DECLARATION

I, Lizil Gilliland, declare that this research report is my own work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

..... (Signature of candidate)

..... day of ..... (month), 20.....

DEDICATION

To Johan. Thanks for always believing in me and supporting me throughout this process.

PUBLICATIONS AND PRESENTATIONS ARISING FROM STUDY

No part of this study have been published or presented as yet.

ABSTRACT

Background: Endotracheal tubes (ETTs) play an integral part in anaesthesia. ETT cuff pressure commonly exceeds the recommended range of 20 - 30 cm H_20 during anaesthesia. This can lead to serious morbidity. No objective means of ETT cuff pressure monitoring is available in the operating theatres of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) and Chris Hani Baragwanath Academic Hospital (CHBAH). The ETT cuff pressure of patients undergoing general anaesthesia is therefore unknown.

Aim: The aim of this study was to determine what the actual ETT cuff pressures were of patients receiving general anaesthesia at CMJAH and CHBAH and to document the cuff inflation techniques that were used to achieve these pressures.

Method: ETT cuff pressure of 96 adult patients undergoing general anaesthesia without nitrous oxide at CMJAH and CHBAH were measured. A RUSCH Endotest aneroid manometer was used to measure ETT cuff pressure in size 7.0 – 8.5 mm ETTs. The cuff inflation technique that was used by the anaesthetist was also documented. Anaesthetists were blinded to the study.

Results: The mean ETT cuff pressure recorded was 47.5 cm H_20 (range 10 –120 cm H_20). ETT cuff pressures exceeded 30 cm H_20 in 64.58% of patients and 18.75% of patients had ETT cuff pressures within the recommended range of 20 - 30 cm H_20. There was no statistically significant difference between the ETT cuff pressures measured at the two hospitals (p=0.2480). Minimal occlusive volume was the most frequent technique used to inflate the ETT cuff (37.5%), this was followed by a predetermined volume of air in 31.25% of cases and palpation of the pilot balloon (27.08%). There was no statistical significant difference between the ETT cuff pressure measured and the inflation technique.

Conclusion: ETT cuff pressures of patients undergoing general anaesthesia at two Johannesburg Academic hospitals were high. ETT cuff pressure should routinely be measured using an aneroid manometer.

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Abbreviations

ASTM: American Society for Testing and Materials

CHBAH: Chris Hani Baragwanath Academic Hospital

CMJAH: Charlotte Maxeke Johannesburg Academic Hospital

CEO: Chief Executive Officer

CT: Computed Tomography

ETT: Endotracheal tube

GCS: Glascow Coma Scale

ICU: Intensive Care Unit

ID: Internal Diameter

MLT: Minimal Leak Technique

MOV: Minimal Occlusive Volume

NMBA: Neuro Muscular Blocking Agent

PEEP: Positive End-Expiratory Pressure

PPV: Positive Pressure Ventilation

PVA: Predetermined Volume of Air

PVC: Poly Vinyl Chloride

SD: Standard Deviation

UK: United Kingdom

CHAPTER ONE: OVERVIEW OF THE STUDY

1.1 Introduction

In this chapter an overview of the study is given.

1.2 Background

Endotracheal tubes (ETTs) are used to secure airways and play an integral role in anaesthesiology. The ETT has a cuff near the distal end and the function of the ETT cuff is twofold: to seal the airway to prevent aspiration of gastric content and to facilitate positive pressure ventilation (PPV) without volume loss (1). Cuff inflation with air achieves a seal between the cuff and the tracheal wall. A set volume of air will not deliver the same cuff pressure in each patient and the pressure exerted by the ETT cuff can lead to complications and severe morbidity, in both over or under inflated cuffs. These can include a sore throat and cough, nerve palsies, tracheomalacia, tracheal stenosis, aspiration and volume loss during PPV. Due to shortcomings in estimation and cuff inflation techniques it is recommended that cuff pressures be measured using a manometer or a suitable measuring device. (2)

Research has shown that ETT cuff pressure during anaesthesia commonly exceeds the recommended range. A study conducted in the United States of America documented ETT cuff pressures during anaesthesia, administered without nitrous oxide, in an academic university hospital and two private hospitals. Results indicated that 50% of the ETT cuff pressures measured exceeded 30 cm H_20. Only 27% of the ETT cuff pressures were within the recommended range of 20 - 30 cm H_20, with the remaining 23% less than 20 cm H_20. The mean ETT cuff pressure measured was 35.3 cm H_20. The study concluded that ETT cuff pressure should be measured with a manometer. (2)

Results from a study conducted in Denmark showed that out of 119 patients provided with an ETT undergoing anaesthesia, the ETT cuff pressure exceeded 30 cm H_20 in 54 patients. In 33 patients the ETT cuff pressures were higher than 40 cm H_20 and ETT cuff pressures ranged from eight to 100 cm H_20. The study indicated that nitrous oxide was not used. (3)

Trivedi et al. (4) studied 75 patients undergoing general anaesthesia with an ETT in a government teaching hospital in India. Red rubber ETTs (re-usable) were used in 14 patients. The remaining patients (n=61) were intubated with Poly Vinyl Chloride (PVC) ETTs, and in this group 26.2% of ETT cuff pressures were higher than 30 cm H_20 and 14.8% were less than 20 cm H_20. Nitrous oxide was only started after the ETT cuff pressure had been measured.

A study conducted at Groote Schuur Hospital in Cape Town evaluated the ETT cuff pressure of 100 patients in the theatre complex. They documented a mean ETT cuff pressure of 25 cm H_20 with 23% of pressures that were higher than 30 cm H_20. There were no ETT cuff pressure exceeding 80 cm H_20 in this study and the researchers "tried" to exclude cases where nitrous oxide were used. (5)

Various ETT cuff inflation techniques are used to estimate adequate cuff pressures in the absence of an accessible measuring device. These include minimal leak technique (MLT), minimal occlusive volume (MOV), palpation of the pilot balloon as guide for the quantity of air needed to inflate the cuff and inflating the cuff with a predetermined volume of air (PVA).

Stewart et al. (6) compared ETT cuff pressures obtained by direct measurement using a manometer with estimation techniques during anaesthesia that included the use of nitrous oxide. Palpation of the pilot balloon as an estimation technique was used by 88% of anaesthesia care providers, 10% used MLT and 2% used a predetermined volume of air to inflate the ETT cuff. It was documented that 65% of ETT cuff pressures were greater than 40 cm H_20 and only 30% of ETT cuff pressures were within the ideal range. Estimation techniques were inaccurate in assessing the adequacy of ETT cuff pressure. Data was collected from a training institution that had no access to a manometer.

In a South African study conducted in 11 different intensive care units (ICU's) in the Free State (private and public), it was demonstrated that 38% (43 / 112) of registered nurses working in these ICU's believed that the ETT or tracheostomy cuff's main function was to secure the tube in position to prevent self-extubation. Only 7.5% (5 / 66) of responding nurses working in public ICU's were aware of an accurate way to measure cuff pressures. (7)

1.3 Problem statement

Cuffed ETTs are used daily in patients presenting for general anaesthesia in two academic hospitals in Johannesburg, Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) and Chris Hani Baragwanath Academic Hospital (CHBAH). Although the use of a manometer is considered the standard to determine ETT cuff pressures, there are no manometers available in the operating theatres of these hospitals. The actual ETT cuff pressures of patients undergoing general anaesthesia and the inflation techniques used by anaesthetists to obtain these cuff pressures are not known.

1.4 Aim and objectives

1.4.1 Aim

The aim of this study is to determine what the actual ETT cuff pressures are of patients receiving general anaesthesia at CMJAH and CHBAH and to document the cuff inflation techniques that were used to achieve these pressures.

1.4.2 Objectives

The objectives of this study are to:

- determine the ETT cuff pressures of patients receiving general anaesthesia
- describe the technique used by the anaesthetist to inflate the ETT cuff
- compare the measured ETT cuff pressure with the ETT size
- compare the measured ETT cuff pressure with the ETT cuff inflation technique
- compare the ETT cuff pressures between the two hospitals

1.5 Research assumptions

In this study the following definitions will be used.

Anaesthetist: A doctor administering anaesthesia; includes interns rotating in anaesthesia, registrars, medial officers and specialist anaesthesiologists.

Adult: A person 18 years or older.

Recommended ETT cuff pressure: Miller's (8) recommends safe ETT cuff pressure to be within 25 - 30 cm H_20 (18 – 22 mm Hg). In this study a recommended ETT cuff pressure of 20 – 30 cm H_20 is used as this is in keeping with numerous studies done on the subject(2, 4, 9, 10).

Inflation Techniques: This includes MOV, MLT, PVA technique and palpation technique. This is used to inflate and assess the adequacy of cuff inflation subjectively or indirectly.

Minimal Occlusive Volume (MOV) technique: Inflating the ETT cuff with a sufficient amount of air to abolish any air leak on inspiration during positive pressure ventilation (PPV) (1).

Minimal Leak Technique (MLT): Inflating a sufficient amount of air in the ETT cuff to allow for a small leak on inspiration during PPV (1).

Predetermined Volume of Air (PVA) Technique: Using a predetermined volume of air to inflate the ETT cuff.

Palpation Technique: A finger estimation of the ETT pilot balloon that gives a gross indication of the ETT cuff pressure.

Aneroid manometer: A scientific instrument in which the gas pressure measured is indicated by a revolving pointer moved by a diaphragm or Bourdon tube exposed to the pressure. In this study it will be referred to as a manometer. (11)

ETT cuff pressure: In this study it will be referred to as cuff pressure.

7.0, 7.5, 8.0 and 8.5 mm Internal Diameter (ID) ETT: Will be referred to as size 7.0, 7.5, 8.0 and 8.5 ETT in this study.

1.6 Location

The study was conducted in the operating theatres of two academic hospitals, CMJAH and CHBAH that are affiliated to the University of the Witwatersrand, Johannesburg, Gauteng. Although the registrars affiliated to these hospitals rotate between the two sites,

consultants who do the practical teaching of ETT cuff pressure management remain at the respective hospitals.

1.7 Ethical considerations

Approval to conduct this study was obtained from the relevant authorities (Appendix 1).

Deferred informed, written consent was obtained from the patient (Appendix 2) and informed, written consent was obtained from the anaesthetist in charge of the patient (Appendix 3).

The study was conducted according to the principles of the Declaration of Helsinki (12) and Good Clinical Practice.

1.8 Research methodology

1.8.1 Study design

A prospective, contextual, descriptive research design was used in this study.

1.8.2 Study population

Adult patients presenting to the operating theatres of CMJAH and CHBAH for surgeries under general anaesthesia administered with a cuffed ETT.

1.8.3 Study sample

1.8.3.1 Sample size

In consultation with a biostatistician a sample size of 96 was calculated using the Stat Calc function of Epi-info. This was based on an expected frequency of 45% of ETT cuff pressures being greater than 30 cm H_20. The expected frequency was obtained by using data based on previous international studies that measured ETT cuff pressures during anaesthesia. A 10% precision and 95% confidence level was used to calculate the sample size.

1.8.3.2 Sampling method

A convenience sampling method was followed.

1.8.3.3 Inclusion criteria

The following inclusion criteria were used:

- adult patients of either sex undergoing elective and emergency surgery during normal working hours;
- under general anaesthesia with a cuffed ETT in situ; and
- where oral, straight, single lumen ETTs 6.5 – 8.5 mm ID with low-pressure, high-volume cuffs were used.

1.8.3.4 Exclusion criteria

The following exclusion criteria were used:

- patients intubated before arriving in theatre;
- patients undergoing head and neck surgery including maxillo-facial procedures;
- patients undergoing thoracic surgery;
- nitrous oxide used during anaesthesia;
- patients with known anatomical laryngeo-tracheal abnormalities;
- patients who are coughing; and
- patients with nasogastric tubes in situ.

1.8.4 Data collection

Data was collected at CHBAH and CMJAH on weekdays during normal working hours. Patients undergoing general anaesthesia were screened for enrolment in the study.

The anaesthetic technique and the anaesthetic agents used were at the discretion of the anaesthetist in charge of that patient. Inflation of the ETT cuff was done according to the method preferred by the intubating anaesthetist. There was no restrictions to the treatment that the patient received before the ETT cuff pressure was measured.

After anaesthesia was established and the cuffed ETT was in situ and secured, written consent from the anaesthetist in charge of the patient was obtained before measurement took place.

No ETT cuff pressure was measured within the first 10 minutes after intubation. The ETT cuff pressure was measured using a Teleflex Medical® manometer. If the ETT cuff pressure was found to be above the recommended limit the pressure was adjusted to fall within these limits. ETT cuff pressures that were below the recommended limit were communicated to the anaesthetist in charge of the patient.

Informed written consent was obtained from the study participants in a deferred manner.

1.8.5 Data analysis

In consultation with a biostatistician descriptive and inferential data analysis were done using STATISTICA 12.

1.9 Significance of this study

ETT cuffs can cause tracheal morbidity ranging from mild to severe. Cuffed ETTs are used daily in our practice when administering general anaesthesia. International data reveals cuff pressures above the recommended range are commonly found during anaesthesia if objective measurement of the cuff pressure is not done. No ETT cuff pressure measuring devices are available in the operating theatres of CHBH and CMJAH. No data was available on the ETT cuff pressures in patients presenting for general anaesthesia in these hospitals. Results of this study may change practice at the two hospitals in the following manner:

- anaesthetists may become more aware of their ETT cuff inflation practice
- ETT cuff pressure monitoring devices may become available in theatre
- monitoring ETT cuff pressure during anaesthesia may become standard practice in the operating theatres of the two hospitals.

1.10 Validity and reliability

Various measures were undertaken to ensure validity and reliability.

1.11 Project outline

This research project is presented as a research report and is comprised of the following chapters.

Chapter One: Overview of the study.

Chapter Two: Discussion of relevant literature.

Chapter Three: The methodology used in this research project will be discussed in detail.

Chapter Four: The results of this study will be reported and discussed.

Chapter Five: Summary, limitations, recommendations and conclusions drawn from this study are discussed.

1.12 Summary

In this chapter the background, problem statement, aim and objectives, research assumptions, location and ethical considerations of this research project was introduced together with a brief description of the methodology and the significance of the study.

In the following chapter the literature relevant to this study is discussed.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

In this chapter an overview of the literature related to ETT cuff pressures is reviewed. Literature that is pertinent to aspects associated with cuff pressures during anaesthesia will be discussed. The history and generations of ETT cuffs, tracheal perfusion pressure and the factors influencing it as well as factors influencing ETT cuff pressure will be highlighted. ETT cuff inflation and pressure monitoring techniques are documented together with complications arising from ETT cuffs.

Endotracheal intubation plays an integral role in anaesthesia. ETT cuffs have evolved since they were introduced commercially in the 20th Century. The main function of the ETT cuff is twofold: to limit the air leakage that occurs during PPV and to prevent aspiration of gastric content, therefore creating a seal between the patient's trachea and the cuff (1). A critical first step towards patient safety is inflating the cuff to pressures that will not lead to tracheal morbidity. ETT cuff pressure monitoring with a manometer should form part of standard practice in theatre.

2.2 History

In 1000 AD gold and silver cannulas were used for orotracheal intubation and according to Avicenna this was the first account of orotracheal intubation. A curved metal cannula replaced the gold and silver cannulas in 1788 and in 1878 Sir William MacEwan used a brass tube to perform an oral intubation and administer anaesthesia. In 1889 a rubber tube was devised by Annandale which Magill then standardised in 1917. (13) According to Gilespie, in Dunn and Goulet (14) , Trendelenburg fitted a thin rubber bag over the end of a tracheostomy tube in the early 1870's and that is believed to be the start of the inflatable cuff.

In 1893 the first use of a cuffed ETT was described by Eisenmenger (13). Cuffs were introduced to rubber tubes in the late 1920's by Guedel and Waters, and became known as low-volume high-pressure cuffs. Guedel demonstrated the effectiveness of his cuff by

subjecting a dog to intubation and ventilation using Water's closed circuit in an underwater tank. The dog was unharmed after several successful demonstrations. (10) The use of a pilot balloon as an estimate of the cuff pressure was initially described by Green in 1906 and later by Hewer in 1938. In 1964 the first PVC ETT was used and the use of high-volume, low-pressure cuffs came about in 1970 after tracheal injuries were associated with low-volume high-pressure cuffs. (14)

2.3 Cuff generations

During the last 40 years ETT cuff design has evolved from first generation, low-volume, high-pressure cuffs made from rigid material (re-usable rubber), to high-volume, low-pressure cuffs made from softer more malleable and disposable material (1, 14). Today high-pressure cuffs, made of nondisposable silicone, are no longer used for prolonged intubations since they cause ischeamia of the mucosa that can lead to tracheal injury (10).

Second generation cuffs are high-volume, low-pressure cuffs that reduces the incidence of tracheal mucosal damage, therefore these cuffs are generally recommended (15). Today all ETTs have highly compliant, high-volume, low-pressure cuffs usually made of PVC (50 – 80 micron) as it is nontoxic, smooth, transparent, and inexpensive. It also has thermoplastic properties and conforms to the patient's anatomy at body temperature. (14) These cuffs can adapt easily to the varying shapes of the trachea but can increase the incidence of aspiration. This occurs when folds, acting as microchannels, are formed in the excessive material of the cuff. (1) These cuffs can reach a diameter one and a half to two times that of an average adult human trachea when fully inflated. They may therefore be associated with a sore throat as the mucosal contact area is larger . (16).

Third generation cuffs are also high-volume, low-pressure cuffs. They are made from ultrathin (10 micron) polyurethane with better tracheal sealing properties to reduce the passage of fluid, and leakage of air past the inflated cuffs. (17)

Cuff shapes have evolved to improve the seal created between the trachea and cuff, from cylindrical and conical to a tapered design that allows the cuff and tracheal diameters to match at some point along the cuff. (10)

In the United States of America the cuff inflation system of an ETT must conform to the American Society for Testing and Materials (ASTM) standards. It usually consists of a pilot balloon attached to an inflating tube incorporated into the ETT wall connected to the cuff. The pilot balloon contains a valve for inflation, which also prevents air loss after cuff inflation. The inflation status of the cuff can roughly be monitored by the pilot balloon. The maximum distance the proximal end of the cuff may be from the bevelled end of the ETT is specified by the ASTM. The cuff must inflate symmetrically around the ETT and must not impinge on the murphy eye or herniate over the tube tip. (10, 14, 15)

In South Africa currently there is no formal standard to which the ETT cuff inflation system must conform to. However the Minister of Health has appointed the Medicines Control Council to take on this responsibility.

2.4 Anatomy of the trachea

In adults the trachea is a cartilaginous and membranous tube, 10-20 cm long and approximately 1.2 - 2.5 cm in diameter with varying shapes (C, D, O and oval). It stretches from the lower part of the larynx and descends behind the arch of the aorta where it divides into the left and right primary bronchi. (18) It has a flat posterior surface where it is bordered by the oesophagus, and it contains 16-20 horse-shoe shaped cartilaginous rings. Tall, columnar, pseudostratified epithelium containing 13 different cell types, line the cartilaginous airways (see Figure 1). This lining produces mucus which is an important respiratory defence mechanism. Ciliated epithelial cells aids in mucus propulsion and resorption of secretions via microvilli found on the cell surface. (19)

The blood supply of the trachea is segmental and derived from branches of the thyroid arteries, more specifically the inferior thyroid artery as well as the bronchial arteries. The vessels supplying blood to the anterior cartilage of the trachea are more susceptible to pressure effects. (19)

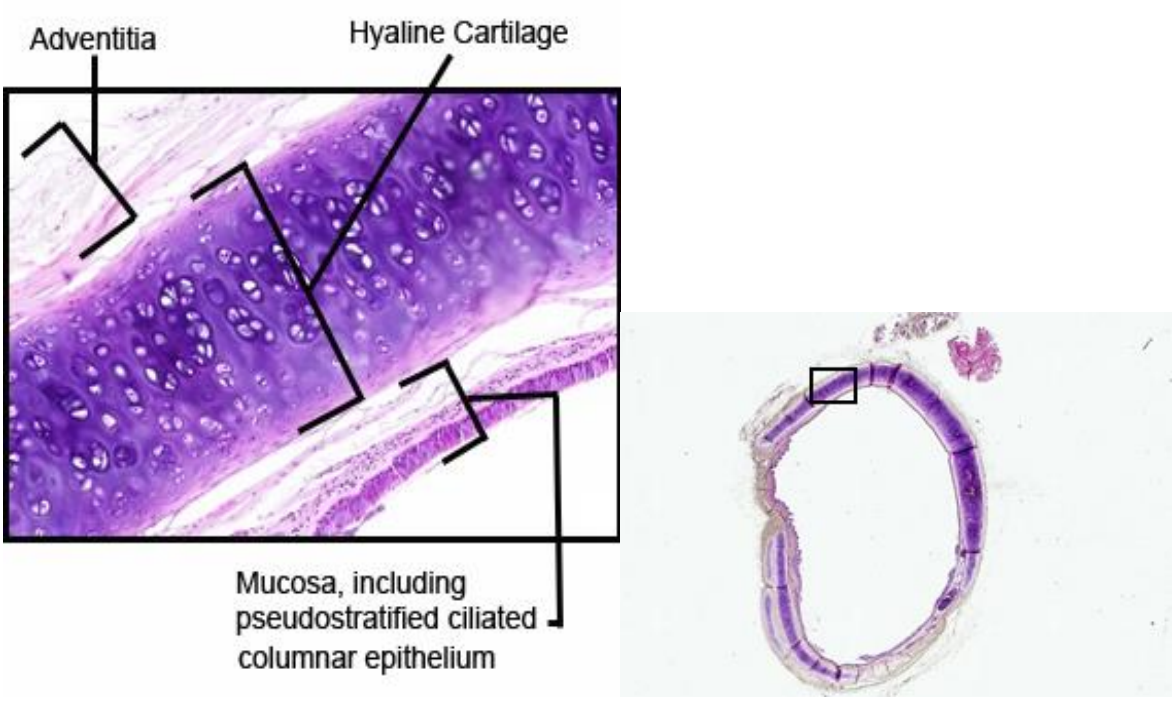


Figure 2.1: Microscopic view of tracheal mucosa (18).

2.5 Tracheal perfusion pressure

The pressure exerted on the tracheal mucosa by the ETT cuff should be as low as possible to avoid complications from obstructing tracheal mucosal blood flow but high enough to form an effective seal when delivering PPV. Tracheal perfusion pressure, that is estimated to be 22 mm Hg – 30 mm Hg, must not be exceeded by the ETT cuff pressure. Tracheal injury with pathological changes begins when ETT cuff pressure exceeds the capillary blood pressure supplying the trachea followed by ischaemia with inflammation. This can lead to mucosal necrosis, ulceration, granulation and the formation of scar tissue leading to stenosis. (1, 15)

The pressure exerted on the tracheal mucosa approximates ETT cuff pressure but the two pressures are not equivalent. In an Australian study micro-chip sensors were used to measure tracheal mucosal pressures directly in 10 patients undergoing general anaesthesia with an ETT. This was then compared to the measured ETT cuff pressure, calculated mucosal pressure and ETT cuff volume. They calculated mucosal pressures by subtracting in vitro ETT cuff pressure from in vivo ETT cuff pressure at different set cuff volumes. With ETT cuff volumes greater than 5 ml, data showed that measured ETT cuff pressure and calculated mucosal pressures were higher than directly measured mucosal pressures. Data

obtained from these indirect methods are therefore only moderate predictors of mucosal pressures. (20)

Bunegin, Albin & Smith (21) showed that in an animal model, depending on the cuff characteristics, the directly measured tracheal mucosal pressure may be up to 5 mm Hg (6.8 cm H_20) lower than the measured ETT cuff pressure. The Australian study as well as this animal study suggests that measured ETT cuff pressures are an over-estimation of tracheal mucosal pressures and therefore a safety margin exists.

In a study by Seegobin and van Hasselt (22) 40 adult patients receiving general anaesthesia with an ETT in situ were studied while varying the cuff pressure and using an endoscopic photographic technique to monitor tracheal mucosal blood flow. It was found that there is endoscopic evidence of obstruction to mucosal blood flow if the lateral tracheal wall pressure exceeds 30 cm H_20 (22 mm Hg). The mucosa overlying the tracheal rings and the posterior tracheal wall had absent blood flow at pressures of 50 cm H_20.

In 1976 Nordin (22) found that there was damage to the tracheal mucosa in rabbits within 15 minutes at a lateral wall pressure of 27 cm H_20; however the damage was not progressive with time. With pressures of 68 cm H_20, partial denuding of the basement membrane of the tracheal mucosa was observed which did not progress with time (beyond 15 minutes).

2.6 Factors influencing tracheal perfusion pressure

Tracheal perfusion pressure is influenced by several factors. By using an analogy to Ohm's Law (if applied to the circulation), the pressure is related to the tracheal blood flow and to the resistance in the tracheal vasculature. During episodes of low systemic perfusion pressures and vasoconstriction mucosal blood flow will be decreased, more so if states of low oxygen delivery prevails such as anaemia, hypoxia and metabolic acidosis. (15)

In an animal study done in Texas, tracheal blood flow was measured at the area of contact between the ETT cuff and the tracheal mucosa during hypotension and normotension. During normotension there was a decline in tracheal blood flow one hour after cuff inflation (cuff pressures exerting 15-18 mm Hg on the tracheal mucosa) and this reduction in blood

flow gradually declined up to three hours post cuff inflation. Tracheal blood flow decreased significantly during hypotension placing the mucosa at risk of ischaemia, this was maximal after cuff inflation but it remained unchanged thereafter. Tracheal blood flow at the cuff site was reduced by ± 75% with ETT cuff pressures of 20 mm Hg (27.2 cm H_20). (15, 21)

Brimacombe, Keller & Giampalmo (20) studied the pressures exerted on the tracheal mucosa by the cuffed and non-cuffed areas of a size 8.5 ETT in adult patients during anaesthesia. The results showed that the directly measured tracheal mucosal pressures were highest against the anterior aspect of the cuff and lowest against the anterior tip of the tube. They found that measured cuff pressures were moderate indicators in predicting directly measured tracheal mucosal pressures and that the intra-cuff volume was not a good indicator. It was demonstrated that the pressure transmitted to the tracheal mucosa exceeded 30 mm Hg (40.8 cm H_20) with cuff volumes of 5 ml. With different head and neck positions the directly measured tracheal mucosal pressures increased significantly at the site of the proximal tube in the flexed head position. The only significant increase in tracheal mucosal pressure associated with the cuffed portion of the ETT showed in the rotated head position at the lateral aspect of the cuff.

2.7 Factors influencing ETT cuff pressure

Several factors can influence the ETT cuff pressure and some of the most common factors will be discussed briefly.

2.7.1 ETT tube

Quality of ETT

The quality of ETTs varies between the different manufactures. In the United States of America, the ASTM has set standard to which the cuff inflation system of an ETT must conform to. (14)

An in-vitro study done using a PVC tracheal model and 13 different size 8.0 ETT concluded that in order to attain a seal, a PVC ETT cuff must be thin and compliant but yet tough enough to resist perforation. The ETT cuff pressures needed to seal the tracheal model as

well as the physical properties of the ETT cuffs varied widely. Low ETT cuff pressures were related to the compliance, thickness and diameter of the ETT cuff. (23)

A study done in Cape Town found no relationship between the two ETT brands (Mallinckrodt® and Rusch®) used in their study. Both these brands are well known brands and the question whether this is true for all brands arises. (5)

Volume of air inflated in ETT cuff

Sengupta et al. (2) used the measured ETT cuff pressure and the volume of air that was used to obtain that pressure, to demonstrate a linear pressure-volume relationship in 93 patients with ETTs ranging from size 7.0 to 8.5. An average ETT cuff volume of 4.4 ± 1.8 ml was documented, and by using the regression equation it was concluded that in order to achieve ETT cuff pressures between 20 and 30 cm H_20 volumes between 2 – 4 ml of air were needed, independent of ETT size. The researchers demonstrated that the median amount of air needed to produce a cuff pressure of 20 cm H_20 was similar with each tube size, but the range of volumes varied considerably.

Lichtenthal and Borg (24) tested the above hypothesis in excised canine tracheas with four diameters (18, 20, 23 and 26 mm) using six different brands of size 7.5 ETTs. They concluded that an ETT cuff pressure of 25 to 30 cm H_2O correlated to a steep linear rise in ETT cuff pressure if small increments of volume were added to the cuff.

An animal study done in New York found that there was a 97% correlation between ETT cuff volume and pressure. They used a size 7.0 ETT and studied the ETT cuff pressures and volumes in four anaesthetised and ventilated canines. The range of actual cuff pressures measured were 2 - 120 cm H_2O and the volumes of air used to achieve this, ranged from 0.5 – 9 ml of air. This resulted in a near-perfect linear relationship but it is debatable whether the canine upper airway correlates with human in vivo conditions. Their results indicated that the margin for error in over inflating the cuff is small as the volume of air needed to reach a pressure of 50 cm H_2O is 50% greater than that needed to produce safe ETT cuff pressures. (25)

2.7.2 Head, neck and body position

The position of the head and neck can alter the ETT cuff pressure as was shown in an Australian study. The ETT cuff pressures were measured in different head and neck positions that included neutral, flexed, rotated and extended positions. In the neutral position ETT cuff pressure was set at 30 mm Hg (40.8 cm H_20) and then measured in the other three positions. The highest increase in cuff pressure was demonstrated in the flexed position of the head; however it was shown that cuff pressure also increased significantly in the extended and rotated head positions. (20)

In a recent study the changes in body position on ETT cuff pressure were evaluated in 12 intubated, paralysed and sedated patients in ICU. Sixteen different positions were included and the ETT cuff pressure was measured in each position The positions included: flexion, extension, right and left lateral flexion and right and left rotation of the head, also supine, Trendelenburg (10°), recumbent, semi-recumbent and right and left lateral positioning over 30°, 45° and 90° respectively. ETT cuff pressure was set at 25 cm H_20 in the starting neutral position. They performed a total of 192 ETT cuff pressure measurements (12 patients in 16 positions) and documented a statistically significant change in ETT cuff pressure with all 16 positions. In 40.6% of the measurements the ETT cuff pressure exceeded 30 cm H_20 and only one patient's ETT cuff pressure was within the recommended range of 20 – 30 cm H_20 in all 16 positions. A limitation of this study was that ETT cuff pressure was only measured briefly once the patient was in the desired position. (9)

2.7.3 Trachea

The influence of the compliance of the trachea and the diameter of the ETT cuff in relation to the trachea on the ETT cuff pressure were also highlighted in the previously mentioned study done by Lichtenthal et al. (24). Initially the resting volume of the ETT cuff determined the relationship between pressure and volume but they found that the cuff pressure increased linearly when the force of the tracheal durometer was equal to the ETT cuff pressure. It occurred with ETT cuff pressures of 30 cm H_2O and the compliance of the trachea was reflected by this occurrence.

Bernhard et al. (23) concluded in their study using a tracheal model that the ETT cuff diameter must be greater than 28 mm and exceed the tracheal diameter to attain a seal.

2.7.4 Ventilation

Ventilation parameters can influence the intra-thoracic pressure which in turn affects the ETT cuff pressure. Guyton, Barlow & Besselievre (26) documented the relationship between the minimum occlusive ETT cuff pressure and the peak airway pressure in patients undergoing general anaesthesia with ventilation. Results showed a linear increase in minimum occlusive ETT cuff pressure over the range of measured peak inflation airway pressures. The ETT cuff pressures ranged from 2.2 – 39.7 mm Hg (3 – 54 cm H_20) and the corresponding airway pressures ranged from 16.5 – 59.4 cm H_20 It was reported that a peak airway pressure of 48 cm H_20 corresponds to a cuff pressure of 25 mm Hg (34 cm H_20), therefore in patients with poor lung compliance requiring high pressure ventilation the cuff pressures needed to seal the trachea will be greater than 25 mm Hg (34 cm H_20). The type of surgery performed and whether this could have influenced the obtained pressure readings, were not documented. A further limitation was that the data reflected a single manufacturer of ETTs.

Sole, Penoyer & Su (27) showed in a pilot study using continuous cuff pressure monitoring in ICU that ETT cuff pressures increased with selected clinical activities. These activities included patient coughing, ETT suctioning and patient-ventilator dyssynchrony. There was less variation in measured cuff pressures in patients with lower Glascow Coma Scale (GCS) scores and after administration of sedatives. There was no statistically significant change in cuff pressure over time but a limitation of this observation was that pressures were only monitored for a mean of 9.3 hours.

2.7.5 Anaesthetic agents

Nitrous oxide, if used during a general anaesthesia can diffuse into the cuff when air is used to inflate the cuff and this can cause a great rise in the cuff pressure (15). A study conducted in Brazil documented this when they compared ETT cuff pressures in patients after general anaesthesia with and without nitrous oxide. The mean ETT cuff pressure in the group that received nitrous oxide was 106 cm H_20 and there was a statistically significant difference compared to the group not receiving nitrous where the mean ETT cuff pressure was 60.5 cm H_20. (28)

Muscle relaxation affects the tracheal muscle tone that can influence the ETT cuff pressures. In a study assessing the neuromuscular block at the larynx, resting ETT cuff pressures were

measured before and after administration of a neuromuscular blocking agent (NMBA). There was a mean decrease in cuff pressure of 9 mm Hg (12.2 cm H_20) documented after the administration of a NMBA. (29)

2.7.6 Altitude

Increasing altitude will increase gas volume and when the volume is restricted, according to Boyle's Law there will be a relative increase in pressure (30). It has been shown in aviation medicine that initial ETT cuff pressures of 28 cm H_20 can exceed 50 cm H_20 after increases in altitude of as little as 2000 ± 3000 feet (31).

2.7.7 General

In 119 intubated patients studied during anaesthesia there was no relationship between ETT cuff pressure and body mass index, age, type of surgery or the time from induction of anaesthesia to measurement of pressure (3). In a study done by Sengupta et al. (2) on patients under general anaesthesia without nitrous oxide, the researchers concluded that the measured cuff pressures did not correlate with the patients' sex, age, weight, height or that there was a difference in pressures measured between different sized ETTs.

A study conducted in Cape Town determined that there was no statistically significant difference between ETT size and cuff pressure (5).

2.8 ETT cuff Inflation techniques

There are several techniques available to inflate ETT cuffs and to assess the adequacy of the inflation. MOV and MLT are described by Pierce (1) to be sufficient in creating a sealed airway to enable PPV and to prevent aspiration and tracheal mucosal damage. It is advised even with these techniques that cuff pressure should be measured objectively. MOV has the advantages of no volume loss during PPV and a smaller risk for aspiration whilst the theoretical risk of injury to the tracheal mucosa is higher than with the MLT. The latter decreases pooling of secretions above the cuff and theoretically causes less damage to the tracheal mucosa whilst increasing the risk for aspiration. Volume loss during PPV can be a problem as there is no evidence available to quantify the minimal leak that is acceptable. (1)

MLT is performed by injecting air into the cuff until no leak is heard when auscultating over the trachea. Air is then removed in 0.1 ml increments until a small leak is heard over the trachea. MOV is attained by auscultating over the trachea and injecting air into the cuff until no leak is heard. Air is then removed in small increments until a leak is heard, and then reintroduced until no leak is audible on inspiration. (1)

The aim of a recent survey conducted in an Australian ICU was to highlight the practice variation among nursing staff using MOV as a cuff inflation technique. There are aspects of the MOV technique that lack rationale and the survey highlighted these. Responding nurses identified three different methods for the MOV technique. The first technique described full cuff deflation to document the volume of air in the cuff, followed by re-inflation with the same amount of air and then 1 ml incremental air removal until a leak was detected. The addition of 1 ml of air restored the MOV when using this technique. This was the preferred method used by 59% of nurses. The next technique identified consisted of full ETT cuff deflation followed by incremental addition of air until MOV was established and was used by 31% of respondents. Only 2.5% of respondents established MOV without full cuff deflation, using incremental removal of air. The researchers showed no consistency of practice regarding patient positioning during MOV, confirmation of cuff seal and cuff leak management amongst the respondents, despite concern for the risk of aspiration. They concluded that more evidence is needed to support the efficacy of the elements of the MOV technique. (32)

Using a PVA technique to inflate the cuff and palpation of the pilot balloon are other techniques used for cuff inflation but the literature reveals flaws in these techniques (33, 34). Palpation of the pilot balloon is used interchangeably in the literature as an inflation technique but also as a technique for estimating cuff pressure after inflation. Hagberg (19) advises that after intubation, if a cuff pressure gauge is not available, the cuff should be inflated until moderate tension is palpable in the pilot balloon.

The method of inflation of the ETT cuff was observed in a study done in the United States of America. They made use of a previously tested tracheal simulation model and a size 7.5 high-volume, low-pressure cuffed ETT. It was found that 90% of study participants (n=41) inflated the ETT cuff to pressures greater than the upper limit that could be measured by

the manometer i.e. greater than 120 cm H_20, and could therefore not be included in the statistical calculations. The measurable pressures were then used to obtain the average pressure generated with cuff inflation and this was more than 93 cm H_20. Of note was that 59% of study participants used pilot balloon palpation to determine the amount of air needed, and 41% a PVA technique as a method of cuff inflation to ensure adequate cuff pressures. (34)

2.9 Cuff pressure monitoring

ETT cuff pressure monitoring can be either subjective or objective. In this literature subjective methods, referred to as estimation techniques, include palpating the pilot balloon, MOV and MLT. Objective measurement is done with measuring devices such as a sphygmomanometer, manometer and pressure transducer.

2.9.1 Estimation Techniques for ETT cuff pressures

The shortcomings of pilot balloon palpation as an estimation technique was documented by Fernandes, Blanch & Mancebo (35) using a trachea simulator model and 8.0 mm ID, high-volume, low-pressure cuffed ETTs from four different manufacturers. Palpation of the pilot balloon was accurate in detecting 73% of low pressures, 69% of high pressures and 58% of normal pressures. The inter-observer variability and the physical properties of the ETTs made manual estimation unreliable. It was documented that the volume needed to produce the same cuff pressure was different for the various ETTs used and that the volumes needed were smaller when the ETT was in the artificial trachea compared to being without restriction.

In a study done Hoffman, Parwani & Hahn (34), the researchers tested the ability of 41 emergency medicine physicians to palpate the pilot balloon of previously inflated ETT cuffs to determine whether the pressures were appropriate. The participants could only detect overinflated ETT cuff pressures in 22% of cases when using pilot balloon palpation and no one correctly identified all the overinflated ETT cuffs.

A South African study conducted in Johannesburg investigated the ability of paramedics and doctors working in the emergency department to estimate ETT cuff pressure by palpating the pilot balloon. A tracheal simulation model was used with seven 7.5 mm ID ETT cuffs

inflated to pressures ranging from 0 to 100 cm H_20. Of the 44 participants, 55% were doctors. At the extremes of ETT cuff pressures, estimations were more accurate while the ETT cuff with a safe pressure of 20 cm H_20 was estimated as too low by most. Cuff pressures between 40 and 100 cm H_20 were estimated to be safe by 25-50% of participants. (33)

Numerous studies (4-6, 33-35) compared the experience of the person assessing the adequacy of the ETT cuff pressure with the accuracy of estimation and no correlation was documented. This indicates that accurate estimation does not depend on experience or training and therefore does not appear to be a skill that is acquired over time.

2.9.2 Objective measurement of ETT cuff pressure

Measurement of ETT cuff pressures can be made with various devices that includes sphygmomanometers, manometers, pressure transducers and pneumatic devices.

A standard sphygmomanometer can be used, but with the introduction of automated blood pressure devices, mercury sphygmomanometers are not easily available. This is a cumbersome method that needs to take the dead space of the manometer tubing into account (1).

The most commonly used measuring device is the manometer. Numerous studies done on cuff pressures during anaesthesia recommended that cuff pressure should routinely be monitored using measuring devices (2-6, 36).

Manometers are handheld instruments that are simple to use if following the manufacturer's guidelines, but these devices are not always available in theatre (1). They are accurate and precise but require calibration, can be expensive and pose an infection risk if used between patients. Manometers function by using a pre-set range of pressures, usually around 25 cm H_20 and pressure-limiting valves that act as reservoirs for excess pressures in the cuff. (10)

Blanch (11) evaluated four brands of ETT cuff inflators (three manometers and one pressure transducer) in a laboratory using a tracheal model. The researcher documented that with cuff pressures ranging from 25 – 34 cm H_20 the four tested devices offered a clinically acceptable degree of accuracy. Contradictory to this it was noted there were measurable differences in precision between the four brands and that none of them could accurately

measure the ETT cuff pressure when pressures were greater than 34 cm H_20. Measuring the ETT cuff pressure could not be performed without causing a decrease in the existing cuff pressure. The higher the initial cuff pressure, the greater the pressure loss during measurement.

Continuous monitoring of ETT cuff pressures can be achieved using a standard pressure transducer with a pressure monitor (depending on the availability of the equipment). In a pilot study in ICU patients in Florida, assessing the accuracy and feasibility of continuous monitoring, it was concluded that pressures obtained with the manometer were congruent with pressures obtained with the transducer. (27)

A pilot study aimed at controlling ETT cuff pressures using a pneumatic device to limit human intervention, was conducted in nine ICU patients. The pneumatic device consisted of a large, encased, inflatable cuff receiving constant pressure from a heavy mass attached to an articulated arm and connected to the ETT cuff. ETT cuff pressure was recorded continuously with a pressure transducer and data was collected over two days. During the control day cuff pressures were monitored with a manometer and during the prototype day the pneumatic device was used while simultaneous pressure recordings were made with the transducer during both days. On the control day, routine (twice daily) cuff pressure checks with a manometer resulted in pressure readings ranging from 30 – 50 cm H_2O in 29 ± 25 % of the 24 hour study period. This percentage of time spent with pressures ranging between 30 and 50 cm H_2O was significantly lower on the prototype day when using the pneumatic device, where it was only 0.3 ± 0.3%. The pneumatic device prevented pressure peaks associated with coughing and the time spent with ETT cuff pressures > 30 cm H_2O was negligible. (37)

2.10 Complications of ETT cuffs

Complications associated with ETTs in general are numerous and can be life threatening, but only those associated with the ETT cuff will be discussed. The ETT cuff can cause tracheal and respiratory morbidity and lead to mortality in some cases. A very narrow pressure range is reported to be safe. Complications may arise from ETT cuff pressures that are not only too low or too high, but even those inflated within the recommended pressure range.

2.10.1 Complications arising from impaired tracheal mucosal perfusion

ETT cuff overinflation can lead to pressures that exceed the perfusion pressure of the tracheal mucosa and this may cause a downward spiral leading towards tracheal morbidity. Ischaemia and inflammation result and can lead to necrosis of the tracheal mucosa with ulceration and even haemorrhage. During the healing process of the mucosa, scar tissue and granuloma formation ensues which may lead to stenosis and obstruction of the trachea. (1)

Stenosis of the trachea is a serious, but rare, consequence of mucosal damage and is usually multifactorial in origin. The most common sites of stenosis are where the ETT cuff has been in contact with the tracheal mucosal wall, although it can occur from the level of the ETT tip to the glottic area. (38) An estimated population incidence of post-intubation laryngeal stenosis of 4.9 cases per million per year is reported in the literature from the United Kingdom (UK) (39).

A retrospective study included 31 patients with tracheal stenosis, in which 11 developed post endotracheal intubation with the remaining (n=20) developing post tracheostomy. The mean duration of intubation was 5.2 days in the post endotracheal intubation group, and the mean length of the area stenosed was greater than in the tracheostomy group. The most common type of stenosis was web-like fibrosis, developing along the area where the cuff was in contact with the tracheal mucosa. (38)

Less frequently, dilatation of the trachea can develop if the ischaemic process involves the cartilage and tracheomalacia may follow. Trachea-oesophageal or trachea-vascular fistulas can develop, but these complications are rare with the ETT cuffs used today. (1)

2.10.2 Complications due to ETT cuff over inflation

Not only do overinflated ETT cuffs lead to pressures that exceed the tracheal mucosal perfusion pressure, but they may lead to tracheal rupture, nerve palsies or airway obstruction.

Tracheal rupture following intubation has seldom been reported. A university hospital in France documented six cases of tracheal rupture associated with endotracheal intubation in seven years. Two cases were thought to be related to ETT cuff overinflation. (40)

Unilateral recurrent laryngeal nerve injury producing vocal cord paresis or paralysis can develop if an overinflated ETT cuff is positioned in the immediate subglottic region. A bilateral nerve injury can compromise the airway although this is exceptionally rare (14). This phenomenon was described in a case report of a patient undergoing uncomplicated oral intubation. This is believed to be the first reported case of bilateral recurrent laryngeal and bilateral hypoglossal nerve injury associated with orotracheal intubation. (41)

Cuff herniation over the end of the ETT caused by an overinflated cuff can lead to airway obstruction (14). Cuff overinflation was documented to be the cause of critical ETT obstruction in a case reported in 2010. The inflated cuff of a 6.0 mm ID ETT compressed its confining wall and caused critical narrowing of the tube lumen leading to respiratory compromise. Coincidently this happened while the patient was having a Computed Tomography (CT) scan, so the cause of the obstruction was clarified retrospectively. The researchers tried to reproduce the case in an experimental study using tracheal models and simulated conditions. No visible obstruction of the tested ETTs by their inflated cuffs could be documented, even with excessive cuff pressures. (42)

2.10.3 Complications associated with recommended ETT cuff pressure

ETT cuff pressures that fall within the recommended pressure range can lead to postoperative respiratory morbidity. Sore throat and cough are common complaints in patients undergoing general anaesthesia with endotracheal intubation.

A study done in 2010 correlated postoperative respiratory complications associated with endotracheal intubation to controlled ETT cuff pressures intra-operatively. The researchers studied the incidence of post-operative sore throat, hoarseness, cough and blood streaked expectorants by means of a structured questionnaire, to assess the benefits in controlling ETT cuff pressure during general anaesthesia. (36)

The study population included 509 patients undergoing general anaesthesia (without nitrous oxide) for elective surgery, randomised into two groups. In the control group (n=273) ETT cuff pressure was not measured, while in the study group (n=236) ETT cuff pressure was measured and then adjusted, using a manometer, to range from 15 -25 mm Hg (20.4 - 34 cm H_20). Mean ETT cuff pressure in the study group was 43 ± 23.3 mm Hg (58.5 ± 31.7 cm H_20) before adjustment and 20 ± 3.1 mm Hg (27.2 ± 4.2 cm H_20) after

adjustment. The outcome revealed no significant difference in the incidence of coughing 24 hours after extubation between the two groups. The incidence of hoarseness, sore throat and blood streaked expectoration were lower by 8%, 10%, and 7% respectively in the study group. (36)

There was no statistically significant difference in the duration of intubation, with a mean of 168 minutes in the control group versus 162 minutes in the study group. It was noted that when the intubation time exceeded 180 minutes, the incidence of sore throat and blood streaked expectoration increased significantly from 38% to 55% and 7% to 18%, respectively in the control group. Interestingly the incidence of sore throat in the study group also increased from 26% to 54% with longer duration of intubation. (36)

Fiberoptic bronchoscopic examinations were done in 20 patients randomly selected from each group, where the duration of intubation was between 120 and 180 minutes. The tracheal mucosa was injured to varying degrees in both groups. Of note was that these injuries were more severe in the control group and formation of patchy haemorrhagic ulceration was observed in three patients in this group. (36)

2.10.4 Complications due to ETT cuff under inflation

Aspiration beyond ETT cuffs

Inadequate cuff pressures can lead to infectious complications from the aspiration of oral and gastric secretions. In prolonged intubations this can lead to the development of ventilator associated pneumonia. This is of relevance in ICU and will not be discussed. During anaesthesia a proper seal between the cuff and tracheal wall is important to protect against the leakage of fluid past the cuff especially in the patient presenting for emergency surgery with a full stomach.

Folds can develop in inflated cuffs of ETTs and these serve as a potential site for aspiration of secretions that pool above the cuff (1). These secretions may be colonized with bacteria and can lead to pulmonary infections. In a study by Seegobin et al. (22) the researchers noted excessive folding in the material of large volume cuffs with sputum tracking down the channels formed by these folds. They conducted a further study to look at the incidence of aspiration of liquid past high-volume, low-pressure ETT cuff's inflated to 25 cm H_20 during anaesthesia. ETTs from three manufacturers were used and 2 ml of Indocyanine green dye

was instilled immediately above the cuff. The dye passed beyond all the cuffs and as observed with a bronchoscope this passage was related to channels formed by folds in the cuffs. Inflating two of the manufacturers cuffs (n=10) to 50 cm H_20 did not obliterate the dye filled folds. A potential limitation in this study was that the viscosity of the dye used was not the same as the viscosity of secretions; also the dye was placed beyond the vocal cords. (43)

In a bench-top study conducted in Italy a comparison between the available high-volume, low-pressure ETT cuffs were performed. Using a PVC model of the human trachea, six ETTs were tested for fluid leakage across their cuffs, during a 24 hour study period. The sealing properties of the cuffs (at constant pressures of 30 cm H_20) were evaluated at incremental positive end-expiratory pressure (PEEP) levels. There was a significant decrease in fluid leakage across the cuff with incremental PEEP levels. All the fluid leaked across the cylindrical PVC cuffs with no PEEP and no fluid leakage was observed at a PEEP of 15 cm H_20. (16)

Not only do the ETT cuff pressure and the effect of PEEP applied during PPV play a role in aspiration past the cuff but the material and shape of the cuff also play a role in creating a seal. The above mentioned study demonstrated that PVC cuffs had the worst sealing properties when compared to guayule latex and polyurethane. Conical shaped cuffs had higher sealing properties than cylindrical shaped cuffs. The cylindrical PVC cuffs performed poorly at PEEP levels of zero with all the water leaking past the cuff within two to 184 minutes. The viscosity of the fluid used could have favoured leakage across the ETT cuff and a tracheal model was used in the vertical position limiting this study. (16)

Air leakage past ETT cuffs

Low ETT cuff pressure can cause a loss of tidal volume during PPV that will reduce the efficacy of ventilation and usually presents as an audible air leak around the ETT cuff during inspiration. Dullenkopf, Schmitz & Frei (17) compared the cuff pressures needed to prevent air leakage in conventional ETTs with the Microcuff® ETT which has an ultra-thin poly-urethane cuff membrane. The researchers documented that much lower pressures were needed to prevent air leakage with the Microcuff® when compared to conventional ETT cuffs. In the 50 participating patients, a mean ETT cuff pressure of 18 cm H_20 (range of 8 -

42 cm H_20) was needed to obliterate an audible air leak, whereas the Microcuff® ETT required significantly lower mean sealing cuff pressures of 9.5 cm H_20 (range of 8 - 12 cm H_20).

2.11 ICU

Awareness of objective cuff pressure measurement and complications arising from over and under inflated cuffs are emphasised in the intensive care literature. In an audit done at Mayday University Hospital's ICU in the UK, 66% of cuff pressures were within the recommended range of 20-30 cm H_20. Pressures were high in 22% of cases and underinflated cuffs were found in 12% of patients. In a telephone survey, conducted by the same researchers, including 79 ICU's across the UK, results revealed that 68% of ICU's routinely measured cuff pressures (ranging from once per day to once per shift). The survey found no uniformity in the cuff pressure targeted by these ICU's. (44)

2.12 Emergency department

ETTs are not only used in theatres and ICU's but also in out of hospital settings by emergency medical staff. With uncontrolled cuff pressures tracheal mucosal damage can occur if the time spent before reaching the hospital is long. The incidence of ETT cuff pressures > 27 cm H_20 in 107 French out-of-hospital patients were 79% (n=85). This included intubated patients being transferred between two hospitals. Mean pressures recorded were 63 cm H_20 and cuff pressure corrections were made in 72% of cases. (45)

The mean ETT cuff pressure of 91 patients in a Cape Town trauma centre was 55 cm H_20. The site of intubation of these patients significantly influenced the cuff pressure with the highest mean pressure recorded in patients intubated on scene (71 cm H_20), followed by patients intubated at the referral hospital (57 cm H_20), followed by patients intubated in the hospital's trauma centre (42 cm H_20). (5)

2.13 Feasibility of ETT cuff pressure protocol

Jaber, El Kamel & Chanques (46) evaluated the impact of implementing a cuff pressure monitoring protocol on reducing the incidence of cuff over inflation in a 16-bed ICU. Before implementation the mean cuff pressure in 30 patients (during a one month period) was 42 ± 22 mm Hg (57 ± 29.9 cm H_20). The protocol was then introduced to the staff and pressures were to be measured whenever there was a manipulation that could influence the cuff pressure and during every team shift. One month after the protocol was introduced mean cuff pressures measured over a one month period, were found to be significantly lower, 26 ± 3 mm Hg (35.4 ± 4 cm H_20). Three years later the study was repeated, where they again measured cuff pressures for a month and included 32 patients. Cuff pressures were found to be lower than in the previous two study months and the mean pressure was 21 ± 19 mm Hg (28.6 ± 25.8 cm H_20). This indicates adherence to the protocol that had been introduced.

A 2010 audit of cuff pressures in a Wrexham ICU was done in two phases that were separated by a clinical intervention introducing measurement devices and training on their use. Before the measurement intervention, the average ETT cuff pressure was 43 mm Hg (58.9 cm H_20) with a range of 18 – 68 mm Hg (24.5 – 92.5 cm H_20), and after the introduction of measuring devices with a protocol, the average pressure was 30 mm Hg (40.8 cm H_20), with a smaller range of 22 - 38 mm Hg (29.9 – 51.7 cm H_20). (47) This demonstrated the positive effect of the clinical intervention.

2.14 Summary

In this chapter the literature related to ETT cuff pressure was reviewed. Factors influencing cuff pressures and tracheal mucosal perfusion pressure were highlighted. The importance of ETT cuff pressure monitoring was discussed in view of the complications associated with ETT cuffs.

In the following chapter the methodology used in this research report will be discussed.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

In this chapter an in-depth discussion of the methodology used in this research project is presented.

3.2 Problem statement

Cuffed ETT are used daily in patients presenting for general anaesthesia in two academic hospitals in Johannesburg, CMJAH and CHBAH. Although the use of a manometer is considered the standard to determine ETT cuff pressures, there are no manometers available in the operating theatres of these hospitals. The actual ETT cuff pressures of patients undergoing general anaesthesia and the inflation techniques used by anaesthetists to obtain these cuff pressures are not known.

3.3 Aim and Objectives

3.3.1 Aim

The aim of this study was to determine what the actual ETT cuff pressures were of patients receiving general anaesthesia at CMJAH and CHBAH and to document the cuff inflation techniques used to obtain these pressures.

3.3.2 Objectives

The objectives of this study were to:

- determine the ETT cuff pressures of patients receiving general anaesthesia
- describe the technique used by the anaesthetist to inflate the ETT cuff
- compare the measured ETT cuff pressure with the ETT size
- compare the measured ETT cuff pressure with the ETT cuff inflation technique
- compare the ETT cuff pressures between the two hospitals.

3.4 Ethical considerations

The researcher gained approval to conduct this study from the Post Graduate Committee and Human Research Ethics Committee (Medical) of the University of the Witwatersrand. The CEO's of the respective hospitals; CMJAH and CHBAH were approached for permission to conduct this study at these hospitals. (Appendix 1)

Deferred informed, written consent was obtained from the study participants by means of an information document (Appendix 2).

Written, informed consent to measure the ETT cuff pressure was obtained from the anaesthetist in charge of the patient (Appendix 3) and confidentiality was maintained. If the ETT cuff pressure was found to be above the recommended limit the anaesthetist was informed and the pressure was adjusted to fall within these limits. ETT cuff pressures that were below the recommended limit was communicated to the anaesthetist in charge of the patient.

The study was conducted according to the principles of the Declaration of Helsinki (12) and the South African Good Clinical Practice Guidelines.

3.5 Research Methodology

3.5.1 Study Design

A prospective, contextual, descriptive research design was used.

Prospective study

This study was a prospective study measuring ETT cuff pressures of patients undergoing general anaesthesia for surgery in the operating theatres of CMJAH and CHBAH.
As opposed to retrospective studies where variables that have already occurred are evaluated, in prospective studies the direction of the enquiry is forward (48).

Contextual study

This study was contextual in design as it described the practice of ETT cuff inflation and ETT cuff pressure of patients undergoing general anaesthesia in two academic hospitals in Johannesburg.

Descriptive study

A descriptive design is used in studies where more information is required in a particular field through the provision of a picture of the phenomenon as it naturally occurs (48). The study described the ETT cuff pressures of adult patients who presented for surgery and underwent general anaesthesia with an ETT in situ. The ETT cuff inflation practices used by anaesthetists in the two hospitals were described.

3.5.2 Study Population

Adult patients that presented to the operating theatres of CMJAH and CHBAH for surgery under general anaesthesia administered with a cuffed ETT.

3.5.3 Study Sample

3.5.3.1 Sample size

In consultation with a biostatistician a sample size of 96 was calculated using the Stat Calc function of Epi-info. This was based on an expected frequency of 45% of ETT cuff pressures greater than 30 cm H_20. The expected frequency was obtained by using data based on previous international studies that measured ETT cuff pressures during anaesthesia. A 10% precision and 95% confidence level was used to calculate the sample size.

3.5.3.2 Sampling method

A convenience sampling method was used. This is a subtype of non-random sampling where the most readily accessible individuals were used to obtain an estimate of a particular element of interest (49). Patients were included in the study when convenient for the researcher.

3.5.3.3 Inclusion criteria

The following inclusion criteria were used:

- adult patients of either sex who underwent elective and emergency surgery during normal working hours;
- under general anaesthesia with a cuffed ETT in situ; and
- where oral, straight, single lumen ETTs 6.5 – 8.5 mm ID with low-pressure, high-volume cuffs were used.

3.5.3.4 Exclusion criteria

The following exclusion criteria were used:

- Patients who were intubated before arriving in theatre;
- patients undergoing head and neck surgery including maxillo-facial procedures;
- patients undergoing thoracic surgery;
- nitrous oxide used during anaesthesia;
- patients with known anatomical laryngeo-tracheal abnormalities;
- patients who were coughing; and
- patients with nasogastric tubes in situ.

3.5.4 Data Collection

Data was collected at CHBAH and CMJAH on weekdays during normal working hours. The emergency theatres and theatres where elective general, vascular, plastic, orthopaedic, gynaelogical and urological surgery took place were used.

The anaesthetic technique and the anaesthetic agents used were at the discretion of the anaesthetist in charge of that patient. Inflation of the cuff was also done according to the method preferred by the intubating anaesthetist. There were no restrictions to the treatment that the patient received before the ETT cuff pressure was measured.

After anaesthesia was established and the cuffed ETT was in situ and secured the anaesthetist in charge of the patient was approached by the researcher and invited to take part in the study. If the anaesthetist agreed, written, informed consent was obtained before measurement took place. (Appendix 3)

A minimum of 10 minutes after intubation elapsed before the ETT cuff pressure was measured. The time from intubation to ETT cuff pressure measurement was documented (in minutes) along with the age of the patient (in years), the sex of the patient, and the surgical specialty. (Appendix 4) The anaesthetist responsible for inflating the ETT cuff was asked what technique was used for cuff inflation and this was then documented together with the ETT cuff pressure obtained with measurement (in cm H_20).

Take note:

- the cuff pressure measurements of any one intubating anaesthetist was not included more than three times in this study; and
- cuff pressure measurements from the same anaesthetist was not used consecutively or more than once on the same day.

The ETT cuff pressure was measured using a manometer from Teleflex Medical®, RUSCH Endotest. This manometer was only used for study purposes and was calibrated by the manufacturer prior to use for data collection. The manometer was attached to the pilot balloon of the ETT and the cuff pressure was recorded at end-expiration. If the cuff pressure was found to be above the recommended limit the anaesthetist was informed and the cuff pressure was adjusted to fall within these limits. ETT cuff pressures that were below the recommended limit were communicated to the anaesthetist in charge of the patient. The manometer was cleaned between patients using 70% alcohol spray.

Informed written consent was obtained from the study participants in a deferred manner. (Appendix 2) This was done in the ward after the patient had recovered from anaesthesia. Since it was the anaesthetist in charge of the patient's decision to use an ETT, deferred consent was the most appropriate manner to obtain the patients consent. If a patient did not consent to partake in the study, the data collected from them was discarded. Data collection took place until 96 study participants cuff pressure measurements were acquired and consent was obtained from these patients.

3.5.5 Data Analysis

Data were captured onto a Microsoft® Excel spread sheet. A STATISTICA 12 package was used to perform the statistical analysis of the data. In consultation with a biostatistician descriptive and inferential data analysis was done. Normally distributed data were reported using means and standard deviations (SD). Data not normally distributed were reported using medians, ranges and interquartile ranges. Numbers and percentages were used to summarise data. Chi-square and Fisher's exact tests were used to find associations between categorical variables. The Mann-Whitney-Wilcoxon test was used to compare the ETT cuff pressures between the two hospitals.

3.6 Validity and Reliability

Reliability refers to the consistency of values obtained with a measuring instrument. Values should only have a small amount of random error in order for the instrument to be regarded as reliable (50).

Validity is determined by the ability of the instrument to reflect the true value of the sample being tested (50).

This study was valid and reliable in that:

- ETT cuff pressures were measured by the researcher only;
- the same manometer was used for every patient;
- the manometer was calibrated by the manufacturer before data collection began;
- the manometer was used for this study only; and
- the same technique of measurement was used in every patient.

3.7 Summary

In this chapter an in-depth discussion was done on the methodology used in this research project. In the following chapter the results of this study are presented and discussed.

CHAPTER FOUR: RESULTS AND DISCUSSION

4.1 Introduction

In this chapter the results of the study are presented. The data presented include demographic data of the study sample, the ETT cuff pressure measured and the inflation technique used by the anaesthetist.

The objectives of this study were to:

- determine the ETT cuff pressures of patients receiving general anaesthesia
- describe the technique used by the anaesthetist to inflate the ETT cuff
- compare the measured ETT cuff pressure with the ETT size
- compare the measured ETT cuff pressure with the ETT cuff inflation technique
- compare the ETT cuff pressures between the two hospitals

4.2 Results

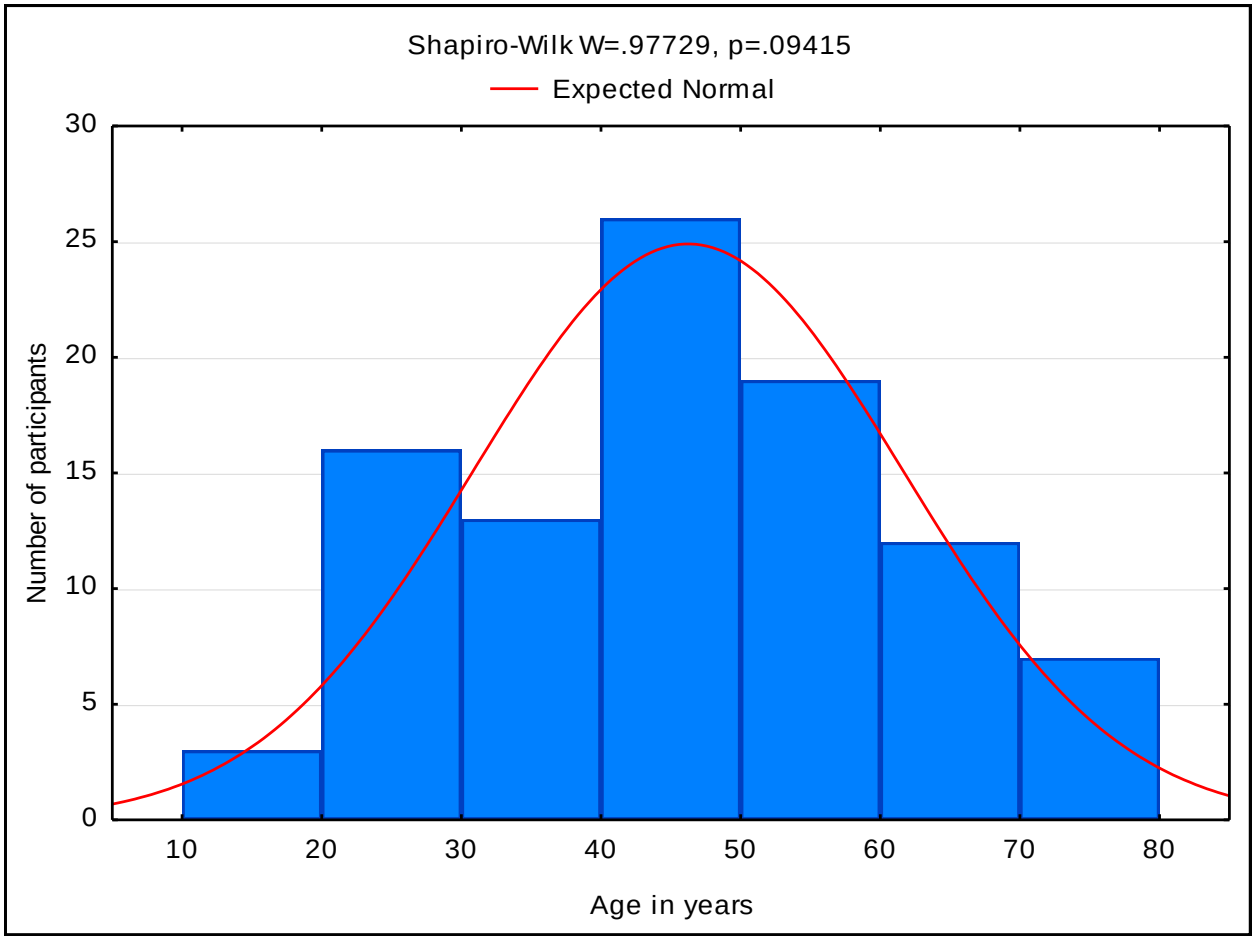
Results relating to the objectives of the study are discussed. The findings are described and analysed using descriptive and inferential statistics and percentages are rounded off to two decimal places.

4.2.1 Demographic data

The study was conducted at CMJAH and CHBAH from October 2011 to December 2013. ETT cuff pressures were measured and recorded at the convenience of the researcher.

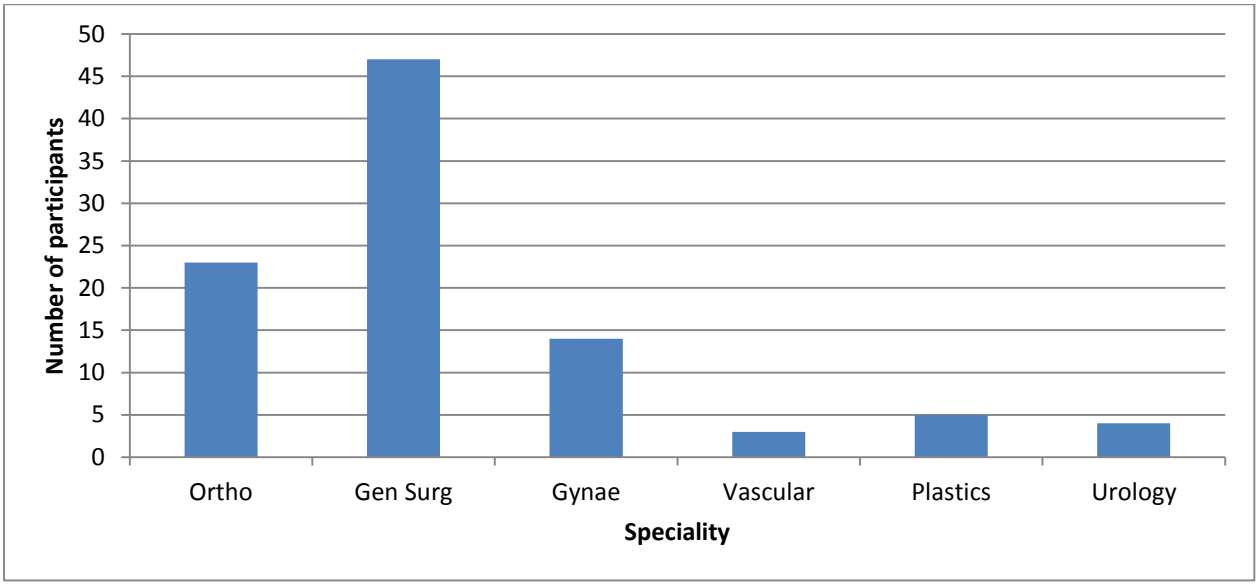
There were 96 ETT cuff pressures measured. Of these 48 (50%) were obtained from CHBAH and 48 (50%) from CMJAH. The patients taking part in this study included 39 males (40.63%) and 57 females (59.36%). The mean age of the patients was 46.25 years (SD 15.38) and is normally distributed as Shapiro-Wilk W = 0.97729 (p = 0.09415) as seen in Figure 4.1.

Figure 4.1 Ages of patients participating in the study



With regards to the different specialties, orthopaedic surgery comprised of 23 (23.96%), general surgery 47 (48.96%), gynaecology 14 (14.58%), vascular surgery 3 (3.13%), plastic surgery 5 (5.21%) and urology 4 (4.17%) patients respectively. These data are presented in Figure 4.2.

Figure 4.2 Number of patients per specialty



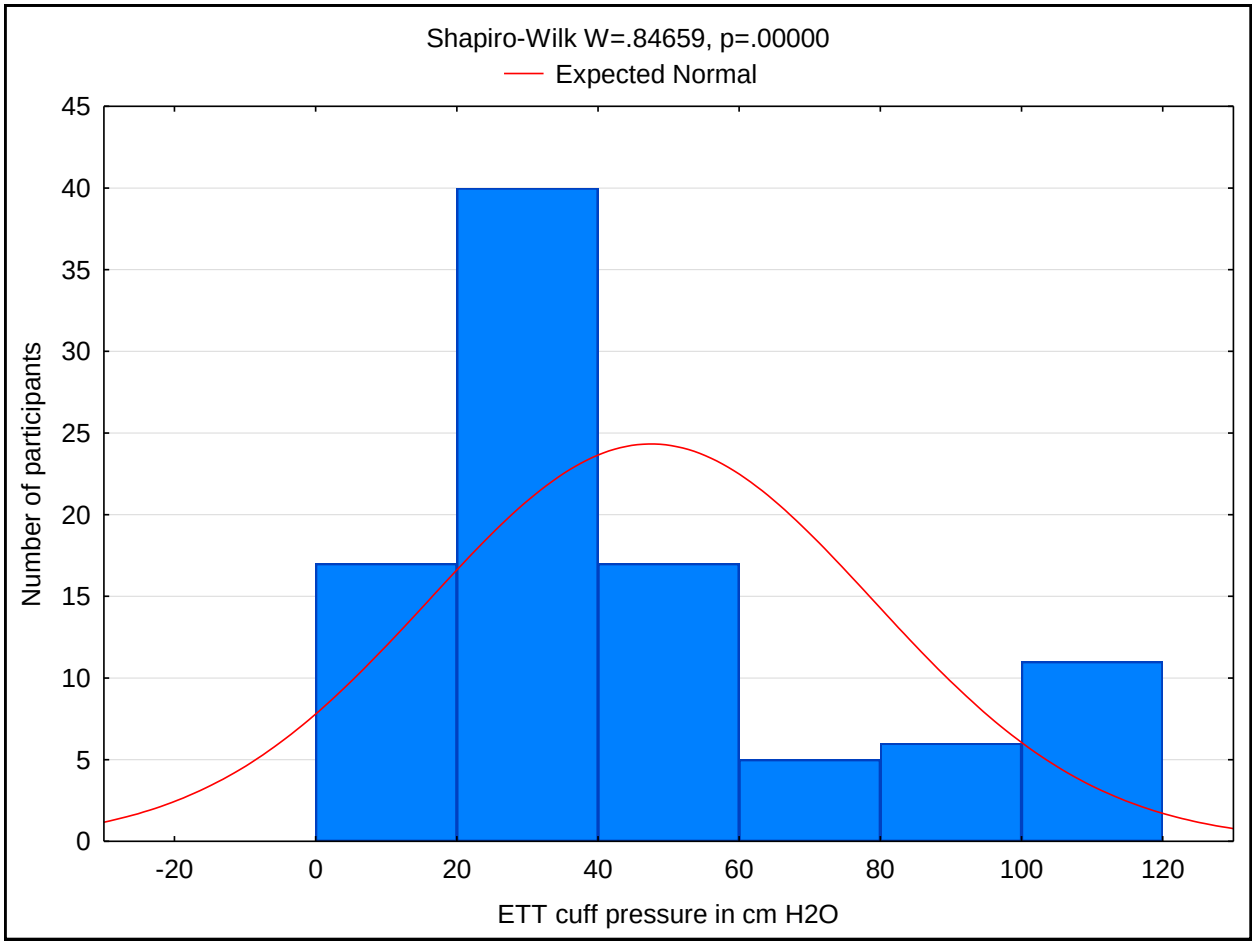
Anaesthetists took part in this study only once in 71 (73.96%) cases and in 25 (26%) cases anaesthetists were included more than once. Of the latter only two anaesthetists participated in this study three times and both the ETT cuff pressures recorded were high (>30cm H_20) on the third occasion.

The mean time from intubation to measurement of the ETT cuff pressure was 64 minutes (range 15 – 300 minutes).

4.2.2 Determination of the ETT cuff pressures of patients receiving general anaesthesia

The mean ETT cuff pressure recorded was 47.5 cm H_20 (range 10 –120 cm H_20). The manometer could only record up to a maximum of 120 cm H_20, therefore pressures higher than that (n=4) were recorded as 120 cm H_20 for statistical analysis. The ETT cuff pressures were found to be high (>30 cm H_20) in 62 (64.58%) patients, with a mean pressure of 61.87 cm H_20 in this group. Only 18 (18.75%) patients had a cuff pressure ranging between 20 - 30 cm H_20, where the mean pressure was 26.89 cm H_20. The remaining 16 patients (16.67%) had ETT cuff pressures lower than 20 cm H_20, with a mean pressure of 15 cm H_20. Figure 4.3 displays the data and it can be seen that it is not normally distributed (Shapiro-Wilk $p < 0.001$). ETT cuff pressures of > 100 cm H_20 were recorded in 12 (12.5%) patients.

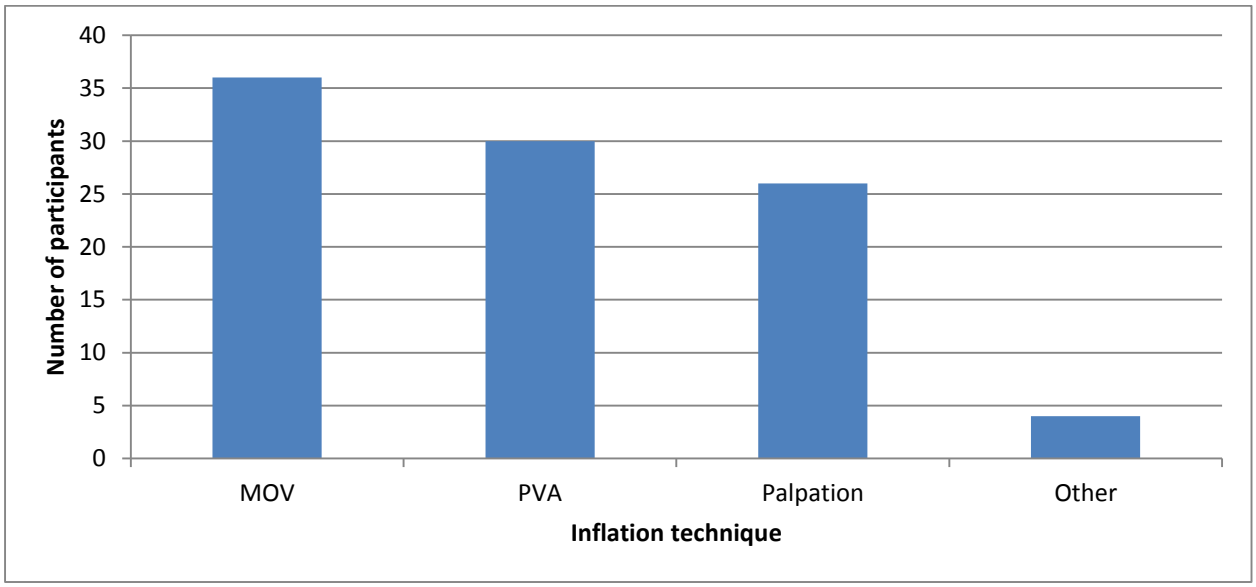
Figure 4.3 Histogram of ETT cuff pressures recorded



4.2.3 Description of the technique used by the anaesthetist to inflate the ETT cuff

MOV was the most frequent technique used by anaesthetists to inflate the ETT cuff and as seen in Figure 4.4 this was used in 36 (37.5%) patients. Using the PVA technique to inflate the cuff was utilised by anaesthetists in 30 patients (31.25%) and palpation of the pilot balloon as an estimate of ETT cuff pressure was used in 26 (27.08%) patients. The remaining techniques used included MLT used in one patient, a manometer used in another and a combination of techniques used in the remaining 2 patients.

Figure 4.4 Number of patients per ETT cuff inflation technique



As seen in Table 4.1 MOV was used in 20 (41.67%) cases at CMJAH and in 16 (33.33%) cases at CHBAH. Palpation of the pilot balloon was the most common technique used in 19 (39.58%) cases at CHBAH, versus 7 (14.58%) cases at CMJAH. The PVA technique was used in 17 (35.42%) and 13 (27.08%) cases at CMJAH and CHBAH respectively. Other techniques were used in 4 (8.33%) cases at CMJAH that included MLT in one case, a manometer in one other and a combination of techniques in the remaining 2 cases.

Table 4.1 Inflation techniques used at each hospital

	MOV	**PVA**	**Palpation**	**Other**	**Total**
CMJAH	20 (41.67%)	17 (35.42%)	7 (14.58%)	4 (8.33%)	48
CHBAH	16 (33.33%)	13 (27.08%)	19 (39.58%)	0	48

4.2.4 Comparison between the measured ETT cuff pressure and the ETT size

A size 7.0 ETT was used in 27 (28.13%) patients, a 7.5 ETT was used in 53 (55.21%) patients, a size 8.0 ETT and 8.5 ETT was used in 15 (15.63%) and 1 (1.04%) patients respectively. For statistical analysis the size 8.0 ETT and 8.5 ETT were grouped together. Table 4.2 shows the different ETT sizes and pressures obtained in each group. Using Fisher's exact test the ETT size compared with the pressures measured proved to be not statistically significant (p=0.364).

Table 4.2 ETT size and ETT pressure groups

	Pressure < 20 cm H_20	**Pressure 20-30 cm H_20**	**Pressure > 30 cm H_20**	**Total**	**P-value**
Size 7.0 ETT	3 (11.11%)	5 (18.52%)	19 (70.37%)	27 (28.13%)	
Size 7.5 ETT	8 (15.09%)	9 (16.98%)	36 (67.92%)	53 (55.21%)	
Size 8.0 & 8.5 ETT	5 (31.25%)	4 (25%)	7 (43.75%)	16 (16.67%)	0.364

4.2.5 Comparison between the measured ETT cuff pressure and the ETT cuff inflation technique

Table 4.3 illustrates the different inflation techniques versus the pressures obtained. Using Fisher's exact test there was no statistically significant difference (P=0.127) between the different inflation techniques and the cuff pressures obtained.

Table 4.3 Inflation technique versus ETT pressure groups

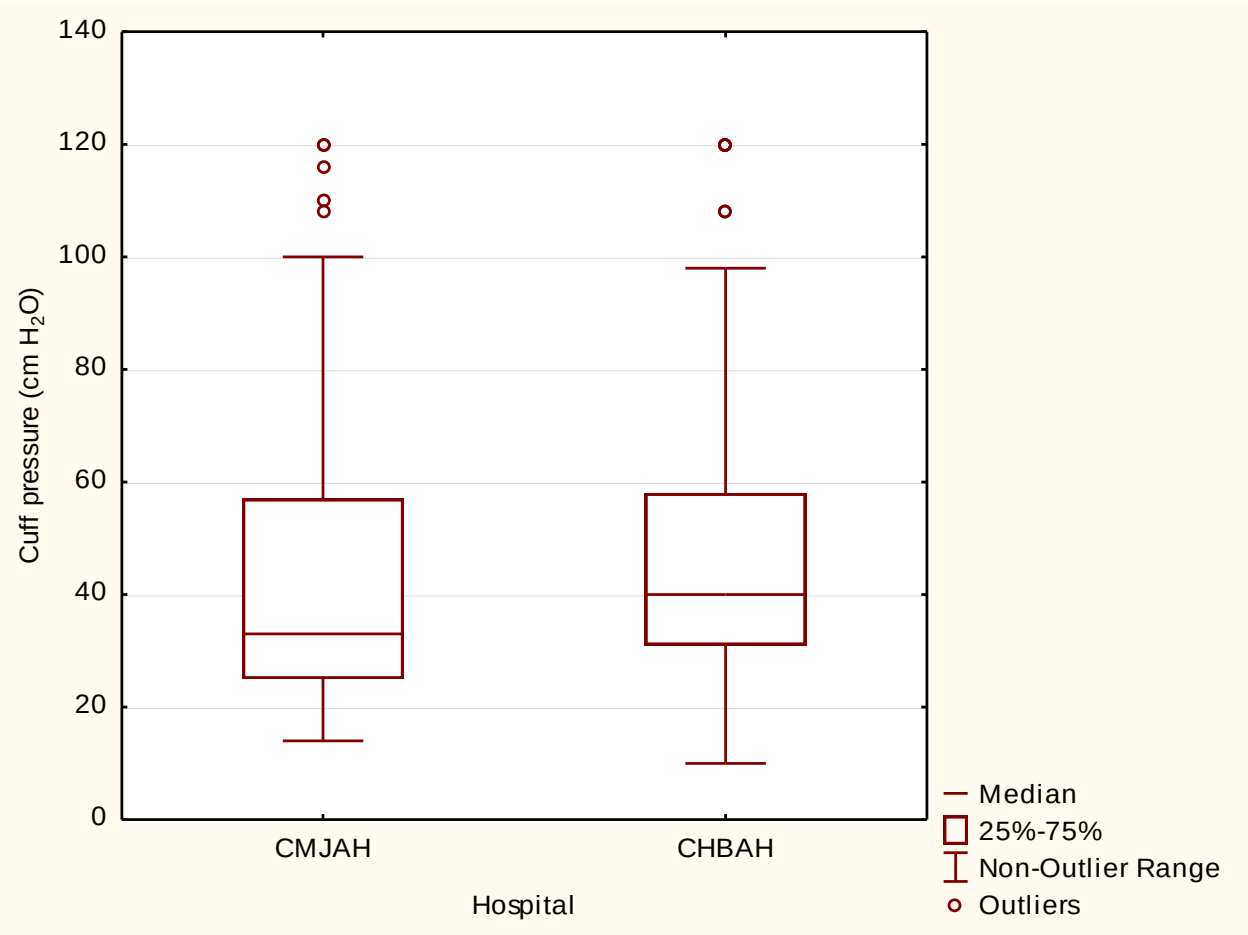
	Pressure < 20 cm H_20	Pressure 20-30 cm H_20	Pressure > 30 cm H_20	Total	P-Value
MOV	10 (27.78%)	8 (22.22%)	18 (50%)	36 (37.5%)	
PVA	4 (13.33%)	5 (16.67%)	21 (70%)	30 (31.25%)	
Palpation	2 (7.69%)	3 (11.54%)	21 (80.77%)	26 (27.08%)	
Other	0	2 (50%)	2 (50%)	4 (4.17%)	0.127

As previously discussed a manometer that is owned by one of the participating anaesthetist, was used to inflate the ETT cuff in one case. The ETT cuff pressure measured by the researcher in this case was 34 cm H_20.

4.2.6 Comparison between the ETT cuff pressures at the two hospitals

Data were collected from two academic hospitals, CMJAH and CHBAH. At CMJAH 54.17% (n=26) of pressures measured were > 30 cm H_20, the mean pressure was 45.38 cm H_20 and the median 33 cm H_20. At CHBAH 75% (n=36) of pressures were > 30 cm H_20, the mean pressure was 49.63 cm H_20 and the median 40 cm H_20. The 25^{th} and 75^{th} percentile pressure was 25.5 and 56.5 cm H_20 at CMJAH compared to 31.5 and 57 cm H_20 at CHBAH. Figure 4.5 illustrates the pressures obtained at each site.

Figure 4.5 Box and Whisper plot of pressures at each hospital



Using the Mann- Whitney-Wilcoxon test comparing the pressures measured at the two hospitals proved to be not statistically significant, p = 0.2480.

A Chi-Square test was used to examine the relationship between the hospitals and three pressure groups, < 20 cm H_20, 20 - 30 cm H_20 and > 30 cm H_20 respectively. Results revealed no statistically significant difference (p = 0.067) as shown in Table 4.4.

Table 4.4 Hospital versus ETT pressure groups

	Pressure < 20 cm H_20	**Pressure 20-30 cm H_20**	**Pressure > 30 cm H_20**	**Total**	**P-value**
CMJAH	9 (18.75%)	13 (27.08%)	26 (54.17%)	48 (50%)	0.067
CHBAH	7 (14.58%)	5 (10.42%)	36 (75%)	48 (50%)	

4.3 Discussion of results

ETTs are used daily by anaesthetists in the operating theatres of CMJAH and CHBAH without any objective means available to measure the ETT cuff pressures. Both international and local research has shown that ETT cuff pressure during anaesthesia commonly exceeds the maximum recommended pressure of 30 cm H_20.

In a study conducted in the United States of America the mean ETT cuff pressure of patients during anaesthesia was 35.3 cm H_20 (2). This is above the recommended range, although lower than the results of our study, where the mean cuff pressure was 47.5 cm H_20. Mean ETT cuff pressures of 27.07 cm H_20 were recorded in a study conducted in a government teaching hospital in India (4). Bernon et al. (5) in 2013, in an academic hospital in Cape Town reported a mean cuff pressure of 25 cm H_20 in anaesthetised patients. A study conducted in Denmark showed a median ETT cuff pressure of 30 (range 8 – 100) cm H_20 compared to the median pressure of 36 (range 10 – 120) cm H_20 recorded in our study (3).

In our study 64.58% of patients had ETT cuff pressures higher than 30 cm H_20, compared to 50% in the American study, 45% of patients in the Danish study, 26.2% in the Indian study and 23% in the Cape Town study. Only 18.75% of patients in our study had an ETT cuff pressure within the normal range whereas in the American study 27% of patients had normal ETT cuff pressures and in the Indian study 59% of ETT cuff pressures were normal. ETT cuff pressures of less than 30 cm H_20 were reported in 77% of patients in the Cape Town study. (2-5)

It is important to note that in our study data was collected at times convenient for the researcher over an extended period of time (October 2011 to December 2013). This may reflect the normal practice of the anaesthetist more accurately than the Denmark and Cape Town studies where mean ETT cuff pressures much lower than ours were reported. The anaesthetists in these two studies were aware that a study was being conducted whereas in our study the researcher arrived at random times on random days at each hospital to record the ETT cuff pressures. (3, 5) Also, a maximum of three ETT cuff pressure measurements from any one anaesthetist was included in our study. None of the discussed studies (2-5) specified the maximum number of ETT cuff pressure measurements recorded by any single anaesthetist that was allowed in the study.

In the Danish study they only used one brand of ETT and in the Cape Town study they used two brands of ETTs (3, 5). In our study it was not documented which brand ETT was used, however, various ETTs from lesser known manufactures are available in our theatres. The quality of some of these ETTs may be questionable as there are currently no minimum standards in South Africa to which medical products have to comply with. Physical characteristics of the ETT cuff including the thickness, compliance and material of the ETT cuff have been shown to affect the ETT cuff pressure (23). Dullenkopf et al. (51) state that ETT cuffs made of ultrathin polyurethane can achieve a seal at pressures as low as 9,5 cm H_20.

The two most common inflation techniques used in our study were MOV (37.5%) and PVA (31.25%). This was followed by the palpation technique in 27.08% and other inflation techniques in 4.17% of cases. No statistically significant difference was found between the inflation technique and the ETT pressures obtained. This had been documented in other studies where the reliability of cuff pressure estimation techniques were deemed to be very low (2, 4, 5, 35).

A manometer owned by the intubating anaesthetist was used in one patient to inflate the ETT cuff in our study. This patient's ETT cuff pressure was found to be 34 cm H_20 and possible reasons could include faulty calibration of the manometer, different compressible volumes of the two manometers or overshoot of the pressure whilst inflating the cuff (11). Another explanation could be that the patients head position was altered after the ETT cuff was inflated and before the researcher recorded the ETT cuff pressure. A previous study has documented increased cuff pressure in the flexed, extended or rotated head position (20).

Previously mentioned studies (2, 5) have compared the ETT size with the ETT cuff pressure and have found that there was no statistically significant difference between the two parameters. This was also evident in our study where there was no statistically significant difference was found between the ETT size and the ETT cuff pressure. In our study the most common ETT size used was a 7.5, compared to a size 8.0 in the study done by Sengupta et al.(2). The study done in Cape Town does not mention the number of patients included in each ETT size group (5).

There was no statistically significant difference between ETT pressures measured at CMJAH and CHBAH. This is in keeping with a study done in two American ICU's where they found no difference in overinflated cuffs between the two hospitals (52). The mean ETT cuff pressure at CMJAH was 45.38 cm H_20 (median 33 cm H_20) and 54.17% of pressures measured were greater than 30 cm H_20. At CHBAH the mean ETT cuff pressure was 49.63 cm H_20 (median 40 cm H_20) and 75% were greater than 30 cm H_20. This discrepancy is an interesting observation particularly when it is taken into consideration that the same registrars rotate through the two hospitals. One possible explanation could be that less experienced medical officers and interns, who do not rotate, inflated the ETT cuffs at CHBAH and attributed to this. Unfortunately the designation and experience of the intubating anaesthetist was not documented to ensure confidentiality. Although it has been shown that the experience of the person inflating the ETT cuff does not influence the pressure obtained (2, 5, 6, 34, 35).

4.4 Conclusion

The results obtained from this study compare unfavourably to other local and international studies and prove that there is room for improvement pertaining to ETT cuff pressure management during anaesthesia. Only 18.75% (n=18) of ETT cuff pressures were within the recommended range (20 – 30 cm H_20) and it was discouraging to document four cases where ETT cuff pressures were higher than 120 cm H_20. It is therefore prudent that manometers become available in the operating theatres of these hospitals.

4.5 Summary

In this chapter the results of the study were presented and discussed according to the objectives of the study. The data included demographics of the study population and the ETT cuff pressures measured in theatre at each hospital together with the cuff inflation technique employed by the anaesthetist. The findings were analysed and described using descriptive and inferential statistics.

In the next chapter a final summary, recommendations, limitations, and conclusion of this study will be presented.

CHAPTER FIVE: SUMMARY, LIMITATIONS, RECOMMENDATIONS AND CONCLUSION

5.1 Introduction

In this chapter the aim, objectives, study design and the study results will be reviewed. Limitations, recommendations for clinical practice, research and a conclusion to the study are presented.

5.2 Summary of the study

5.2.1 Aim of the study

The aim of this study was to determine what the actual ETT cuff pressures were of patients receiving general anaesthesia at CMJAH and CHBAH and to document the cuff inflation techniques that were used to achieve these pressures.

5.2.2 Objectives of the study

The primary objectives of this study were to:

- determine the ETT cuff pressures of patients receiving general anaesthesia
- describe the technique used by the anaesthetist to inflate the ETT cuff
- compare the measured ETT cuff pressure with the ETT size
- compare the measured ETT cuff pressure with the ETT cuff inflation technique
- compare the ETT cuff pressures between the two hospitals.

5.2.3 Summary of the methodology

A prospective, contextual, descriptive research design was used. The population group studied were adult patients that presented to the operating theatres of CMJAH and CHBAH for surgery under general anaesthesia administered with a cuffed ETT. A convenience sampling method was used. In consultation with a biostatistician a sample size of 96 was calculated.

Data was collected in the operating theatres of CHBAH and CMJAH on weekdays during normal working hours. Adult patients undergoing general anaesthesia were screened for enrolment in the study. Written informed consent from the anaesthetist in charge of the patient was obtained before ETT cuff pressure measurement took place (Appendix 3). The time from intubation to ETT cuff pressure measurement was documented (in minutes) along with the age of the patient (in years), the sex of the patient and the surgical specialty (Appendix 4). The anaesthetist responsible for inflating the ETT cuff was asked what technique was used for ETT cuff inflation and this was documented together with the ETT cuff pressure obtained (in cm H_20). Informed written consent was obtained from the study participants in a deferred manner (Appendix 2). Data collection took place until sample realisation.

5.2.4 Results

ETT cuff pressures were measured in 96 patients, 48 from each hospital. This included 39 males (40.63%) and 57 females (59.36%). The mean age of the patients was 46.25 years. Orthopaedic surgery comprised of 23 (23.96%), general surgery 47 (48.96%), gynaecology 14 (14.58%), vascular surgery 3 (3.13%), plastic surgery 5 (5.21%) and urology 4 (4.17%) patients respectively. Anaesthetists took part in this study only once in 71 (73.96%) cases and in 25 (26%) cases anaesthetists were included more than once, with only two anaesthetists taking part three times. The mean time from intubation to measurement of the ETT cuff pressure was 64 minutes.

The mean ETT cuff pressure recorded was 47.5 cm H_20 (range 10 –120 cm H_20). The ETT cuff pressures exceeded 30 cm H_20 in 62 (64.58%) patients, with a mean cuff pressure of 61.87 cm H_20 in this group. Only 18 (18.75%) patients had ETT cuff pressures in the recommended range (20 – 30 cm H_20), where the mean cuff pressure was 26.89 cm H_20. The remaining 16 patients (16.67%) ETT cuff pressures were below 20 cm H_20, with a mean cuff pressure of 15 cm H_20.

MOV was the most frequent technique used by anaesthetists to inflate the ETT cuff and was utilised in 36 (37.5%) patients. This was followed by the PVA technique that was used in 30 patients (31.25%) and palpation of the pilot balloon as an estimate of ETT cuff pressure was

used in 26 (27.08%) patients. The remaining techniques utilised included MLT used in one patient, a manometer used in another and a combination of techniques used in the other two patients. There was no statistically significant difference between the inflation technique and ETT cuff pressure measured.

A size 7.0 ETT was used in 27 (28.13%) patients, a 7.5 ETT was used in 53 (55.21%) patients, a size 8.0 and 8.5 was used in 15 (15.63%) and 1 (1.04%) patients respectively. The tube size compared to the ETT cuff pressure measured was not statistically significant. At CMJAH the mean cuff pressure was 45.38 cm H_20 and this was not statistically significant when compared to CHBAH where it was 49.63 cm H_20.

5.3 Limitations of the study

This study design was contextual and conducted at two hospitals in Johannesburg, therefore the results may not be generalizable to other academic hospitals in South Africa. However, this study provides insight into the ETT cuff pressures of patients receiving general anaesthesia at CMJAH and CHBAH.

The designation and experience of the intubating anaesthetist was not documented to ensure confidentiality. This is a limitation of this study as interns and medical officers work at both hospitals and only rotate through the department of anaesthesia for a set period of time. They are usually responsible for intubation and inflation of the ETT cuffs, as they need to obtain experience in a limited period of time. The results, therefore may not accurately reflect the ETT cuff management practice of the entire anaesthetic staff affiliated to these two hospitals.

The ETT brand was not documented when the ETT cuff pressure was measured. This limits the interpretation of results, as lesser known manufactures of ETTs are used in the theatres of the two hospitals. This may have resulted in higher ETT cuff pressures as the researcher could not find guidelines on the standards that South African ETTs must conform to.

5.4 Recommendations from the study

5.4.1 Recommendations for clinical practice

This study demonstrates unfavourable results pertaining to ETT cuff pressures during general anaesthesia at CMJAH and CHBAH. It is therefore recommended that ETT cuff pressures be measured with a manometer in the operating theatres of these hospitals. No manometers are currently available in the operating theatres and it would be advisable that they be made available.

The results of this study will be communicated to the anaesthetic departments of both hospitals and it is recommended that an educational program regarding ETT cuff pressure management be implemented especially for all the staff that rotate through the department.

5.4.2 Recommendations for further research

- Research on the standards and quality of the different brands of ETTs available in the operating theatres of CMJAH and CHBAH should be undertaken.
- Regular clinical audits on ETT cuff pressures at the two hospitals should be conducted.
- Post-operative complications arising from the ETT cuff pressures should be followed up.
- Supraglottic airway devices are commonly used in the operating theatres of the two hospitals and research on the cuff pressures of these devices should be undertaken.

5.5 Conclusion

The results pertaining to this study indicates that ETT cuff pressures of patients undergoing general anaesthesia at CMJAH and CHBAH are discouraging. At both hospitals it was found that ETT cuff pressure is higher than the recommended norm of 20 – 30 cm H_20. Since these are two academic hospitals a clear need exists for an objective means of measuring ETT cuff pressure.

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Appendix 1.1: Approval from the Post Graduate Committee

Faculty of Health Sciences
Medical School, 7 York Road, Parktown, 2193
Fax: (011) 717-2119
Tel: (011) 717-2076

Reference: Ms Salamina Segole
E-mail: salamina.segole@wits.ac.za
19 July 2011
Person No: 463156
PAG

Dr L Gilliland
P O Box 62
Carlswald
Midrand
1684
South Africa

Dear Dr Gilliland

Master of Medicine (in the specialty Anaesthesia): Approval of Title

We have pleasure in advising that your proposal entitled "*Endotracheal tube cuff pressures in adult patient undergoing general anaesthesia in three Johannesburg academic hospitals*" has been approved. Pleas note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee an formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 1.2: Approval from the Post Graduate Committee

Faculty of Health Sciences
Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172040

Reference: Ms Thokozile Nhlapo
E-mail: thokozile.nhlapo@wits.ac.za

07 January 2014
Person No: 463156
TAA

Dr L Gilliland
P O Box 171
Private Bag X2
Northriding
2162
South Africa

Dear Dr Gilliland

Master of Medicine: Change of title of research

I am pleased to inform you that the following change in the title of your Research Report for the degree of **Master of Medicine** has been approved:

From:

To: **Endotracheal tube cuff pressures in adult patients undergoing general anaesthesia in two Johannesburg Academic Hospitals**

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

Appendix 1.3: Approval from Human Research Ethics Committee

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Dr Lizil Gilliland

CLEARANCE CERTIFICATE	**M110702**
PROJECT	Endotracheal Tube Cuff Pressures in Adult Patients Undergoing General Anaesthesia in Three
Johannesburg	Academic Hospitals
INVESTIGATORS	Dr Lizil Gilliland.
DEPARTMENT	Department of Anaesthesiology
DATE CONSIDERED	29/07/2011
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 29/07/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Ms Juan Scribante

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...

Appendix 1.4: Approval from the CEO of CMJAH

health and social development
Department: Health and Social Development
GAUTENG PROVINCE

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Office of the CEO
Enquiries: L. Mngomezulu
Tell: (011): 488-3792
Fax: (011) 488-3753
Date: 20th September 2011

Dr. Lizil Gilliland
Registrar
Department of Aneasthesiology

Dear Dr. Gilliland

RE: "Endotrachael tube cuff pressures in adult patients undergoing general anaesthesia in three Johannesburg Academic Hospitals"

Permission is granted for you to conduct the above research as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Yours sincerely

Dr. Barney Selebano
Chief Executive Officer

Appendix 1.5: Approval from the CEO of CHBAH

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 22 August 2011

TITLE OF PROJECT: Endotracheal tube cuff pressures in adult patients undergoing general anaesthesia in three Johannesburg academic hospitals

UNIVERSITY: Witwatersrand

Principal Investigator: Dr Lizil Gilliland

Department: Anaesthesiology

Supervisor (If relevant):. Juan Scribante and Helen Perrie

Permission Head Department (where research conducted) Yes

Date of start of proposed study: September 2011

Date of completion of data collection October 2011

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....

Recommended

(On behalf of the MAC)

Date: 22 August 2011

.....

Approved/Not Approved

Hospital Management

Date: 24/08/2011

Appendix 2: Patient Information Letter and Consent Form

Endotracheal tube cuff pressures during anaesthesia in two academic hospitals in Johannesburg.

Hello,

My name is Lizil and I am a doctor in anaesthesia at the University of the Witwatersrand. I am busy with my Master's degree in Medicine and I am doing a study on tubes put in patients' throats when they come to theatre for operations. I would like to invite you to take part in the study.

A tube was put in your throat to help you breathe while you were sleeping during the operation. This tube has a small balloon on the end that is blown up with air, so that the oxygen and gas making you sleep cannot escape. The balloon at the end of this tube also protects your lungs from the fluid in your mouth and stomach while you are asleep for your operation.

I measured the pressure in this balloon and if there was too much or too little air I adjusted it. I would like to use this measurement in my study so that we can learn from it. Other patients in the future can benefit from the results of this study.

You do not need to take part in this study but taking part will assist me with my studies. The information that I got from you will be kept confidential and I will not mention your name or any other personal details in my report.

If you have any questions you can phone me on (011) 933-9334.

The Research Ethics Committee chairperson can be contacted on 011 717 2301.

Thank you for taking part in this study.

Dr L. Gilliland

Consent Form - Patient

I, ……
(name) understand the content of the information letter and I had the opportunity to ask questions and these have been answered to my satisfaction. It was explained to me that I am taking part voluntarily.

I hereby give consent to take part in this study.

……

(Participant)

……..

(Date)

Appendix 3: Anaesthetist Information Letter and Consent Form

Endotracheal tube cuff pressures in adult patients undergoing general anaesthesia in two academic hospitals in Johannesburg.

Dear Colleague

I am conducting a research project for my MMed on endotracheal tube (ETT) cuff pressures in adult patients undergoing general anaesthesia. I would like to invite you to take part in my study.

This is a descriptive, prospective study where I will be measuring ETT cuff pressures in patients undergoing general anaesthesia without the use of nitrous oxide. Measurements will be done at end-expiration using a calibrated manometer from Teleflex Medical®. If the ETT cuff pressure is found to be above the recommended limit it will be adjusted to fall within these limits. Cuff pressures found below the recommended limit will be communicated to you.

I would like to determine the ETT cuff inflation technique used to obtain the pressure that was measured. You will be asked what technique was used to inflate the cuff and this will be documented along with the cuff pressure measured. You may be included in this study up to a maximum of three times. You will not be included consecutively or more than once a day.

Participation is voluntary and anonymous. You may discontinue participation at any time without penalty. No personal information will be required from you in order to take part. The result of this study will be available after completion.

If you have any questions you can contact me on 0722593971, alternatively the Research Ethics Committee chairperson, Professor Cleaton-Jones can be contacted on 011 717 2301.

Thank you for taking part in this research study.

Regards

Lizil Gilliland

Consent Form - Anaesthetist

I, Dr…… (name) understand the content of the information letter and I had the opportunity to ask questions and these have been answered to my satisfaction. It was explained to me that I am taking part voluntarily.

I hereby give consent to take part in this study.

……

(Participant)

……..

(Date)

Appendix 4: Data Sheet used in theatre to obtain demographics

Participant Nr: ……..

Sex: M / F

Age (years): ……

Specialty: ……

ETT size: ……..

Time from induction to ETT cuff pressure measurement (minutes): ……

ETT cuff pressure (cm H_20): ……

Adjusted: Yes / No

Technique used by anaesthetist to inflate cuff: MOV

MLT

Predetermined volume of air

Palpation of pilot balloon

Other:

……

……

……

……

Anaesthetist participated before: Yes / No

If yes how many times: 1 / 2