICU and will be discussed fully in chapter 3.

CHAPTER THREE: MATERIALS AND METHODS

3.1. Study design

This prospective observational one group quasi-experimental study was performed at King Edward VIII hospital (a secondary facility) in Durban, South Africa. The study was conducted in an adult intensive care unit (ICU) which is a 12 bed ICU, admitting medical and surgical patients only. The aim of the study was to identify the extent of endotracheal cuff pressure changes during ventilation and to differentiate between continuous and intermittent monitoring of endotracheal cuff pressure during prolonged intubation in early detection of pressure changes within a set normal range. The study was approved by the Faculty of Health Science Research committee review board at the Durban University of Technology. Because of the nature of the study, the consent was obtained from the surrogates (Next of Kin) of those patients who were eligible for enrolment into the study. Permission to conduct the study was obtained from the provincial department of health and King Edward VIII hospital (refer to Appendix 3, 4 and 7).

3.1.1. Sample

Thirty five critically ill patients admitted to the King Edward VIII Hospital ICU for a prolonged period of intubation on mechanical ventilation were enrolled in this study. This sample size was required to detect significantly more adverse events (measured as a variation in cuff pressure ± 5 cm of H₂O) in the continuous measurement compared to the intermittent measurement with a probability of 95% and a power of 80%. All patients admitted to ICU were screened for eligibility to be enrolled in the study. Patients were included if they were between 18 and 60 years old, intubated and to be mechanically ventilated for a period of more than 24 hours.

Patients that had anatomical laryngeal-tracheal abnormalities, those expected to have a short duration of mechanical ventilation and those with tracheostomy and nasotracheal tubes were not included in this study. Patients that were not accompanied by a relative or did not have visitors were also excluded from the study.

3.1.2. Patient consent

All patients enrolled in the study were initially fully sedated and therefore were not able to sign the informed consent themselves. The principal investigator provided the letter of information to the next of kin (a family member who signs on admission or during visitations) and discussed the details of the study prior to him/her signing the consent form. Patient data was only collected once the informed consent had been signed (appendix 1 and 2).

3.2 Materials

The devices used for this study were the Posey cufflator[®] manometer, a pressure transducer connected to a Nihon Kohden bedside monitor[®], and a laser level. These are the devices that are currently being used in the King Edward VIII ICU with the exception of the laser level. All these devices were placed on special trolley marked “CUFF PRESSURE STUDY” so that when not in use, these devices were not interfered with or removed from the trolley.

3.2.1 Posey cufflator[®] manometer

The Posey cufflator[®] combines the syringe, stop cock assembly, and mechanical manometer into one easy-to-use device (figure 18). The syringe is replaced by the black bulb for inflating. This device is calibrated in

centimetres of water which ranges from 0 – 120 cmH₂O. The green zone (22 cmH₂O – 32 cmH₂O) represents the recommended range of intracuff pressure. The silver port is connected to the pilot tube of the ETT. When inflating the cuff, the bulb is gently squeezed, slowly adding air to the cuff. As air inflates the cuff, the pressure changes are reflected in the mechanical manometer. To deflate the cuff, the red toggle valve on the side of the cufflator is depressed to allow air to be vented to the atmosphere, thus reducing pressure in the cuff. This mechanical manometer is currently used at King Edward VIII hospital adult ICU.

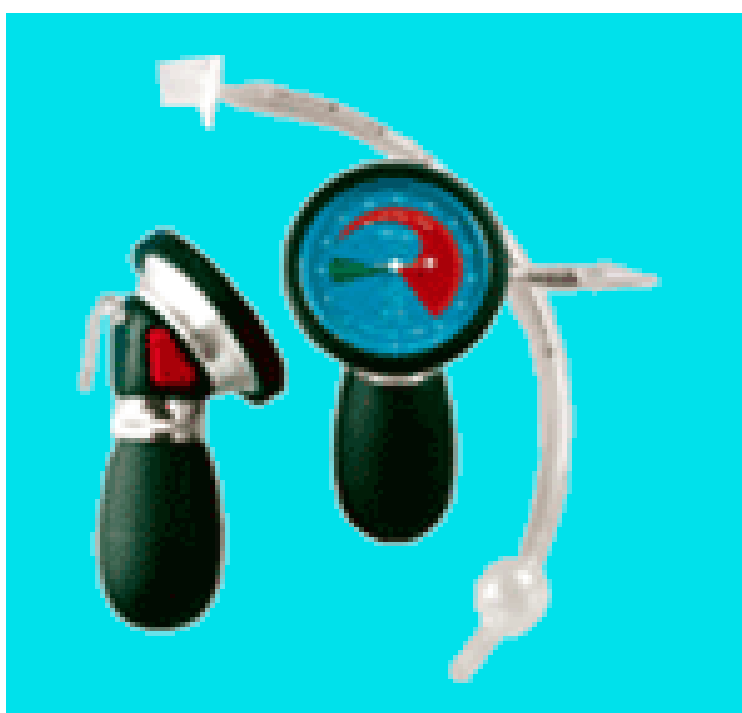


Figure 18, Posey Cufflator[®] manometer with inflated ETT cuff.

3.2.2. Pressure transducer and Nihon Kohden bedside monitor[®]

3.2.2.1 Deltran[®] IV Disposable Pressure Transducer

This is the disposable pressure transducer that is currently being used at King Edward Hospital VIII ICU for invasive pressure monitoring. It is shown in

Figure 19 below. It has a diaphragm (usually made of the crystal of quartz) that deform due to pressure being applied to it. The pressure exerted by fluid/gas is measured and converted into electrical signal. It is a stand alone device, with integral stopcocks, pressure tubing and a flush device. It has an operating pressure range of -50 to +300 mmHg. The product was CE Marked which shows it has been certified to be safe for use. This type of transducer was used for the present study. There was no fluid attached to the transducer.

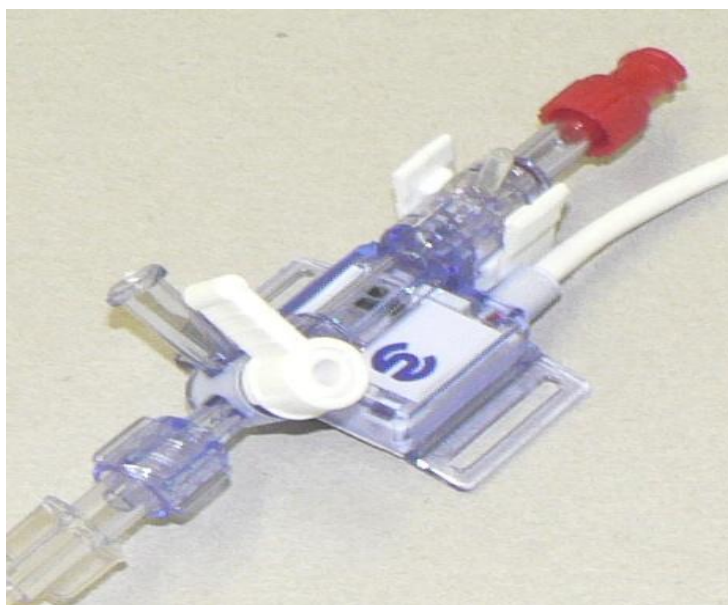


Figure 19, the Deltran® IV Disposable Pressure Transducer.

3.2.2.2 Nihon Kohden BSM®

This is the bedside monitor that is currently being used at King Edward VIII adult ICU. The model number was BSM-9510K from Nihon Kohden Corporation in Japan. This was a monitor that had been designed for a wide variety of applications from monitoring of heart rate to measuring of intracranial pressure. This device was used in the present study for continuous recording. This device complied with the requirements of the European Directive 93/42/EEC for medical devices and was labelled with the

CE mark (CE 0086). The equipment and/or system complied with the International Standard IEC60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or system. It displayed continuously the actual pressure, recorded it every minute and stored in the monitor for up to 48 hours.

3.2.3. Laser Level

The Physiotrac[®] laser level (Edwards Lifesciences, Irvine, California) was used in the study. This device is a patented laser-levelling device that assists in the calibration of various monitoring devices including blood pressure and neurological monitoring equipment. It can achieve extreme accuracy if it is correctly aligned relative to the physical placement of the patient. It is a compact, low-intensity laser level, battery operated device which is easily mounted or slid onto the slide rail or rotating cam (Physiotrac[®] Laser Level, 2010).

3.3. Procedure

Monitoring of cuff pressure at King Edward VIII ICU is a routine procedure. Patients that met the inclusion criteria were enrolled for the study once relatives had signed the consent. Patient's cuff pressure was recorded in two ways (i.e. intermittently and continuously) simultaneously over a 12 hour period in one day.

3.3.1 Patient preparation and measurement

As the patient was admitted to the ICU and everything had been done to settle the patient, the following steps were taken to prepare the patient for the procedure:

- a) The patient was checked if he/she had a high volume, low pressure ETT;
- b) The inclusion criteria was checked for each patient;
- c) If the patient met the inclusion criteria, the principal investigator spoke with surrogates of that patient (this was difficult as some patients did not have visitors, so these were excluded);
- d) Once surrogates understood the details of the study, consent was signed before enrolling each patient;
- e) The principal investigator then allocated a unique ID number using sex, age, date and month of study for each patient (e.g. for a 35 year old male patient who participate on the 25th of June, his ID number was: **M352506**);
- f) In-patient number was also recorded in case there was a need for review of the patient's chart for further treatment;
- g) Positioning of patient was confirmed to be in the normal position with the head end of the bed elevated to approximately 30° angle;
- h) Principal investigator checked that ETT was confirmed to be in place by both auscultation and radiologically (It was a routine procedure to do chest X ray in this ICU to confirm both the ETT and Nasogastric tube (NGT) positions;
- i) The Pcuff was checked and adjusted if necessary (most patients were from theatre, trauma units or another hospital), by ICU staff using the mechanical manometer according to the hospital protocol;
- j) The principal investigator connected a three-way stopcock to the pilot balloon of the ETT cuff making sure that it was closed to air as the cuff may quickly deflate;
- k) The pressure transducer was checked to be airtight by making sure all connections were properly connected;

- l) The pressure transducer system was then connected to the 3-way stopcock already connected to the ETT cuff as illustrated in figure 19 below;
- m) The Principal investigator inserted the pressure transducer into the Deltran® Three Slot Organizer attached to IV Pole Mount on the trolley to hold it in place;
- n) The mark was made at the C6 level of the patient's neck which is the midway of the neck;
- o) The transducer was then aligned with the mark on the patient's neck by moving the slot organizer on the IV pole;
- p) This was confirmed by using the laser level placed horizontally next to the heart of the transducer level and the light pointing to the mark on the neck;
- q) Further alignment, if necessary, was achieved by fine movement of the slot organizer on the IV pole

Intermittent recordings using Posey Cufflator®

Three intermittent recordings were performed as follows:

- When recording intermittent reading, the Posey Cufflator® was connected to the third limb of the 3-way stopcock as illustrated in figure 20;
- Then the 3-way stopcock was turned to "the manometer" to read the pressure;
- The principal investigator allowed 10 seconds for the manometer to read the pressure;
- The dial on the manometer raised to the pressure that was on the ETT cuff;
- Once recording was done, the 3-way stopcock was turned back to "pressure transducer" to continue recording the continuous Pcuff;

- The Principal investigator entered the Pcuff reading onto the record sheet (appendix 6).
- These recordings were done three times in the twelve hour period i.e. at the beginning/zero hour (T_0), midway/6th hour (T_6) and at the end/12th hour (T_{12}).

Continuous recordings using the pressure transducer connected to the Nihon Kohden BSM[®]

This device continuously monitors and records data every minute. The continuous recording occurred concurrently with intermittent recording. This procedure was performed as follows:

- The pressure transducer was first connected to the Nihon Kohden BSM[®].
- The second 3-way stopcock that is on the transducer itself was turned to “air” position to perform zeroing;
- Thereafter the “pressure transducer” was selected and the zeroing button on the monitor was activated to allow for zeroing to take place;
- Once zeroing had completed, the 3-way stopcock was turned back to the “monitor” to start recording;
- Note that zeroing was only done once for the entire recording for that patient.
- When the stopcock on the transducer had been turned to “monitoring”, the Pcuff was displayed on the monitor screen, recorded and the information was stored for up to 48 hours.

3.4. Data Collection

All data was collected by the principal investigator from the mechanical manometer and Nihon Kohden BSM[®] and entered into the laptop at the bedside. All data were entered manually during the whole period of 12 hours.

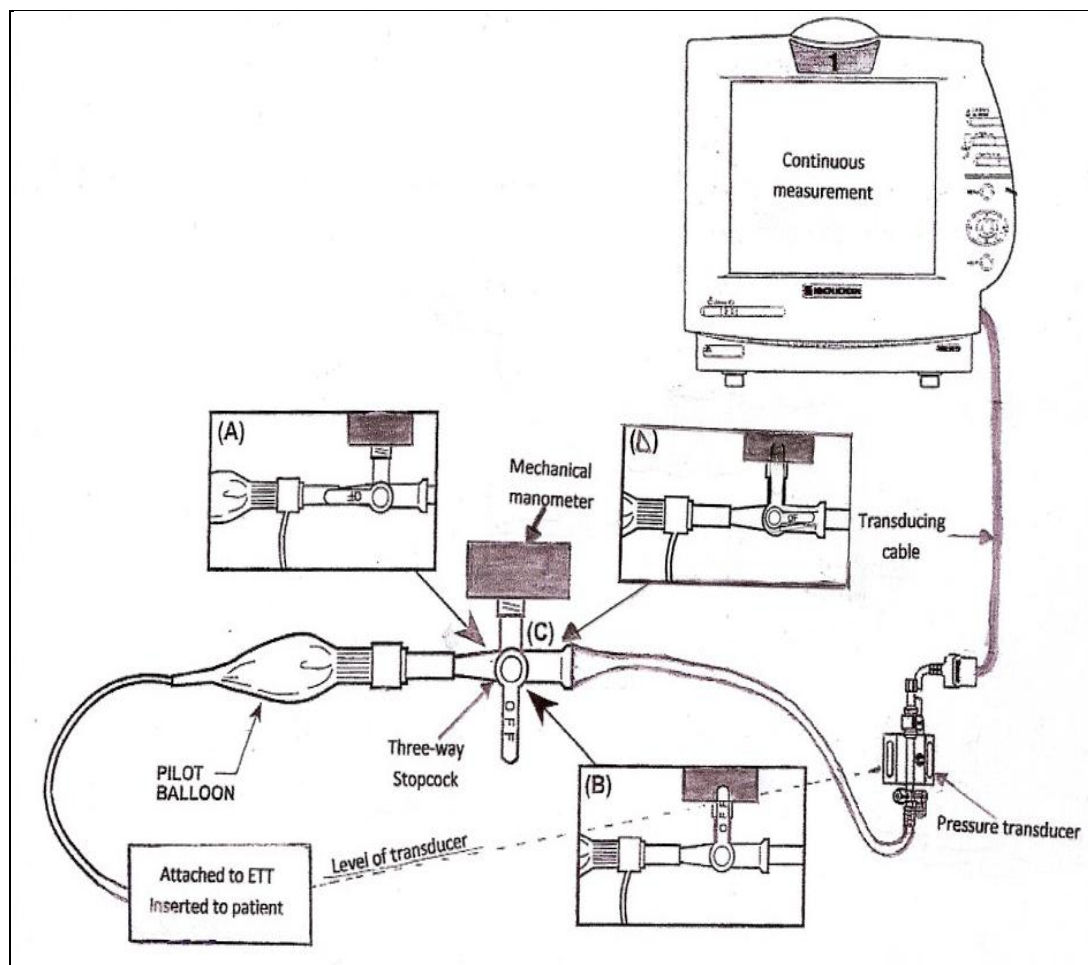


Figure 20 A schematic diagram showing the connections. (A) No connection to the pilot tube. (B) Pressure transducer recording only. (C) All three ports open. (D) Mechanical manometer recording only.

Demographic data were collected from each patient's medical record as illustrated in appendix 5. The display monitor for the mechanical method was separate from the one that was used for monitoring all vital signs of the patient.

3.4.1. Intermittent data recordings

Three intermittent readings were recorded using the Posey cufflator[®] mechanical manometer connected to the 3-way stopcock. Reading was

achieved by rotating the 3-way stopcock to the port connected to the manometer and kept for 10 seconds. Three readings were taken i.e. at the beginning/zero hour (T_0 approximately at 07h00), midway/6th hour (T_6 approximately at 13h00) and at the end/12th hour (T_{12} approximately at 19h00). After each recording was taken, the 3-way stopcock was rotated back to “pressure transducer” making sure that the Pcuff was not increased or decreased and the mechanical manometer was then removed. Cuff pressure was recorded in centimetre of water.

3.4.2. Continuous data recordings

The 12 hour continuous data was recorded by the Nihon Kohden BSM[®] every one minute and stored for up to 48 hour. These data were later manually extracted to a Microsoft[®] MS excel 2007 spread sheet by the principal investigator. Throughout the study, if any leak was detected, the ICU Nurse managing the patient, inflated the cuff using cufflator[®] as needed to stop the leak. At the end of data collection, the transducer was detached, and the ETT Pcuff checked and adjusted to the optimal range if necessary using cufflator[®]. Cuff pressure data collected was in millimetres of mercury (mmHg) and three readings were collected, i.e. Maximum, Minimum and Mean values. All these values in mmHg were converted to cmH₂O for final analysis. This was using the fact that 1mmHg is equivalent to 1.36 cmH₂O. Therefore, all values were multiplied by 1.36 in order to be converted into centimetres of water.

3.4.3. Observational data

During the entire study for each individual patient, the Principal investigator recorded all the events related to airway management except for pharmacological interventions and the time at which these occurred (appendix 5). Table 2 indicates the complete list of all events related to

airway management. These events included suctioning, adjusting of Pcuff, patient coughing and struggling that was noted by the Principal Investigator during the entire period of study for that patient. These events have previously been noted to cause direct increases or decreases in Pcuff (Kao, 1991). Other events such as patient movement of head only or whole body, and changes in position for certain procedures like chest X ray or wound dressing were also recorded. This was done because these events were also expected to cause an increase or decrease in Pcuff. This ensured that all events had been logged. The time on the watch used by principal investigator was synchronised with the Nihon Kohden BSM[®] time. The events were recorded using the table on appendix 5 with notes made of the specific time at which the event occurred. At the end of the procedure for each patient, both the mechanical manometer and the bedside monitor were locked into the cupboard for the next available patient and for later extraction of data.

3.4.4. Data analysis

The cuff pressure readings collected were analysed using signed rank test for paired analysis to compare values on the same patient. Variation in endotracheal cuff pressure was expressed as interquartile ranges and shown graphically for both methods over time. Pearson's correlation was also used to compare the intermittent and continuous readings at the same time.

The number of events recorded were compared using a signed rank test to determine if the continuous readings identified significant adverse events.

Table 2 Events related to respiratory function

CODING	DESCRIPTION
AB	Abnormal breathing pattern/gasping
AT	Attempting to talk
BM	Body movement
CPD	Cuff pressure decreased by ICU personnel
CPI	Cuff pressure increased by ICU personnel
HM	Head movement only i.e. sideways or upwards
NGI	Nasogastric tube insertion
PB	Patient bathed including turning sideways
PC	Patient coughing
PD	Patient died
PF	Positioned flat for procedures like X ray
PT	Physiotherapy
R	Resuscitation
S	Suctioning
ST	Strapping tube
TB	Tube biting by patient
TP	Turning patient by ICU personnel
U	unknown or unrecognised event
VC	Ventilation changed
WD	Wound dressing

CHAPTER FOUR: RESULTS

4.1. Characteristics of the sample

Thirty-five critically ill adult patients were enrolled into the study. Nineteen (54.3%) of the subjects were male. There was a clear preponderance of black subjects (89%) in keeping with the ICU's normal patient profile, the remainder being made up of Indian and Coloured subjects. The complete racial composition of the study group is outlined in Table 3. The mean age of the studied group was 34 years with a range of 18 to 60 years. A breakdown of the different age group ranges is illustrated in Table 3. There is a reasonably even spread of subjects across the arbitrarily assigned age group ranges of 18-25, 26-35, 36-45 and 46-60.

Table 3 Race and age groups.

RACE	MALE	FEMALE	TOTAL
African	15	16	31 (89%)
Indian	3	0	3 (9%)
Coloured	1	0	1 (2%)
AGE RANGE	MALE	FEMALE	TOTAL
18 – 25	3	8	11 (31%)
26 – 35	7	4	11 (31%)
36 – 45	6	1	7 (20%)
46 – 60	3	3	6 (18%)

All patients were to be studied for a 12 hour period. However, only 17 out of 35 subjects were studied for the entire 720 minute period. The mean time of study of the group was 667 minutes with the lowest period being 135 minutes for Patient 4. The observation time in minutes for each patient is reflected in Table 4. Monitoring was discontinued early in 6 patients for the following reasons: Three patients were taken to theatre, one patient died, one patient was extubated and one was restless and ICU staff felt patient should be removed from study as it was impacting on patient care.

Table 4: Continuous cuff pressure data

Patient	Time in minutes	Mean \pm SD Pressure cmH ₂ O			% time at each pressure level (Maximum)		
		Maximum	Minimum	Mean	<20 cmH ₂ O	20-30 cmH ₂ O	>30 cmH ₂ O
		Mean \pm SD	Mean \pm SD	Mean \pm SD			
1	670	23.2 \pm 4.4	12.8 \pm 4.6	22.2 \pm 4.4	6.8%	88.7%	4.5%
2	720	21.5 \pm 7.9	14.3 \pm 4.6	19.9 \pm 5.5	47.6%	43.4%	9.0%
3	700	22.2 \pm 7.7	13.3 \pm 3.9	20.1 \pm 4.7	38.7%	51.8%	9.5%
4	135	27.1 \pm 18.2	13.4 \pm 9.1	23.2 \pm 9.8	57.1%	28.6%	14.3%
5	720	29.7 \pm 4.5	25.8 \pm 4.4	29.2 \pm 4.3	1.4%	65.0%	33.6%
6	720	28.5 \pm 5.3	24.7 \pm 5.1	28.0 \pm 4.9	14.5%	49.0%	36.6%
7	450	67.4 \pm 6.0	63.8 \pm 5.4	66.8 \pm 5.8	0.0%	0.0%	100.0%
8	715	35.3 \pm 5.5	27.0 \pm 4.9	34.8 \pm 5.5	0.0%	16.9%	83.1%
9	720	24.9 \pm 10.8	19.7 \pm 5.8	23.7 \pm 8.4	42.1%	33.1%	24.8%
10	720	28.1 \pm 5.1	26.1 \pm 4.7	27.8 \pm 5.0	0.0%	86.9%	13.1%
11	715	30.8 \pm 4.8	25.3 \pm 3.0	29.9 \pm 4.4	0.0%	56.9%	43.1%
12	720	29.2 \pm 3.8	25.5 \pm 2.6	28.8 \pm 3.8	0.0%	72.4%	27.6%
13	590	26.6 \pm 4.8	25.0 \pm 3.8	26.4 \pm 4.6	0.8%	79.0%	20.2%
14	720	16.6 \pm 2.5	14.3 \pm 1.9	16.3 \pm 2.5	91.0%	9.0%	0.0%
15	715	23.6 \pm 4.7	21.3 \pm 3.0	23.2 \pm 3.7	12.5%	81.9%	5.6%
16	720	29.6 \pm 7.6	24.8 \pm 4.4	28.8 \pm 6.3	0.0%	78.6%	21.4%
17	720	25.1 \pm 5.8	20.1 \pm 3.5	24.6 \pm 5.3	2.8%	89.7%	7.6%
18	720	24.2 \pm 6.1	18.7 \pm 2.5	23.3 \pm 4.8	14.5%	73.8%	11.7%
19	710	27.9 \pm 5.4	18.1 \pm 6.6	26.5 \pm 5.4	0.0%	80.4%	19.6%
20	720	28.4 \pm 5.1	26.4 \pm 4.7	28.0 \pm 5.0	0.0%	85.5%	14.5%
21	390	20.4 \pm 4.1	11.3 \pm 4.5	18.0 \pm 3.0	44.3%	54.4%	1.3%
22	720	27.6 \pm 5.5	18.4 \pm 5.8	26.6 \pm 5.1	0.0%	81.4%	18.6%
23	705	22.2 \pm 3.0	19.2 \pm 2.5	21.7 \pm 2.9	19.0%	80.3%	0.7%
24	720	30.5 \pm 4.8	28.2 \pm 4.5	30.3 \pm 4.4	0.0%	71.0%	29.0%
25	710	24.7 \pm 6.8	22.2 \pm 3.1	24.1 \pm 4.9	0.0%	90.9%	9.1%
26	710	20.2 \pm 4.4	16.4 \pm 1.5	19.7 \pm 2.9	58.7%	39.9%	1.4%
27	720	27.7 \pm 6.1	24.3 \pm 5.0	27.3 \pm 5.7	0.0%	82.8%	17.2%
28	720	29.6 \pm 11.3	21.0 \pm 4.3	27.6 \pm 6.6	0.0%	75.2%	24.8%
29	720	23.7 \pm 4.7	21.3 \pm 3.0	23.3 \pm 3.7	10.4%	84.0%	5.6%
30	580	21.9 \pm 3.8	16.4 \pm 3.1	20.9 \pm 3.6	19.5%	76.3%	4.2%
31	720	29.9 \pm 5.3	17.5 \pm 3.8	28.7 \pm 4.3	0.0%	59.3%	40.7%
32	475	25.6 \pm 4.8	20.1 \pm 2.9	24.7 \pm 4.7	0.0%	88.5%	11.5%
33	710	28.7 \pm 4.0	24.1 \pm 3.4	28.2 \pm 3.9	0.0%	82.5%	17.5%
34	700	31.5 \pm 8.3	27.1 \pm 5.4	30.7 \pm 8.0	0.0%	62.4%	37.6%
35	710	34.3 \pm 4.1	27.0 \pm 4.4	33.9 \pm 4.2	0.0%	10.5%	89.5%
Mean	667	27.4 \pm 9.28	22.1 \pm 8.7	26.6 \pm 8.7	13%	64%	23%

4.2. Cuff Pressure for continuous readings

Continuous cuff pressure data readings were recorded by the Nihon Kohden® monitor at one minute intervals. Of these data, readings taken at 5 minute intervals were used for analysis. The maximum, minimum and mean pressures were recorded and analyzed at each time point (5 minute intervals) for each patient. The mean and standard deviations of each of these three measurements was then calculated for each patient. Table 4 indicates a summary of these data.

The group mean \pm Standard deviation (SD) of each of the three sets of measurements (maximum, minimum and mean) was also calculated and is also indicated in Table 4. These were as follows: Maximum (mean \pm SD) was 27.4 ± 9.3 with a 95% Confidence Interval (CI) of 8.8 – 46.0, Minimum (mean \pm SD) was 22.1 ± 8.7 with a 95% CI of 4.7 – 39.4, Mean (mean \pm SD) was 26.6 ± 8.7 with a 95% CI of 9.2 – 44.0. The median values for each of the three sets of data were 26, 21 and 25 respectively.

The percentage of time that the cuff pressure for each patient was in the different pressure ranges was calculated and is reflected in Table 4. The maximum pressures in each recording set were used for this calculation. The pressures were divided into the three following ranges: < 20 cmH₂O indicating a low pressure, $20 - 30$ cmH₂O indicating a normal range and > 30 cmH₂O indicating a high pressure. The mean percentage of time for the entire group was calculated for each of the three pressure ranges. For the entire group, 13% of the time was spent in the low pressure range (< 20 cmH₂O), while 23% was spent in the high pressure (> 30 cmH₂O). A mean of 64% of the time was spent in the normal pressure range. These data are illustrated graphically in Figure 21. The cuff pressure of Patient 7 remained in the high range for the entire period of observation. Patients 8 and 35 had cuff pressures in the high range for more than 50% of the observed period. Patients 4, 14 and 26 each had cuff pressures in the low range for more than 50% of the observed period. A total of 16 (46%) of patients had no episodes of pressure lower than 20 cmH₂O. No patients had cuff pressures in the normal range for 100% of the time.

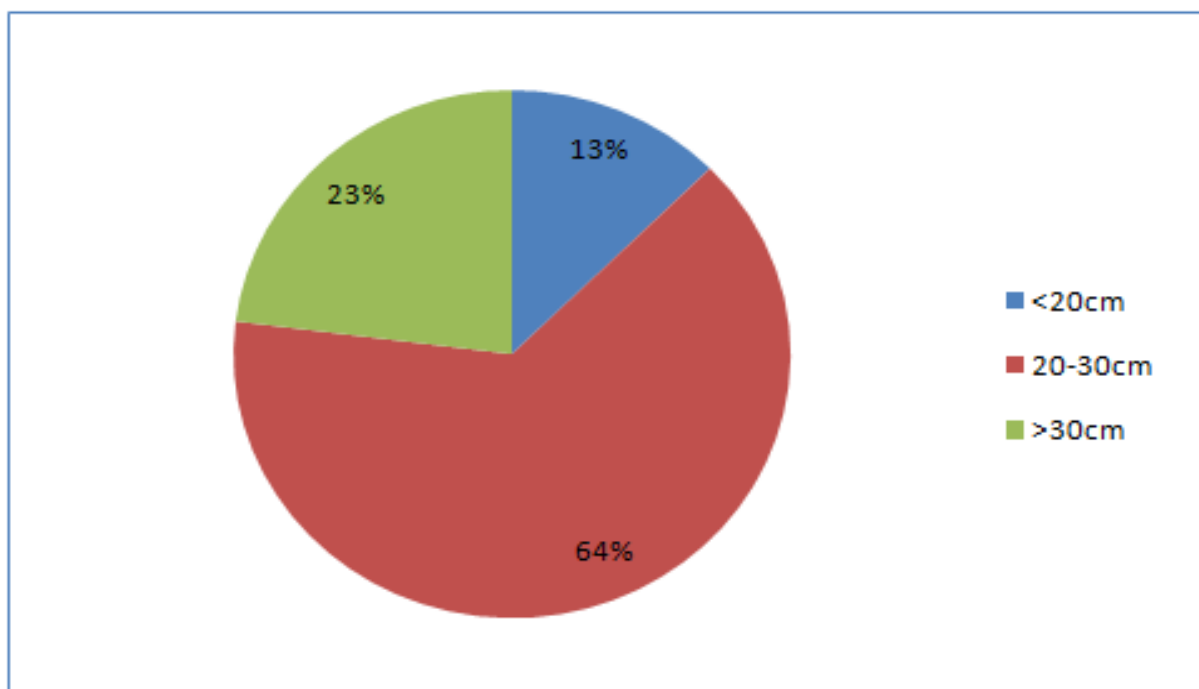


Figure 21 Pie chart of the percentage of time spent in the different pressure ranges when continuous monitoring of cuff pressure was performed.

4.3. Activity during continuous readings

Variations in cuff pressures were documented for the observation period. Cuff pressures were noted to either decrease or increase during various activities. The events causing the changes in cuff pressures, and the frequency of such events are recorded in Table 5. A total of 588 events causing alterations in cuff pressures were recorded for the entire patient set over the total observation period. Each patient averaged 16.8 events (range 5-36) during entire monitoring. Noting that the period of observation varied between patients, the average number of events per hour per patient monitored was 1.5 (range: 0.7 - 3.0)

Overall, the most frequently encountered events that caused pressure changes were body movement, coughing, head movement and suctioning accounting for 26.2%, 20.1%, 19.2% and 9.4% respectively.

Increase in pressure resulted from 85% of the events (500/588) and a drop in pressure in the remaining 15% (88/588). The three most common reasons for increases in pressure were body movement, head movement and patient coughing. Unknown or unrecognized event was the most common cause of a drop in pressure, accounting for 24% of the decreases. Other common reasons for decreases in pressures were body movement (23%) and ventilation changes (14%). Two patients were noted to have Pcuiff's that decreased throughout the entire study. In one, the patient demised and the other, a decrease was noted during wound dressing while the patient was turned.

The degree of pressure changes with the initiating events varied greatly. The highest pressure recorded was 94 cmH₂O during head movement for patient 4. Unfortunately this patient was too restless and ICU staff felt patient should be removed from study as it was impacting on patient care. Therefore the patient was removed from the study. During suctioning, the change in cuff pressure ranged from 12 to 76 cmH₂O. Changes in pressure also occurred with patient positioning, such as turning with cuff pressure ranging from 18 to 63 cmH₂O. The range of pressure changes during coughing events was 11 to 88 cmH₂O. Table 5 also indicates the highest maximal pressures recorded where the event occurred. In this regard, head movement (94 cmH₂O), coughing (88 cmH₂O) and suctioning (76 cmH₂O) were the highest.

Tracking the changes of cuff pressures for each patient over the observation period by means of graphs illustrates the intra-patient variability. Six patients are selected to illustrate this. These patients were selected according to the duration of the study (shortest and longest), number of events recorded (smallest and largest) and lastly, the patients with longest duration below and above recommended Pcuiff. The changes in these patients are shown in Figures 22 to 25. Each of the graphs illustrates the cuff pressure by continuous monitoring, cuff pressure measured intermittently and the events causing a change. A brief explanation of the changes accompanies each graph.

Table 5 Frequency of events and cuff pressure variations.

Event	Frequency	Percent	Pcuff range recorded (cmH ₂ O)
Body Movement	154	26.19%	12-68
Patient coughing	118	20.07%	11-88
Head movement only i.e. sideways or upwards	113	19.22%	11-94
Suctioning	55	9.35%	12-76
Patient bathed including turning sideways	39	6.63%	16-62
Ventilation changes	22	3.74%	14-39
Unknown or unrecognised event	21	3.57%	15-25
Attempting to talk	17	2.89%	15-45
Positioned flat for procedures	17	2.89%	19-54
Turning of patient by ICU personnel	10	1.70%	31-58
Strapping tube	8	1.36%	19-44
Tube biting by patient	5	0.85%	29-61
Nasogastric tube insertion	4	0.68%	20-44
Abnormal breathing pattern/gasping	1	0.17%	26
Patient died	1	0.17%	17
Physiotherapy	1	0.17%	40-55
Resuscitation	1	0.17%	30-41
Wound Dressing	1	0.17%	17-18
Total Events	588	100%	

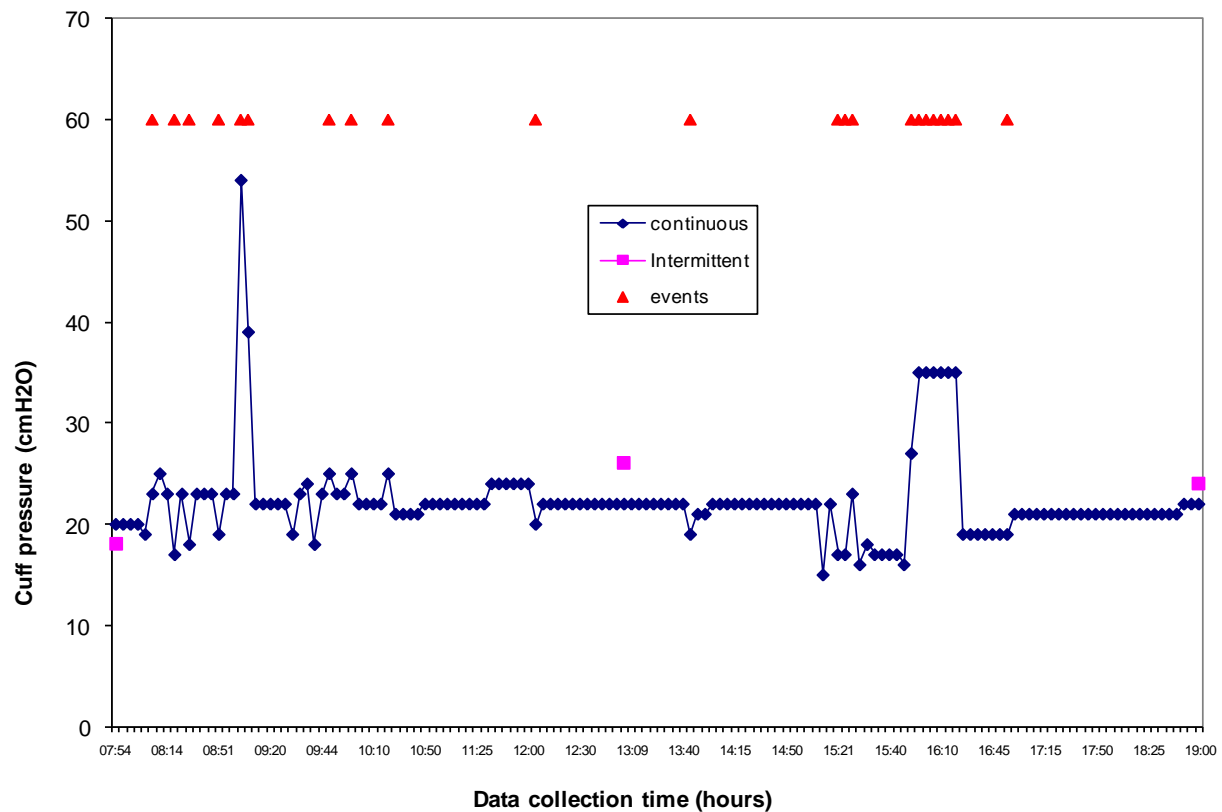


Figure 22 (Patient 1)

Patient 1 (Figure 22) started with P_{cuff} of 20 cmH₂O. At 08h11 ICU staff detected an air leak and adjusted the pressure to 24 cmH₂O. The decrease in P_{cuff} at 08h23 was associated with suctioning. Chest physiotherapy was done at 09h08 causing a spike in pressure to 55 cmH₂O. At 09h52, the patient started to move. This was due to the sedation being discontinued and pressure varied at that time period. The cuff pressure dropped at 15h21 while a wound dressing was done and then subsequently increased during bathing.

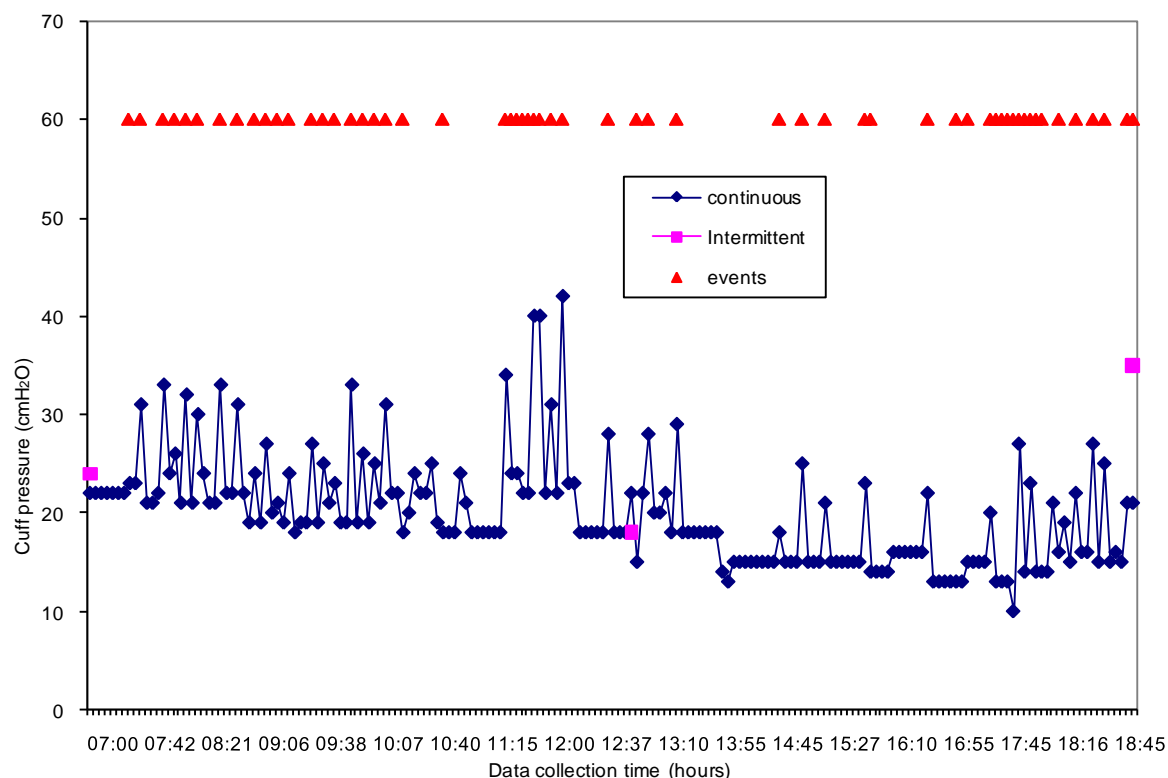


Figure 23 (Patient 2)

At the start of the study, patient 2 (Figure 23) sedation was stopped. At 07h37, the patient started moving both body and head. This is clearly depicted by the many spikes and varying pressures in the subsequent period. At 08h35 the patient started coughing accounting for the variation in cuff pressures. At 10h21 the pressure dropped to below 20 cmH₂O. The event causing this decrease could not be identified and was marked as an unrecognised event. At 13h00, the patient attempted to talk which resulted in an increased pressure. The ICU staff decreased the cuff pressure at 13h25. The pressure decreased at 15h56 due to a changed mode of ventilation. An increase in pressure at 18h26 was due to a change in the patient position for an X ray.

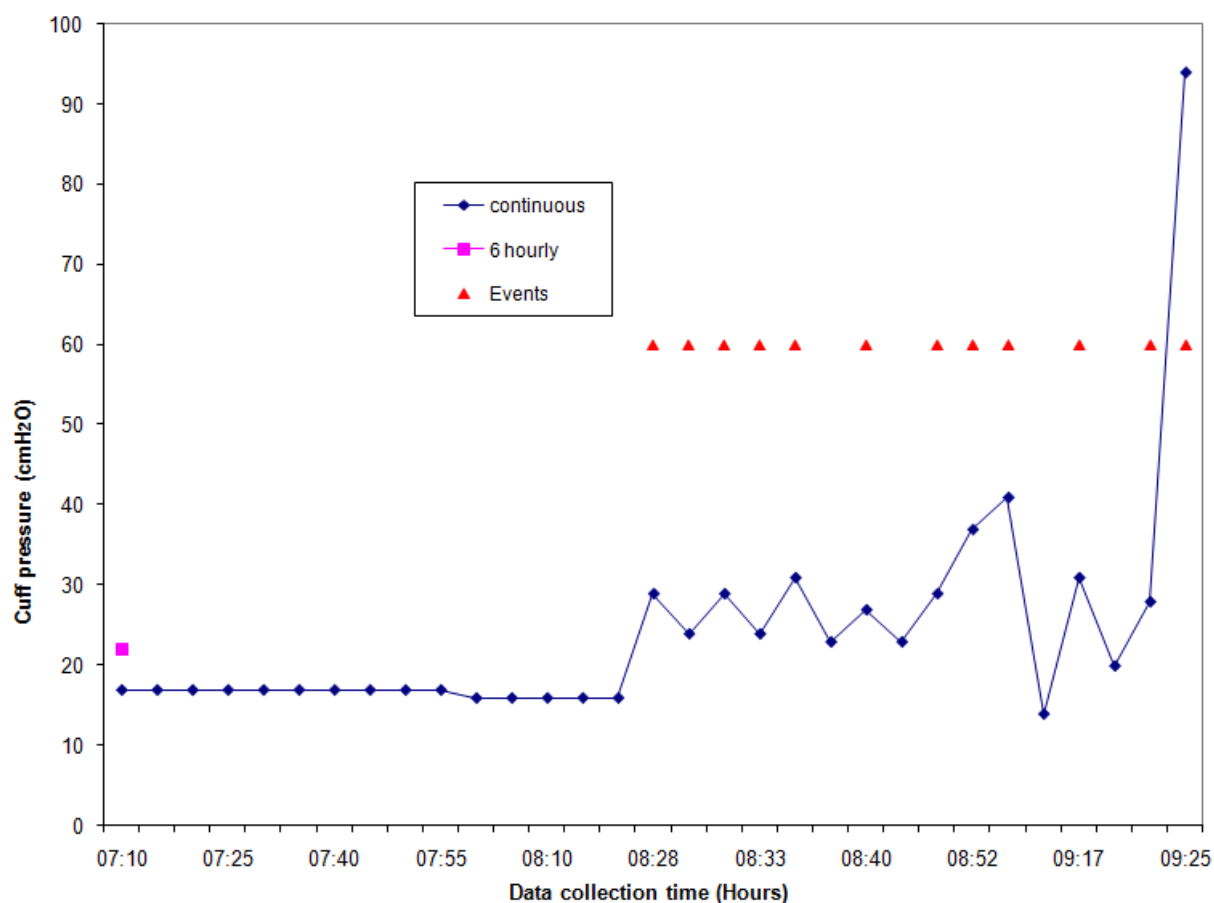


Figure 24 (Patient 4)

Patient 4 (Figure 24) spent the shortest time in the study. The patient started moving the head at 08h28 due to sedation being discontinued an hour and half earlier. An increased pressure was noted. The patient was alert, attempting to talk and wanted to remove the tube. Coughing started at 08h56 with subsequent biting of the tube by the patient. The patient was suctioned and ICU staff advised to terminate the study for this patient at 09h25 due to restlessness.

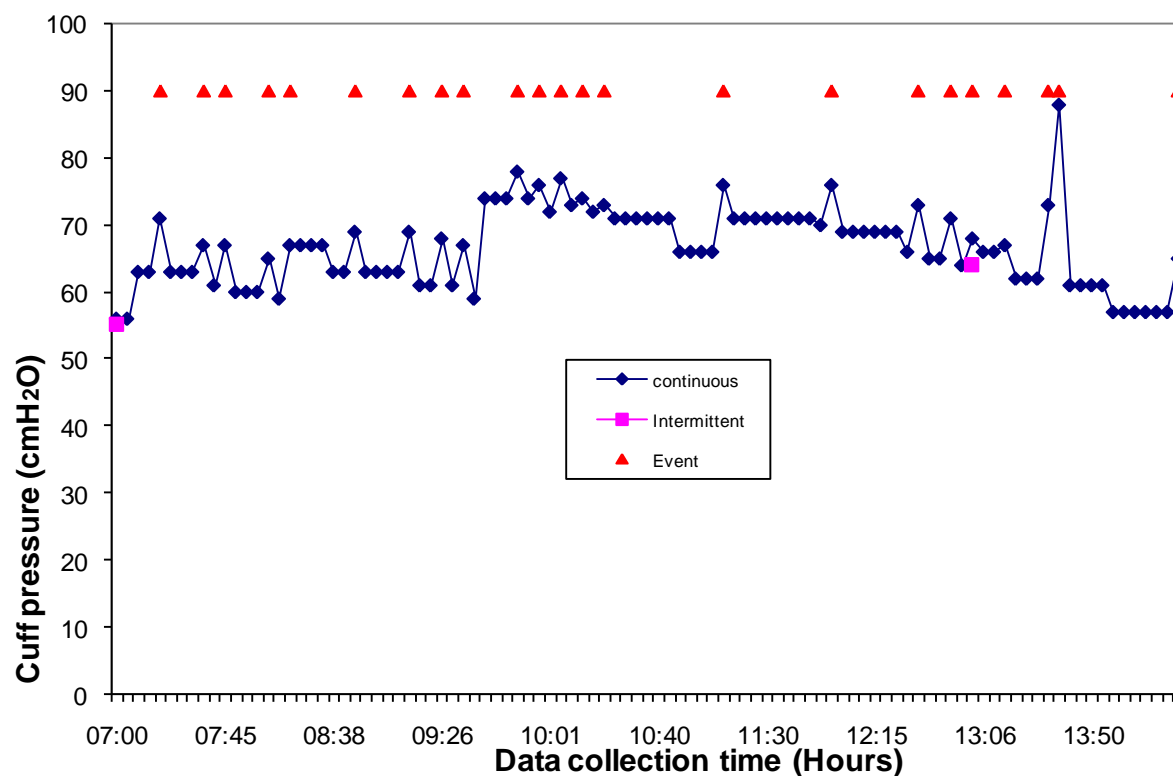


Figure 25 (Patient 7)

Patient 7 (Figure 25) had a very high Pcuff throughout the study period. The ICU staff kept the pressure high as previous air leaks were noted and the patient had previously extubated himself. The patient was on minimum sedation. The spikes in pressure were due to the patient coughing and moving around from the beginning of the study. At 09h43, a further adjustment by ICU staff was done to increase cuff due to an air leak detected. Two adjustments were made at 10h54 and 14h00 to decrease the pressure. The spikes at the end were due to the patient coughing and head movement. The study observation period was terminated as the patient had to be taken to the operating theatre for a re-laparotomy.

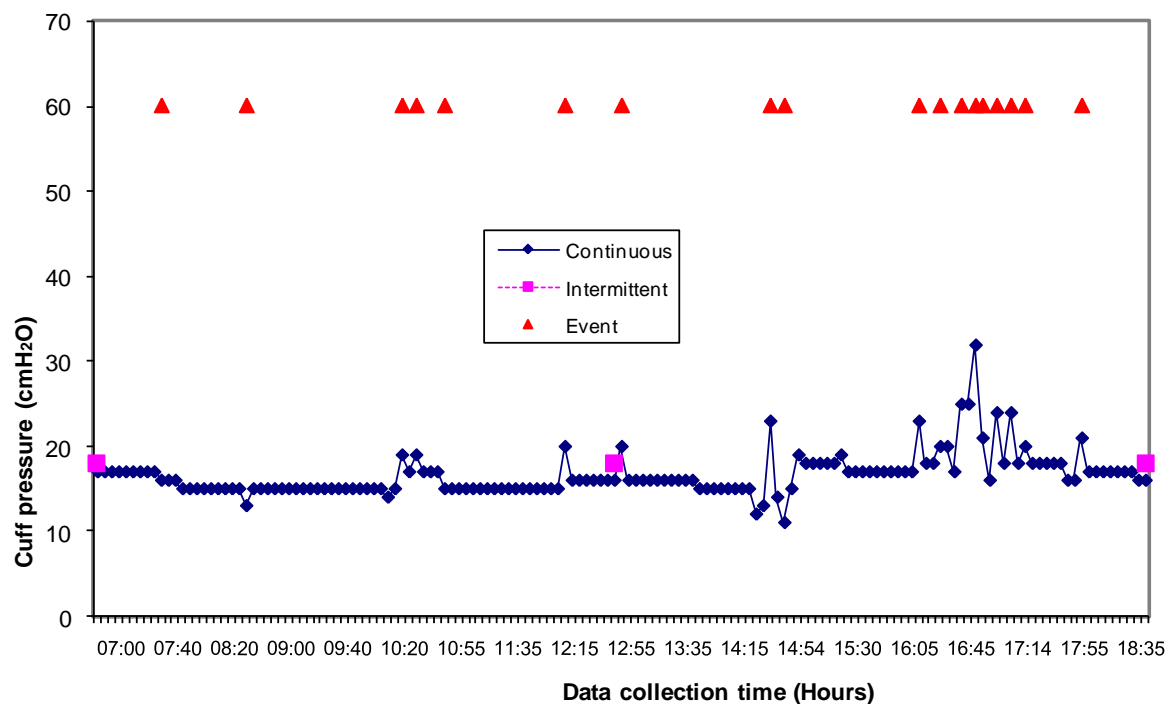


Figure 26 (Patient 14)

Patient 14 (Figure 26) had a cuff pressure below the recommended range throughout the study period. However, there were no air leak detected around the cuff. At 08h48 & 14h44, the cuff pressure dropped further when the patient was being suctioned. The spikes in pressure were associated with body movement and nasogastric tube insertion at 13h00. Patient bathing was responsible for the increase in cuff pressure at 16h00.

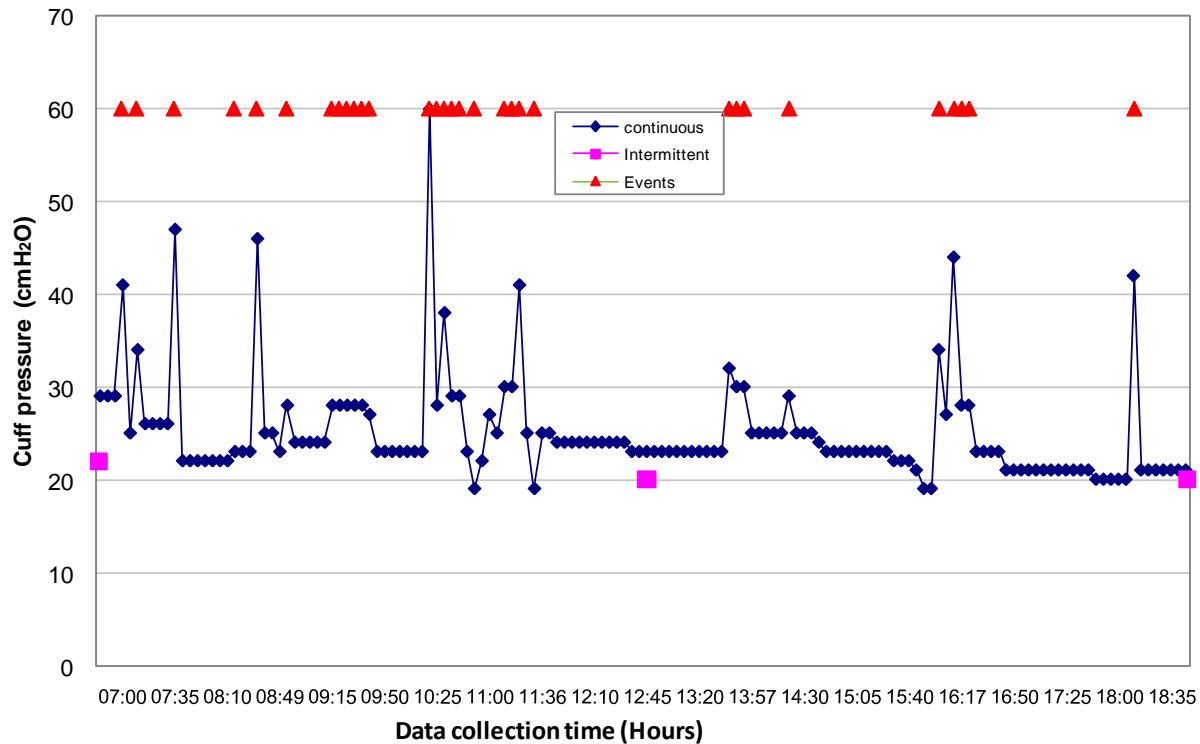


Figure 27 (Patient 17)

Patient 17 (figure 27) had a slowly decreasing baseline cuff pressure throughout the 12 hours. At the beginning, the pressure increased after head movement but the baseline pressure was lower with the head in a new position. Suctioning subsequently caused the pressure to increase but again the resultant baseline was even lower. A peak increase at 10h40 was due to violent patient coughing. Other spikes were associated with patient being bathed, attempting to talk at 14h00, head movement at 16h20 and at 18h25.

In an attempt to illustrate the variability or dispersion of the data from the continuously monitored readings, they are expressed graphically as the interquartile range in Figure 28. Note that the maximum cuff pressures recorded (instead of the minimum or mean) are used for this representation. The median is also reflected in Figure 28. The variability in the high pressure range (> 30 cmH₂O) is notably greater.

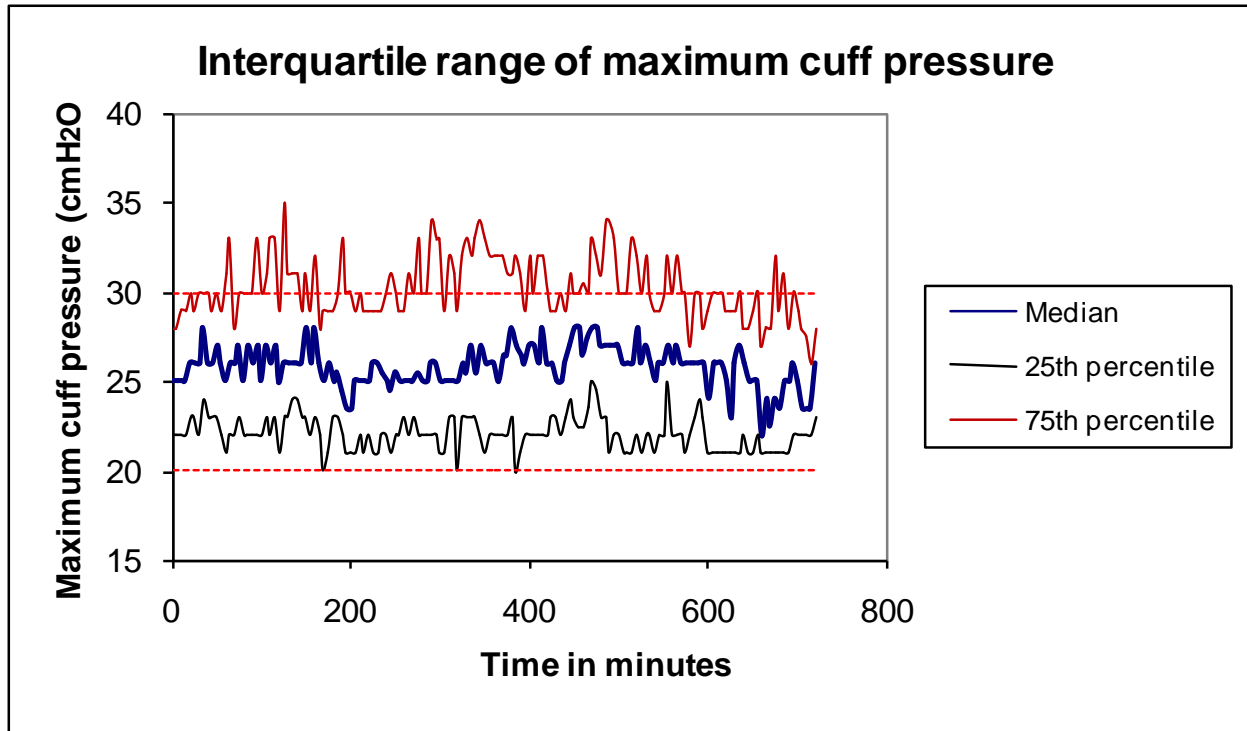


Figure 28, Interquartile range of maximum cuff pressures.

4.4. Intermittent cuff pressure data

The intermittent cuff pressure data are shown in Table 6. Readings were taken at the beginning [zero hour (T_0)], midway [sixth hour (T_6)] and at the end [twelve hour (T_{12})] using a mechanical manometer. For each recording only the maximum pressure was recorded. From each of the three intermittent recordings taken during the observation period a mean and standard deviation have been calculated and are reflected in Table 6. The mean \pm SD of all patients for T_0 was 25.3 ± 6.9 ; for T_6 25.9 ± 8.7 and for T_{12} 24.8 ± 3.8 . The overall mean \pm SD for all readings was 25.6 ± 7.1 .

The percentage of time the cuff pressure was in the various pressure ranges was noted. The percentage of time in the range of 20-30 cmH₂O varied from 0% to 91%. The intermittent readings for 24 (69%) patients had all three intermittent readings within normal range of 20-30 cmH₂O; 6 (17%) had two readings within normal range; 3 (9%)

one reading and 2 (6%) patients 0 readings within normal range. Eight patients (23%) had cuff pressures below 20 cmH₂O, 24 patients (69%) had cuff pressure within the range and 3 patients (8%) had cuff pressure above 30 cmH₂O for all three measurements. For the entire group, 12% of the time was spent in the low pressure range (< 20 cmH₂O), while 5% was spent in the high pressure (> 30 cmH₂O). A mean of 83% of the time was spent in the normal pressure range. These data are illustrated graphically in Figure 29.

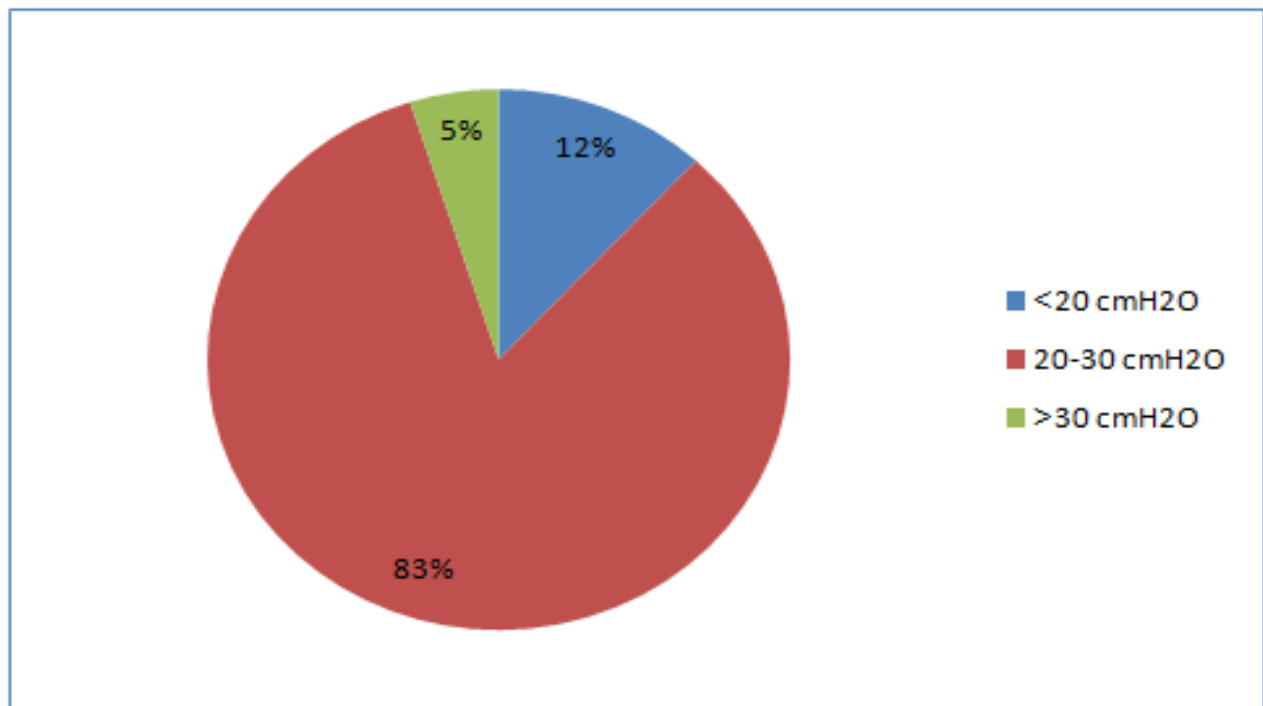


Figure 29 Pie chart of the time spent in the different pressure ranges in intermittent monitoring

Table 6 Intermittent cuff pressure readings

PATIENT	TIME IN HOURS			Mean Pcuff in cmH ₂ O ± SD
	T ₀ (07:00)	T ₆ (13:00)	T ₁₂ (19:00)	
1	18	26	24	22.7 ± 4.2
2	24	18	25	22.3 ± 3.8
3	23	22	20	21.7 ± 1.5
4	22			22.0
5	30	28	26	28.0 ± 2.0
6	24	28	26	26.0 ± 2.0
7	55	64		59.5 ± 6.4
8	38	26	30	31.3 ± 6.1
9	20	12	28	20.0 ± 8.0
10	26	28	24	26.0 ± 2.0
11	26	30	28	28.0 ± 2.0
12	28	28	30	28.7 ± 1.2
13	24	24	28	25.3 ± 2.3
14	18	18	18	18.0 ± 0.0
15	22	24	26	24.0 ± 2.0
16	24	26	30	26.7 ± 3.1
17	22	20	20	20.7 ± 1.2
18	22	19	18	19.7 ± 2.1
19	24	28	20	24.0 ± 4.0
20	28	30	28	28.7 ± 1.2
21	20	16		18.0 ± 2.8
22	25	28	21	24.7 ± 3.5
23	23	20	24	22.3 ± 2.1
24	30	28	26	28.0 ± 2.0
25	24	22	20	22.0 ± 2.0
26	18	20	20	19.3 ± 1.2
27	26	28	22	25.3 ± 3.1
28	24	25	26	25.0 ± 1.0
29	22	24	26	24.0 ± 2.0
30	20	22	21	21.0 ± 1.0
31	26	30	28	28.0 ± 2.0
32	21	19	28	22.7 ± 4.7
33	28	30	28	28.7 ± 1.2
34	24	28	26	26.0 ± 2.0
35	38	42	30	36.7 ± 6.1
Mean	25.3	25.9	24.8	25.6 ± 0.5
SD	6.9	8.7	3.8	7.1

T = Time

T₀ zero hourT₆ sixth hourT₁₂ twelfth hour

4.5. Continuous versus Intermittent Monitoring

Pearson's correlation was used to compare the intermittent and continuous readings at the same time, which measured how close the points lie to a straight line. The correlation between intermittent pressure and the continuous reading at the same time was $r = 0.87$. This correlation of 0.87 is a very strong correlation because it is close to one. The line on the graph indicates total agreement between the two measurements (figure 30). Most points lie below the line than above which suggests that the continuous readings were slightly higher than the intermittent.

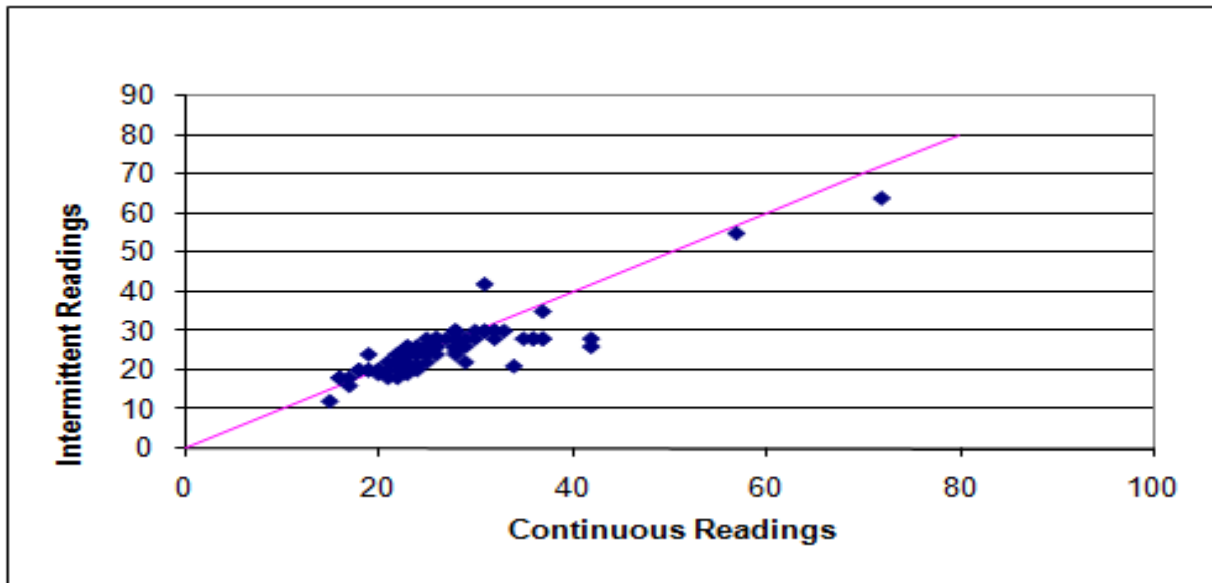


Figure 30 Correlation between intermittent and continuous readings at the same time.

The difference in cuff pressure between the continuous and the intermittent readings was plotted using the mean average and standard deviation for overall patients (Figure 31). The graph shows the slight variation in the mean average cuff pressure of both continuous and intermittent data with continuous readings being slightly higher. The standard deviation of the intermittent readings is lower than that of the continuous readings.

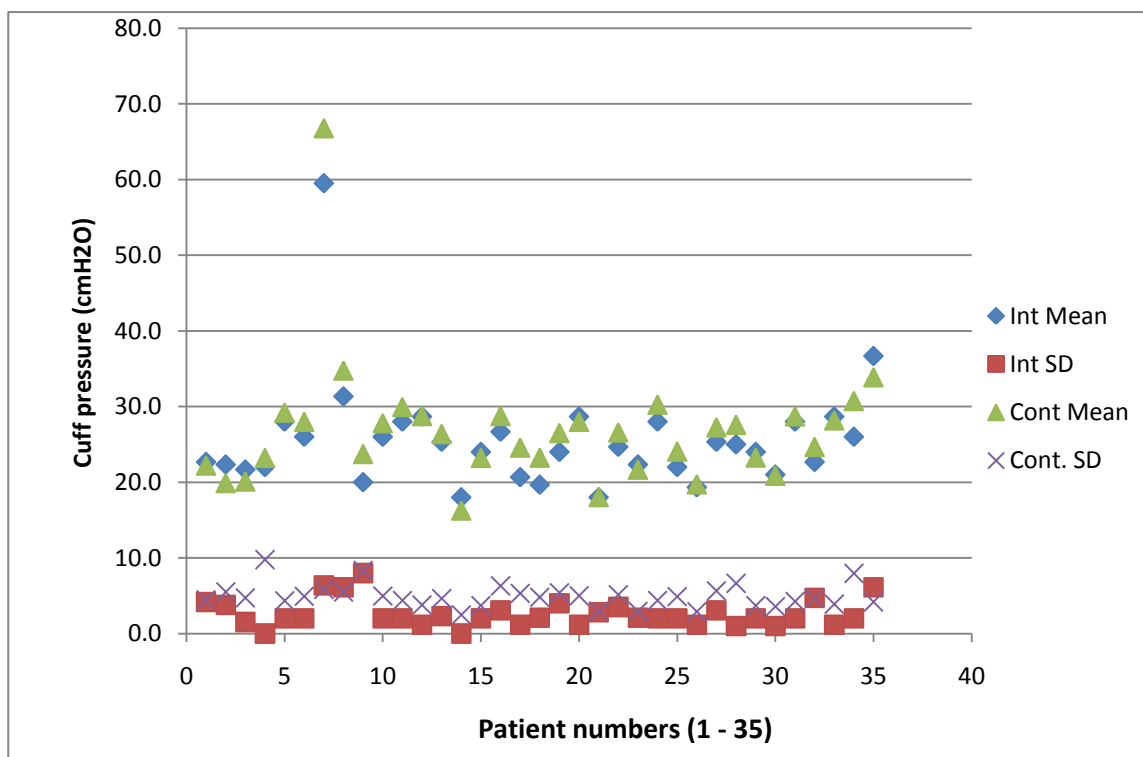


Figure 31 Continuous readings versus intermittent readings.

CHAPTER FIVE: DISCUSSION

The study prospectively compared continuous and intermittent measurements of endotracheal tube cuff pressures in a set of adult patients in the intensive care unit in an attempt to define which of the two methods should become the standard of monitoring.

The aims of the study were threefold:

1. To identify the extent of endotracheal cuff pressure changes during ventilation.
2. To identify the differences between continuous and intermittent monitoring of endotracheal cuff pressure during prolonged intubation.
3. To develop the required standard for monitoring endotracheal cuff pressure.

Endotracheal tube cuff pressure can change drastically by several effects exerted on the cuff. This may lead to side effects due to under-inflated or over-inflated cuffs. Over-inflation of the cuff can cause changes in the tracheal mucosa, granuloma, rupture of the trachea, tracheo-oesophageal fistulae or tracheal stenosis and total blockage of tracheal mucosal blood flow. Under inflation may cause air leakage, risk of pulmonary aspiration and accidental extubation.

The need for precise measurement of endotracheal cuff pressures in patients undergoing prolonged intubation has been previously shown (Braz et al., 1999; Curiel et al., 2001). Precise measurement allows tighter control of cuff pressures within a stipulated range thus minimising the negative effects of over- and under-inflation of the cuff.

The frequency of monitoring has remained controversial. Intermittent monitoring has previously been recommended with some authors recommending measurement three times daily (Granja et al., 2004). However, endotracheal tube P_{cuff} can change drastically by several effects exerted on the cuff like coughing, suctioning and patient struggle (Wujtewicz, 2004). It has been suggested that monitoring for these effects can only be done by a continuous dynamic monitoring device (Kao, 1991).

The results of this study show that there is variation in cuff pressure for intubated critically ill patients. This is evident within one patient or from one patient to another when analysing each individual graph of cuff pressure versus time for continuous measurements. The cuff pressures for 64% of the study time for all patients were within the normal recommended range (20-30cmH₂O) for the entire data collection time which is almost similar to previous study findings by Sole, Penoyer, Su, Jimenez, Kalita, Poalillo, Byers, Bennett and Ludy (2009). Their pilot study of 10 patients reported 54% of studied patients to be within the recommended range. They suggested that the duration of prior intubation and absence of sedation are independent factors of under-inflation of endotracheal cuff pressure.

This study attempted to record cuff pressures continuously for 12 hours in 35 patients. Previous studies (Vyas., Inweregbu and Pittard., 2002; Jaber., El Kamel and Chanques., 2007; Valencia., Ferrer and Farre., 2007), reported important variations in endotracheal cuff pressure in ICU patients. However, these studies differed in that they only intermittently recorded cuff pressures every 3 to 8 hours. Even though manual checking of cuff pressure provides important information, under-inflation and over-inflation frequencies may be missed. Three recent studies (Sole et al., 2009; Nseur, Brisson, Marquette, Chaud, Pompeo, Diarra and Durocher, 2009; Duguet et al., 2007), continuously monitored cuff pressures. In the Sole et al. (2009) study, cuff pressure was recorded continuously for 12 hours with a mean of 9.3 hours in 10 intubated patients receiving mechanical ventilation. Although this was a pilot study, it provided vital information that cuff pressure may vary widely among patients. Only 54% of cuff pressure readings were within the recommended range, 16% were above and 30% were below.

In the study of Nseur et al. (2009), cuff pressure was continuously recorded for 8 hours on 101 patients. Fifty-four patients developed under-inflation, 73 patients developed over-inflation of the endotracheal cuff, and 44 developed both. Study patients spent $75 \pm 26\%$ of the recording time within normal range, $13 \pm 20\%$ below and $11 \pm 21\%$ above the normal range. In the study by Duguet et al. (2007), the cuff pressure was continuously recorded in 9 intubated or tracheotomised patients for 24

hours. Patients spent $29 \pm 25\%$ of recording time with cuff pressures above recommended range and $15 \pm 17\%$ of the recording time below the range. These results are consistent with findings in the present study, where patients spent $64 \pm 27\%$ of recording time with cuff pressure within the normal range, $23 \pm 18\%$ of the recording time below range and $13 \pm 26\%$ of recording time below normal recommended range when continuous measurements were made.

Intermittent measurements of cuff pressure were recorded three times within the entire data collection for each study patient. It only provided a snapshot in time and did not reflect the many factors that influenced cuff pressure. This can give false information that the cuff pressure is well within the recommended range. Twenty-four patients had their cuff pressure within the range for the entire study. This is not the case when you compare it with continuous readings which had variation in cuff pressure with 37% and 77% of patients experiencing pressure below and above the range respectively. It shows that many pressure variations were missed during intermittent recording which may lead to under-inflation or over-inflation not being detected. The mean cuff pressure for all patients was 25.6 ± 0.5 cmH₂O. Only a very small variation was detected with intermittent recordings compared to continuous recordings. The standard deviation for all patients was higher in the continuous than in the intermittent readings. Intermittent pressure and the continuous reading at the same time (figure 29), showed a very strong correlation ($r = 0.87$). This indicates that both methods of measuring P_{cuff} used for this study were accurate and achieved the similar results at the same time interval. Continuous readings were noted to be slightly higher than intermittent reading when recorded at the same time. This is evident with the most points lying below the line in the correlation graph.

A total of 34% of the cuff pressure measurements were less than 20 cmH₂O. This percentage is almost similar to 30% reported by Sole et al., 2009. The other study by Valencia et al. (2007), reported 45% which is higher than in the present study but their measurements were taken intermittently, a difference that makes comparison between the data of the present study and their data difficult. Even though the pressure was less than 20 cmH₂O for a longer period in patients in the present

study, in some cases an audible leak was not observed or low exhaled volume alarm was not triggered on the ventilator. Only 17% of patients had an audible leak and cuff pressure was adjusted accordingly. If compared with 34% of cuff pressure readings below recommended range, some patients did not develop leaks. Audible leaks and triggering of the alarm are mostly considered to be the indicators of an endotracheal tube cuff leak. Some may argue that the cuff therefore had an adequate seal which is not the case with the possibility of silent aspiration (Sole et al., 2009). Episodes of low pressure may increase the risk for aspiration and ventilator-associated pneumonia (VAP) (Rello et al., 1996).

Longer duration of under-inflation and over-inflation are probably associated with high rates of complications (Nseur et al., 2009). In addition, patients with under-inflation for long periods of time tend to have more frequent microaspiration than those with under-inflation for short periods of time. The most important risk factor for VAP is the abundant microaspiration of oropharyngeal and gastric secretions (Metheny, Clouse and Chang, 2006). Tracheal ischaemic lesions are correlated with long duration of over-inflation of cuff pressure (Seegobin and van Hassel, 1984). Nseur et al. (2009), claims that their study was the first one to evaluate risk factors for under-inflation of the endotracheal cuff in intubated critically ill patients. They independently associated the duration of prior intubation and absence of sedation with under-inflation of the endotracheal cuff. The relationship between the duration of intubation and under-inflation could be explained by the fact that the high-volume low-pressure cuff becomes porous when used for several days. Absence of sedation leads to risk of cough and patient-ventilator asynchrony.

These situations are known to be associated with increased airway pressure (Thille, Rodriguez and Cabello, 2006), which may favour deflation of the endotracheal cuff (Guyton, Barlow and Besselievre, 1997). Nseur et al. (2009), demonstrated that under-inflation of cuff pressure increases with time. This concurs with the present study because 9 patients had their pressure gradually increasing throughout the study. Other studies have also noted a decrease in cuff pressure as time progresses (Sole, Poalillo, Byers and Ludy, 2002; Sole, Combs and Willis, 2003).

In the present study 23% of cuff pressure readings were above 30 cmH₂O. This is higher than the findings by Sole et al. (2009), which was 16%. Most previous studies had higher cuff pressures, more than 30 cmH₂O, because of estimation techniques, when routine measurements were not done, and after anaesthesia (Fernandez et al., 1990; Wujtewicz, 2004; Braz et al., 1999; Stewart et al., 2003). Most increase in cuff pressure was associated with patient coughing, suctioning and head movement. These spikes in pressure however did not last for more than five minutes and pressure usually returned to its baseline or slightly higher by ± 2 cmH₂O. More studies should be undertaken in identifying how long will it take for high pressure to cause damage to mucosa. Positioning of patients for procedures and changing neck position by patient seem to increase cuff pressure for longer periods. This is supported by the findings from the study conducted by Inoue et al. (1998).

Baseline pressure determines the frequency at which pressure can increase to above the normal recommended range. In particular, 3 patients in the present study, who had baseline pressure between 25 and 28 cmH₂O, experienced high pressure for almost 83% of the measurements during entire study. These patients had spikes in pressures due to weaning from sedation and mechanical ventilation. They started coughing or moving their heads, being anxious for the tube to be removed and their pressures did not return to baseline pressure. The same findings were shown by the pilot study conducted by Sole et al., 2009. In their findings they stated that patients with baseline pressure of 24 cmH₂O had greater frequency of higher pressure during the study than did the lower baseline pressure. This concurs with the present study. In this study, the interquartile range of maximum cuff pressure for continuous readings showed that most pressures were within the 25th and 75th percentile of the median, as the study progressed, there was a gradual decrease in cuff pressure shown by the 75th percentile moving nearer towards the median.

Factors that contributed to a wide variation in pressure in this study were suctioning, movement or patient activity, routine management like physiotherapy and bathing of

patient, and positioning. These findings are also supported by other studies by Sole et al., (2009); Inoue, Takauchi, Kuro and Ninaga, (1998); Girling, Bedford, Spendlove and Mahajan, (1999). Of the total of 588 events recorded, the vast majority (85%) resulted in increases in Pcuff. Not surprisingly, body movement, head movement and coughing were the main events noted to cause an increase in Pcuff. Most of these occurred during the weaning period of patients from sedation. As these patients were more awake during these periods, more movement and coughing was likely to occur. There is a trend in critical care to use lower amounts of sedation to allow patients to be more awake. Consequently, patients may be expected to have more movements. Hence, increases in cuff pressures may be more likely.

A resultant drop in pressure occurred in the remaining 15% of the events. Surprisingly, an unknown or unrecognized event was the most common cause of a drop in pressure. This is difficult to explain as, in such cases, all the common reasons for pressure changes, were excluded. More predictably, drops in pressure were also noted in patients who were having abnormal breathing patterns, body movements and changes in ventilation modes.

There were several limitations to this present study. The number of patients and the duration of study were limited as the study was conducted in a single ICU with only 11 operational beds. Cuff pressure was continuously recorded for only 12 hours. Therefore, the relationship between variations in cuff pressure and subsequent complications could not be determined. The cuff pressure was not adjusted to a baseline pressure as previous studies have done (Sole et al., 2009). Patients were monitored with the cuff pressure presented with or required by the ICU staff, it was not part of the protocol to adjust cuff pressure. This was to ensure that the study did not interfere with the standard of care of patients. This affected the results because some patients started with pressures below or above the recommended range. However, the main aim of the study was to identify variations in cuff pressure and associated factors causing changes.

Lack of appropriate equipment to conduct the study due to financial constraints was a major limitation to this study. Collection of data was done manually by the principal investigator. The cardiac monitor used did not have the software for downloading data recorded directly to the laptop for analysis. Continuous data was recorded every five minutes. Observational data was also collected manually as compared to the Sole et al. (2009), study which used a handheld personal assistant with specific software. Their program allowed for real time data acquisition to record observations (Spectator_go, 2009). Position of the endotracheal tube at the lip line was not recorded as ETT was already strapped before enrolling patients to the study. All patients were observed continuously but analysis of the effect of medications for sedation was not done because it was not part of the protocol.

Finally, although several patients had cuff pressure below recommended range, no clinically significant leak was observed. This finding suggests that the threshold of 20 cmH₂O, used to define cuff under-inflation, might have been overestimated with the same findings being suggested by the study of Nseir et al. (2009). However, this threshold was based on a previous study on the relationship between cuff under-inflation and subsequent ventilator-associated pneumonia (Rello et al., 1996). Further, under-inflation of cuff pressure could be associated with silent aspiration even when no leak is clinically detected.

The role of self adjusting devices needs further exploration. There is limited literature review of the clinical impact of these devices but the manufacturers claim that these are safe and useful (Smiths medical's manual, 2006; VBM manual, 2008; Tracoe® cuff pressure controller, 2010). Two studies conducted involving these devices suggest a possible benefit (Kunitz et al., 2004; Weiss et al., 2009).

CHAPTER SIX: CONCLUSION

The prospective comparison of continuous and intermittent measurements of endotracheal tube cuff pressures in a set of adult patients in the intensive care unit was successfully achieved in the study with all three aims being met.

Continuous monitoring of Pcuff indicated that the endotracheal cuff pressure varies extensively during mechanical ventilation in critically ill patients, such variation being noted both between patients and within an individual patient. Variations in an individual patient occur both during intrinsic patient activities and those of ICU personnel as part of routine patient maintenance.

In an attempt to compare intermittent and continuous monitoring of endotracheal cuff pressures, a good correlation between the two measurements was demonstrated. However, the variations in pressures noted for an individual patient would not have been detected if endotracheal cuff pressures were monitored intermittently. Hence, with continuous monitoring the pressure changes may be detected earlier, thus allowing appropriate evaluation and correction as required. Theoretically, this may reduce the incidence of under-inflation or over-inflation for longer periods and thus reduce the complications during ventilation.

Continuous monitoring of cuff pressure during mechanical ventilation in intensive care units is thus recommended for all patients. Where such monitoring is limited by, for example, cost, intermittent monitoring should be performed. In such cases monitoring more frequently than eight-hourly should be considered. This should be further complemented by rechecking the cuff pressure after any event that may interfere with the endotracheal tube. In all cases, the pressures should be clearly documented as part of the patient monitoring chart. Where pressures are deemed to be too high or too low, these should be appropriately adjusted and documented as such. It is recommended that a pressure range of 20-30 cmH₂O still be used as the normal range. The role of self adjusting pressure devices, although needing further exploration, holds much promise.

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APPENDICES

Appendix 1(a)

Durban University of Technology
Department of Biomedical and Clinical Technology
(Anaesthetic and Critical Care – KEH ICU)

Letter of Information

Dear Next of kin

You are invited to volunteer for your relative to be in the research study. The information in this letter will help you understand what the study research is about and how will it benefits your relative and other patients in intensive care units. If you have any questions, which are not fully explained in this letter, do not hesitate to ask me, the Principal Investigator or Intensive Care Unit (ICU) staff.

Title of the Research Study

A prospective comparative study of continuous and intermittent endotracheal tube cuff pressure measurement in an adult intensive care unit.

Principal Investigator

Mr M E Memela, student in Masters in Technology: Clinical Technology at Durban University of Technology.

Brief Introduction and Purpose of this study

Your relative has a tube inserted down the throat and there is a cuff on the tube. This cuff creates a seal so that air can be pumped effectively into the lungs resulting to some pressure exerted onto the throat. It is important that the pressure in this cuff is carefully monitored to ensure a good seal is maintained. This study checks the different ways of observing the pressure in these cuffs.

Outline of the Procedure

All patients that are having the tube down their throat and mechanically ventilated are having their endotracheal tube cuff pressure being monitored. For this study, mechanical manometer is going to be used that is currently used periodically to record cuff pressure and then removed. In addition another machine (Nihon Kohden BSM®) will also be used which will continuously monitor the cuff pressure. Participation for your relative will be for 12 hours.

The principal investigator will record endotracheal tube cuff pressure, all events related to airway management and the times these events occur during the entire twelve hours of study.

Patient's rights to participate

Participation in this trial is entirely voluntary and you can refuse for the patient to participate or stop at any time. Your withdrawal will not affect access to medical care. The investigator retains the right to withdraw the participant from the study if it is considered to be in his/her best interest.

Risks or discomfort to the Subject

Participating in the study does not place the patient at any risks. By participating the patient will actually be more intensely monitored which is in fact beneficial to him/her.

Benefits

Participant may benefit directly, e.g. if an event is detected, the Physician looking after that patient can adjust the patient cuff pressure accordingly.

Confidentiality

All information obtained during the course of this trial is strictly confidential. Data that may be reported in scientific journals or published will not include any information that identifies you as a patient in this trial. In connection with this trial, it might be important for the Faculty of Health Sciences Durban University of Technology, Nelson Mandela School of Medicine and King Edward VIII Hospital ICU to be able to review his/her medical records pertaining to this trial.

Persons to contact in the event of any problems or queries:

Mr M Memela

Dr D P Gopalan

Dr J K Adam

Principal Investigator

Supervisor

Supervisor

031-3603582/3

031-2604326/8

031-3735291

Appendix 1 (b)

Informed Consent Form

Date : _____

Title of research study : **A prospective comparative study of continuous and intermittent endotracheal tube cuff pressure measurement in an adult intensive care unit.**

Names of supervisors : Dr P D Gopalan and Dr J K Adam

Telephone (031) 2604328 and (031) 3735291

Name of research student : Mr M E Memela

Telephone : (w) 031-373 5293 © 084 4577123

PLEASE CIRCLE THE APPROPRIATE ANSWER:

- | | |
|--|--------|
| 1. Have you read the research information sheet? | YES/NO |
| 2. Have you had the opportunity to ask questions regarding this study? | YES/NO |
| 3. Have you received satisfactory answers to your questions? | YES/NO |
| 4. Have you had the opportunity to discuss this study? | YES/NO |
| 5. Have you received enough information about this study? | YES/NO |
| 6. Do you understand the implications of your involvement in this study? | YES/NO |
| 7. Do you understand that you are free to withdraw from this study? | |
| a) At any time? | YES/NO |
| b) Without having to give a reason for withdrawing? | YES/NO |
| c) Without affecting your future health cares? | YES/NO |
| 8. Do you agree to voluntarily participate in this study? | YES/NO |
| 9. Whom have you spoken to? | _____ |

Please ensure the researcher completes each section with you.

If you have answered NO to any of the above, please obtain the necessary information before signing.

Please print in block letters:

Patient's Name _____

Person giving consent _____ Signature _____

WITNESS Name _____ Signature _____

RESEARCH STUDENT Name _____ Signature _____

DURBAN UNIVERSITY OF TECHNOLOGY

Appendix 2(a)

(Zulu version)

Durban University of Technology
Department of Clinical Technology
(Anaesthetic and Critical Care – KEH ICU)

Incwadi yolwazi ngocwaningo

Sawubona Mngeneli

Isingeniso:

Isihlobo sakho siyamenywa ukuba singenele lolulwazi locwaningo ngokuzinikela kwakho. Umyalezo okuleliphepha ukwazisa kangcono ngokuzokwenziwa kulesisifundo socwaningo kanye nemiphumela engenza izinga elingcono lokunakekelwa kweziguli egumbini labagula kakhulu. Uma ngabe unemibuzo ongayiqondisisi kahle kulencwadi, uvumelekile ukubuza abasebenzi bakuleligumbi labagulakakhulu noma umcwaningi omkhulu.

Isihloko:

Isifundo socwaningo olubandakanya ukubheka i-cuff pressure epayipini lokuphefumula ngendlela eqhubekayo (izikhathi zonke) noma ngezikhathi ezithile egumbini labagula kakhulu (ICU).

Inhloso yalesisifundo:

Isihlobo sakho sinepayipi emphinjeni elenze incindezi. Lencidezi emphinjeni ingadala izinkinga uma ingabhekwa ngendlela efaneleyo. Lokhu kungavala ukuhamba kwegazi emithanjeni yomphimbo, kufake isiguli egcupheni yokungenwa ngamanzi emaphashini nokuphuma kwepayipi lokuphefumula kungahlosiwe. Inhloso yalolucwaningo ukuba lithole indlela yokubhekwa kwe-cuff pressure, ukuze kuncishiswe izinkinga zokuphefumula.

Indlela yokwenza lolucwaningo:

Zonke iziguli ezifakwe ipayipi lokuphefumulo ziphefumulelwa umshini, kuzobhekwa izinga le-cuff pressure. Njengoba kusentshenziswa i-machanical manometer ukuqopha i-cuff pressure

bese iyasuswa esigulini, sizophinde sisebenzise omunye umshini (Nihon Kohden BSM®) ebheka i-cuff pressure ngezikhathi zonke eziqhubekayo ayisuswa. Lomshini uzooxhunywa endaweni eyodwa nalakuxhunywa khona i-mechanical manometer, okusho ukuthi asikho isidingo sokwandisa enye indawo yokuxhuma esigulini. Isiguli sisinye sizongenela lolucwaningo usuku olulodwa kube ngamahora ayishumi nambili kuphela.

Umcwangingi omkhulu uzoqopha phansi i-cuff pressure yepayipi lokuphefumula, zonke izigigaba eziphathelene nokunakekelwa komphimbo nezikhathi lokhu okwenzeka ngazo.

Ilungelo leziguli lokungenela lolucwaningo:

Ukungenela lolucwaningo akuphoqelekile, unganqaba ukuba isiguli singenele noma usimise noma yinini uma sesingenile. Ukuyeka kwakho kulolucwaningo ngeke kuvimbele ukuthola usizo lokelashwa ngokujwayelekileyo. Umcwangingi omkhulu unalo ilungelo lokukukhipha kulolucwaningo uma ebona kunesidingo.

Izinto ezingaba yingozi noma izinhlungu esigulini:

Azikho izinto ezizokwenziwa esigulini ezingabangela ubungozi noma izinhlungu ngoba kusetshenziswa izinto ezikusona ukubheka i-cuff pressure kuphela.

Imfihlo:

Imininingwane yakho yonke yalolucwaningo ngeke idalulwe kumuntu izogcinwa iyimfihlo. Ulwazi lonke kanye nemiphumela etholwe emva kwalolucwaningo ezofakwa kuzincwadi zochwepheshe noma ezincwadini zokuqhakambisa ngeke idalule noma iveze ukuthi isiguli esithize besizimbandakanye nalolucwaningo. Mayelana nalolucwaningo, kuzokwenzeka ukuthi ifaculty of health sciences, Durban University of Technology, nodokotela uDr D Gopalan (Nelson Mandela School of Medicine/KEH), kanye no-Mr Mduduzi Memela – umcwangingi omkhulu (DUT-Clinical Technology) bahlolisise kabanzi ngokugula kwakho maqondana nalolucwaningo.

Abantu ongaxhumana nabo uma unenkinga noma unemibuzo:

Mr M E Memela

Dr D P Gopalan

Dr J K Adam

Umcwangingi omkhulu

Usuphavaza

Usuphavasa

031-3603582/3

031-2604326/8

031-3735291

Appendix 2(b)

IFOMU LOKUZIVUMELA

Usuku : _____

Isihloko socwaningo : Isifundo socwaningo olubandakanya ukubheka icuff pressure epayipini lokuphefumula ngendlela eqhubekayo (izikhathi zonke) noma ngezikhathi ezithile egumbini labagula kakhulu (ICU).

Igama likasuphavaza : **Dr P D Gopalan and, Dr J.K Adam**

Ucingo : **(031) 260 4328 and (031) 373 5391**

Igama lomfundi ocwaningayo : **Mduduzi E Memela**

Ucingo : **(w) 031-373 35293 © 0844 577123**

Uyacelwa Ukuba Ufake Isikokela Kanje Empendulweni efanele:

- | | |
|---|----------|
| 1. Ulifundile iphepha elinolwazi locwaningo? | YEBO/CHA |
| 2. Ubenalo ithuba lokubuza imibuzo mayelana nalolucwaningo? | YEBO/CHA |
| 3. Ukutholile ukwaneliseka ezimpendulweni ozinikiwe? | YEBO/CHA |
| 4. Ubenalo yini ithuba lokuthi niluxoxe lolucwaningo? | YEBO/CHA |
| 5. Ulutholile ulwazi olwanele ngalolucwaningo? | YEBO/CHA |
| 6. Uyazi ngokwanele ngemiphumela yokuthi ungenele lolucwaningo? | YEBO/CHA |
| 7. Uyazi ngokwanele ukuthi ukhululekile ukuthi ungaluyeka lolucwaningo: | |
| a) Noma ngasiphi isikhathi | YEBO/CHA |
| b) Ngaphandle kokuthi uthole isizathu | YEBO/CHA |
| c) Ngaphandle kokuthi ulahlekelwe amalungelo akho okulashwa | YEBO/CHA |
| 8. Uyavumelana nokuthi uzivumele ukungenela lolucwaningo | YEBO/CHA |

Uyacelwa ukuthi uqiniseke ukuthi unesi/umcwaningi uligcwalisa nawe lolucwaningo. Uma uphendule ngo Cha kulokhu okungenhla. Uyacelwa ukuthi uthole ulwazi olwanele ngaphambi kokuba usayine.

Uyacelwa ukuthi ubhale ngamagama amakhulu

IGAMA LESIGULI _____

IGAMA LONIKA IMVUME _____ SAYINA _____

IGAMA LIKAFAKAZI _____ SAYINA _____

UMFUNDI ONCWANINGAYO _____ SAYINA _____

Durban University of Technology



**Faculty of Health Sciences
Department of Biomedical and Clinical Technology**

Date: 10 September 2008

KwaZulu/Natal Provincial Government
Department of Health
Natalia Building
Pietermaritzburg

Dear Sir/Madam

Re: Approval for conducting a study at King Edward VIII Hospital (KEH) ICU

I am **Mduduzi Emmanuel Memela** currently a registered Master's degree student at the Durban University of Technology (DUT) under faculty of Health Sciences. The main requirement for the programme is to conduct a full research study and submit the thesis.

I would like to request for the approval to conduct a study at King Edward VIII hospital in the Intensive care unit. The topic of my study is "**A prospective comparative study of continuous and intermittent endotracheal tube cuff pressure measurement in an adult intensive care unit.**" My supervisor for the study is Dr D Gopalan, Head of Anaesthetics at Nelson R Mandela Medical School and Dr J K Adam, Associate Director at DUT.

Currently at KEH ICU patient's cuff pressure are monitored three times a day (i.e. in 24hours). In this study we will be monitoring cuff pressure three times in 12 hours during the day. We will also connect a pressure transducer to monitor cuff pressure continuously using the same monitors that are currently used at the ICU. The aim of this study is to identify the extent of endotracheal cuff pressure changes during ventilation and hopefully to develop the required standard for monitoring cuff pressure. Research has shown that it is extremely vital to maintain the cuff pressure within a recommended range to prevent complications such as fistulae, aspiration and accidental removal of tube.

Your consideration will be highly appreciated.

Kind regards

Mr M E Memela (Student)
Lecturer – Clinical Technology
Tel: 031-3735293/5411
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Associate Director
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**Faculty of Health Sciences
Department of Biomedical and Clinical Technology**

Date: 20 June 2008

Mr M Bhekiswayo
Hospital Manager
King Edward VIII Hospital
Congella, Durban

Dear Mr Bhekiswayo

Re: Permission to conduct a study at King Edward VII Hospital (KEH) ICU

I am **Mduduzi Emmanuel Memela** currently a registered Master's degree student at the Durban University of Technology (DUT) under faculty of Health Sciences. The main requirement for the programme is to conduct a full research study and submit the thesis.

I would like to request the permission to conduct a study at your Intensive care unit. The topic of my study is "**A prospective comparative study of continuous and intermittent endotracheal tube cuff pressure measurement in an adult intensive care unit.**" My supervisor for the study is Dr D Gopalan, Head of Anaesthetics at Nelson R Mandela Medical School and joint supervisor is Dr J K Adam, Associate Director at DUT.

Currently at your ICU patient's cuff pressure are monitored three times a day (i.e. in 24hours). In this study we will be monitoring cuff pressure three times in 12 hours during the day. We will also connect a pressure transducer to monitor cuff pressure continuously using the same monitors that are currently used at the ICU. The aim of this study is to identify the extent of endotracheal cuff pressure changes during ventilation and hopefully to develop the required standard for monitoring cuff pressure. Research has shown that it is extremely vital to maintain the cuff pressure within a recommended range to prevent complications such as fistulae, aspiration and accidental removal of tube.

Your consideration will be highly appreciated.

Kind regards

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CC: Hospital Nursing Manager
ICU directors and nursing manager

Appendix 6 - Record form for intermittent cuff pressure recording.

Patient Data Record Form – Intermittent Monitoring

Patient details:

Patients ID _____ Age _____

Gender _____ Race _____

Time	Cuff Pressure
T ₀	
T ₆	
T ₁₂	

By: _____ Date: _____ Signature: _____



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Research Programming

3 March 2009

Mr. M. Memela
P.O. Box 61590
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Dear Mr. Memela

Request to conduct research at King Edward VIII Hospital
**Protocol: A prospective Comparative Study of Continuous and Intermittent
Endotracheal Tube Cuff Pressure Measurement in an Adult Intensive Care Unit.**

Your request is hereby acknowledged and refers.

Kindly ensure that you have submitted the following details/ documents. (Item ii)

- (i) Research proposal and protocol.
- (ii) **Proof of ethical and/ or higher degrees approval/s.**
- (iii) **Details of other research presently being performed by yourself, if in the employ of King Edward VIII Hospital. (Individually or as a collaborator).**
- (iv) **Details of any financial or human resource implication to the hospital, including all laboratory tests, EEG's, x-rays, use of nurses etc.**
- (v) **Declaration of all funding applications/ grants, please supply substantiating documentation.**

Yours faithfully

MR. M. BHEKISWAYO
CHIEF EXECUTIVE OFFICER

uMnyango Wezempilo . Departement van Gesondheid

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