

**AN OBSERVATIONAL STUDY ON THE INCIDENCE OF POSTOPERATIVE  
SORE THROAT IN RELATION TO ENDOTRACHEAL TUBE CUFF PRESSURES  
IN KENYATTA NATIONAL HOSPITAL MAIN THEATRE**

**BY**

**KARIUKI KILLIAN WANYORO**

**H58/74585/2014**

**A RESEARCH SUBMITTED IN PARTIAL FULFILLMENT OF THE  
REQUIREMENTS FOR THE AWARD OF MASTER'S DEGREE OF MEDICINE IN  
ANAESTHESIA AT THE UNIVERSITY OF NAIROBI**

**SEPTEMBER 2018**

## STUDENT'S DECLARATION

This research is my original work and has not been presented for a degree at any other university

**Dr. Killian Kariuki Wanyoro, MBChB**

**Post Graduate Student in Anaesthesiology & Critical Care Medicine,**

**University of Nairobi**

Signature .....

Date .....

### **Principal investigator**

Dr. Killian Kariuki Wanyoro

P.O. BOX 413-00618

Telephone: 0722770104

Email: [kariukikillian@gmail.com](mailto:kariukikillian@gmail.com)

### **Supervisors**

Dr. Wangaka Stephen

Consultant Anesthesiologist,

Telephone 0722745791

Email: [wangakaws@gmail.com](mailto:wangakaws@gmail.com)

Dr. Thomas Chokwe

Lecturer and Consultant Anesthesiologist,

College of health sciences, University of Nairobi

Telephone 0722528537

Email: [tchokwe@yahoo.com](mailto:tchokwe@yahoo.com)

Dr. Caroline Mwangi

Lecturer and Consultant Anesthesiologist,

College of health sciences, University of Nairobi

P.O. BOX 19676-00202

Telephone: 0721546600

Email: [carlomwa@yahoo.com](mailto:carlomwa@yahoo.com)

## SUPEVISORS' APPROVAL

This Research has been submitted for Examination with our Approval as University Supervisors.

**Dr. Stephen Wangaka MBChB, MMed, Cert (Crit Care)**

Consultant Anesthesiologist, The Nairobi Hospital

Signature ..... Date.....

**Dr. Thomas Chokwe, BSc, MBChB, MMed (Anaesth)**

Lecturer and Consultant Anesthesiologist

Department of Anaesthesia, University of Nairobi

Signature ..... Date.....

**Dr. Caroline Mwangi MBChB, MMed (Anaesth), Cert (Card)**

Lecturer and Consultant Anesthesiologist

Department of Anaesthesia, University of Nairobi

Signature ..... Date.....

## **DEDICATION**

I dedicate this thesis to my family for their support and input through the whole process.

## **ACKNOWLEDGEMENT**

I acknowledge the guidance, patience and input from my supervisors, Dr Caroline Mwangi, Dr. Thomas Chokwe and Dr. Stephen Wakaba.

Martin Njenga for your time and dedication during data collection

Kenneth Mutai for your statistical input during data analysis

## TABLE OF CONTENTS

STUDENT'S DECLARATION .....	ii
SUPEVISORS' APPROVAL .....	iii
TABLE OF CONTENTS .....	vi
LIST OF TABLES AND FIGURES.....	viii
ABBREVIATIONS .....	ix
DEFINITION OF TERMS.....	x
ABSTRACT .....	xi
<b>CHAPTER ONE .....</b>	<b>1</b>
1.0 INTRODUCTION .....	1
1.1 Research Question.....	2
1.2 Hypothesis.....	2
1.3 Broad Objective.....	2
1.4 Specific objectives.....	2
1.5 Study Justification .....	2
<b>CHAPTER TWO .....</b>	<b>4</b>
2.0 LITERATURE REVIEW .....	4
2.1 Effect of cuff pressure on the tracheal mucosa .....	5
2.2 Endotracheal tube cuff pressure measurement.....	6
2.3 Endotracheal tube cuff pressure changes during general anaesthesia.....	7
2.4 Risk factors that may contribute to post-operative sore throat.....	9
2.5 Effect of pharmacologic agents on post-operative sore throat.....	11
<b>CHAPTER THREE .....</b>	<b>13</b>
3.0 RESEARCH METHODOLOGY.....	13
3.1 Study population .....	13
3.2 Study site .....	13
3.3 Sampling.....	13
3.3.1 Sample size .....	13
3.4 Eligibility.....	14
3.4.1 Inclusion criteria .....	14
3.4.2 Exclusion criteria .....	14
3.5 Recruitment and Study procedure .....	14

3.6	Measurement tool.....	15
3.7	Outcome .....	15
3.8	Data management and analysis .....	16
3.9	Ethical considerations .....	16
	<b>CHAPTER FOUR.....</b>	<b>17</b>
4.0	RESULTS .....	17
	<b>CHAPTER FIVE .....</b>	<b>30</b>
5.0	Discussion .....	30
5.1	Conclusions .....	31
5.2	Recommendations .....	31
5.3	Limitations .....	32
	<b>REFERENCES.....</b>	<b>33</b>
	<b>APPENDICES .....</b>	<b>38</b>
	Appendix I: Budget.....	38
	Appendix II: Data Collection Tool .....	39
	Appendix III: Explanation and Consent for the Patient/Next of Kin.....	41
	Appendix IV: Assent Form.....	45
	Appendix V: Ramsay Sedation Scale .....	47
	Appendix VI: Approval Letter.....	48
	Appendix VII: Antiplagiarism certificate .....	49

## LIST OF TABLES AND FIGURES

### **Tables**

Table 1: Association of cuff pressures and various factors .....	29
Table 2: Cuff pressure association with POST .....	29

### **Figures**

Figure 1: Age distribution.....	17
Figure 2: Gender Distribution.....	17
Figure 3: Distribution of Procedures.....	18
Figure 4: Mallampati.....	19
Figure 5: ETT size used .....	19
Figure 6: Syringe used for ETT cuff inflation .....	20
Figure 7: Intubation Characteristics.....	21
Figure 8: Maintenance Characteristics.....	22
Figure 9: Positioning.....	22
Figure 10: Emergence and extubation characteristics .....	23
Figure 11: patients with cuff pressures above 30 cmH2O.....	24
Figure 12: Box Plot of cuff pressures from minute zero to 180 .....	25
Figure 13: Mean cuff pressures (cmH20) at time intervals .....	26
Figure 14: Number of patients reporting sorethroat at time intervals.....	27

## ABBREVIATIONS

<b>ERC</b>	:	Ethics and Research Committee
<b>ETT</b>	:	Endotracheal tube
<b>GA</b>	:	General Anaesthesia
<b>HVLP</b>	:	High volume low pressure
<b>HPLV</b>	:	High pressure low volume
<b>KNH</b>	:	Kenyatta National Hospital
<b>PACU</b>	:	Post anaesthesia care unit
<b>POST</b>	:	Post-Operative Sore Throat
<b>UON</b>	:	University of Nairobi
<b>VS</b>	:	Versus

## DEFINITION OF TERMS

- Normal ETT cuff pressure** : Cuff pressure less than 30cmH<sub>2</sub>O
- High ETT cuff pressure** : Cuff pressure greater than 30cm H<sub>2</sub>O
- The throat** : The cavity from the arch of the palate to the glottis and superior opening of the esophagus
- Sore throat** : Scratchy throat, dryness of the throat, continuous throat pain, throat pain while talking or with swallowing.

# ABSTRACT

## **Introduction**

The endotracheal tube cuff prevents aspiration and air leak during positive pressure ventilation. The recommended cuff pressures lie between 20 -30 cmH<sub>2</sub>O. Cuff pressures above the recommended range can result in complications ranging from postoperative sore throat to tracheal rupture.

## **Objective**

To determine the incidence of postoperative sore throat in relation to endotracheal tube cuff pressures in patients undergoing surgery at the Kenyatta National Hospital.

## **Methods**

Patients were recruited at the Kenyatta National Hospital theatre complex. Suitability for inclusion was assessed. Once anaesthetized, cuff pressures were assessed immediately after inflation. Subsequent measurements were done at intervals until the completion of the procedure. Assessment of POST began in PACU when the patient achieved a Ramsay sedation score of 2. Assessment of POST continued in the ward at 6, 12 and 24 hours

## **Results**

120 patients were recruited. Endotracheal tube cuff pressures were found to be elevated in 94.2% of patients. The mean cuff pressure was 59.1 cmH<sub>2</sub>O. The incidence of sore throat was 61.9 %. There were greater odds of developing sore throat with higher endotracheal tube cuff pressures (odds ratio 3.78). Nitrous oxide was found to be significantly associated with sore throat (p=0.038).

## **Conclusion**

Endotracheal tube cuffs were inflated to pressures above the normal limit in 94.2% of patients. 61.9% of patients developed postoperative sore throat.

# CHAPTER ONE

## 1.0 INTRODUCTION

The endotracheal tube cuff prevents aspiration and air leak during positive pressure ventilation.<sup>(1,2)</sup> High volume low pressure (HVLP) cuffs are the most commonly used.<sup>(3)</sup> The HVLP cuff offers some advantages over the High pressure low volume cuff (HPLV). The HVLP cuff attains a seal at a lower maximum pressure than the HPLV cuff.<sup>(3)</sup> This results in shallower mucosal erosions. For long term intubation the HVLP should result in fewer complications. Endo tracheal Intubation less than 6 hours has resulted in a greater incidence of POST with the use of a HVLP cuff as opposed to a HPLV cuff.<sup>(4)</sup> This is despite the HPLV cuff having deeper mucosal erosions due to greater cuff pressures.<sup>(4)</sup> The length of the cuff trachea contact area is thought to be contributory to sore throat.<sup>(4)</sup> The contact area is greater with a HVLP than a HPLV cuff.

High cuff pressures result in complications such as tracheal rupture, tracheal stenosis, trachea-esophageal fistula and post extubation pain. Monitoring of endotracheal tube cuff pressures is recommended to avoid complications.<sup>(5)</sup> Various modes of cuff pressure estimation are used. Palpation is commonly used despite being inaccurate.<sup>(3)</sup> Minimal occlusive and minimal leak technique offer a greater level of accuracy.<sup>(5)</sup> The gold standard is use of a manometer to measure the cuff pressure directly. An ideal cuff pressure has not been firmly established. Recommendations are between 20- 30 cmH<sub>2</sub>O.<sup>(5-7)</sup> During anaesthesia cuff pressures may vary.<sup>(8-10)</sup> Nitrous oxide anaesthesia leads to a progressive increase in cuff pressure due to diffusion of nitrous oxide from blood into the cuff. High airway pressures, insufflation during laparoscopy, patient position and altitude also affect cuff pressures.<sup>(8-11)</sup>

Factors other than cuff pressures associated with POST include: duration of anaesthesia, smoking history, number of intubation attempts, un-cuffed endotracheal tubes, endotracheal tube size, nasogastric tubes, laryngoscope type, suctioning, thyroid surgery, and pharyngeal packs.<sup>(12-17)</sup>

## **1.1 Research Question**

What is the incidence of postoperative sore throat in relation to endotracheal tube cuff pressures?

## **1.2 Hypothesis**

Endotracheal tube cuff pressure does not have an effect on the incidence of postoperative sore throat.

## **1.3 Broad Objective**

To assess the incidence of sore throat in relation to intra-operative endotracheal tube cuff pressures

## **1.4 Specific objectives**

- To determine the incidence of postoperative sore throat.
- To determine the endotracheal tube cuff pressures during general anaesthesia.
- To assess risk factors that may contribute to postoperative sore throat.

## **1.5 Study Justification**

Endotracheal intubation with cuff inflation is common practice during general anaesthesia. High cuff pressures may result in tracheal morbidity. The risks associated with high cuff pressures include tracheal rupture, tracheal stenosis, tracheo-esophageal fistula, bleeding, post-intubation pain, postoperative sore throat and postoperative hoarseness. In our local setup palpation is widely used in the estimation of cuff pressures. This is despite a local study showing that 94.7% of participants inflated the cuff to high pressures with the palpation technique. The average pressure was reported at 91cmH<sub>2</sub>O. Palpation method results in high cuff pressures even in experienced hands.

Nitrous oxide is widely used in general anaesthesia in our local setup. The use of nitrous oxide causes a progressive increase in cuff pressures when cuffs are inflated with air. This is due to diffusion of nitrous oxide from blood into the cuff. This may result in an increase in cuff volume hence pressure. This may be averted by the use of saline or lidocaine to inflate cuffs. The use of 40% nitrous oxide to inflate the cuffs has also been recommended but is not

practiced locally. Local practice is inflation of the cuff with air with use of nitrous oxide anaesthesia. This may result in high cuff pressures.

Postoperative sore throat and post extubation pain are not routinely assessed for in our local set up. The incidence of post-operative sore throat has been shown to be as high as 92% in local studies. The ASA closed claims database reported 6% of claims related to airway injury. Postoperative sore throat may be an early symptom in pharyngeoesophageal perforation and arytenoid subluxation. These complications result in increased morbidity to the patient. Intra-operative measures to decrease incidence of this symptom with postoperative monitoring is prudent.

POST is an unpleasant experience to the patient. In the assessment of post-operative surgery preferences, POST was one of the symptoms patients stated they would like to avoid. Jenkins et al recommended taking into consideration patients preferences when planning anaesthesia care. The use of pharmacological agents to decrease the incidence of POST has been studied. The use of these agents is at an added cost to the patient. This may not be feasible in a limited resource set up.

## CHAPTER TWO

### 2.0 LITERATURE REVIEW

Magill developed the soft rubber tube which he used for nasal and tracheal intubation.<sup>(1,2,18)</sup> Guedel and Waters developed the endotracheal tube cuff. This excluded blood and debris from the trachea and enabled carbon dioxide absorption from Waters device.<sup>(1,2,18)</sup>

The High Volume Low Pressure (HVLP) cuff is commonly used.<sup>(3)</sup> High Pressure Low Volume (HPLV) cuffs though still available are not in widespread use.<sup>(2,3)</sup> HPLV cuffs resulted in tracheal damage especially in prolonged intubations. Cases of tracheal rupture, tracheal stenosis, tracheo-esophageal fistula and tracheal dilatation were reported.<sup>(19-21)</sup> The pressure developed within the HPLV cuff was the cause of the complications.<sup>(2)</sup> The HPLV is less compliant hence deforms the trachea.<sup>(2)</sup> The pressure within this type of cuff does not correlate with the lateral wall pressure.<sup>(2)</sup> This is because of the initial pressure required to expand the less compliant cuff material.<sup>(2)</sup> The development of the HVLP cuff resulted in a more compliant cuff which achieves a seal at lower pressures. The cuff pressure also accurately reflects the lateral wall pressure in the HVLP cuff. Complications are still reported with the HVLP cuff.<sup>(19,22)</sup> There is an increased incidence of postoperative sore throat with the HVLP cuff compared to the HPLV cuff, but the tracheal seal at lower pressures prevents further complications due to tracheal injury.<sup>(18,19,22)</sup> The increased incidence of postoperative sore throat is thought to be due to a larger area of cuff trachea contact.

Other modifications to reduce cuff related tracheal injury include the Lanz valve which maintains cuff pressures within a safe range by auto regulation. The pilot balloon in this cuff is replaced with a larger balloon with an inner pressure regulating valve. This type of cuff is not routinely used and its application is limited to adults as pediatric patients require lower sealing pressures.<sup>(2,18)</sup> The self-inflating foam cuff exerts low tracheal wall pressures; it requires an adapter to allow pressurization during positive pressure ventilation.<sup>(2,18)</sup> An endotracheal tube with 12-20 doughnut shaped thin layers prevents fluid leakage with no histological changes in the trachea. It also results in less reduction in tracheal mucus flow than the standard cuffed tube. Endotracheal tube cuffs made with polyurethane may provide an adequate seal to prevent air leakage at lower cuff pressures than polyvinyl chloride cuffs. Cylindrical HVLP cuffs form folds that may result in micro- aspiration. A tapered cuff shape

may reduce leakage in polyvinylchloride cuffs but not in polyurethane cuffs.<sup>(2,18)</sup> Silver coated cuffs were designed to reduce bacterial colonization in endotracheal tubes. This is mainly applied in prolonged intubations. It delays the delays bio-film formation and lung colonization.<sup>(18)</sup>

## **2.1 Effect of cuff pressure on the tracheal mucosa**

Using a fiber optic bronchoscope, Seegobin et al was able to demonstrate the effect of lateral wall pressure on mucosal blood flow in the human trachea. (6)Lateral wall pressure is the most important factor leading to the morbidity of intubation. The study revealed that at 25cmH<sub>2</sub>O the mucosa was well perfused, at 30 cmH<sub>2</sub>O the anterior mucosa over the tracheal rings was less pink than the mucosa in the inter-cartilaginous areas. At 40cmH<sub>2</sub>O the mucosa over the inter-cartilaginous areas was very pale. At 50cmH<sub>2</sub>O the mucosa overlying the tracheal rings was blanched and no blood flow could be seen in the sub mucosa. Micro aspiration occurred even at cuff pressures at 100cmH<sub>2</sub>O. The capillary perfusion pressure in man has been recorded as ranging from between 22-32 mmHg. The HVLP cuffs can easily be overinflated and use of a manometer was recommended in this study. (6) A lateral wall pressure of 27cmH<sub>2</sub>O resulted in superficial damage at 15 minutes; the damage did not progress with time. At a lateral wall pressure of 100mmHg the damage extended to the basement membrane and mucosal stroma and was progressive with time.<sup>(6)</sup>

Nordin et al, in a study of blood flow in the rabbit tracheal mucosa was able to establish that a decrease in mucosal blood flow occurs with increasing cuff pressures. The blood flow decreased to zero in the 120- 130mmHg range. In this study there was no correlation between tracheal blood flow and cardiac output. (7)

Hoffman et al demonstrated that high cuff volumes resulted in exponential increases in cuff pressure. The study was performed on mechanically ventilated canines. The volumes of air injected varied from 0.5ml to 9.0ml and the pressures ranged from 2cmH<sub>2</sub>0 to 120cmH<sub>2</sub>0. There was a 97% correlation between volume and pressure. They noted the margin for error in inflation is not large. Cuff over inflation can result in complications. These complications vary from membranous tracheal rupture, trachea esophageal fistula, laryngeal nerve palsy and POST.<sup>(23)</sup>

## 2.2 Endotracheal tube cuff pressure measurement

Endotracheal tube cuff pressures can be estimated using various methods. Finger palpation of the endotracheal tube pilot balloon is widely used to estimate cuff pressure. This method is subjective and has been shown to be inaccurate, resulting in high cuff pressures. (3,24,25) Using the minimal leak technique, the cuff is inflated ensuring only a small leak of 50 – 100mls tidal volume. (5,21) Minimal occlusive technique in which the minimum volume required to prevent air leak is used to inflate the cuff. (5,26) This has been found to result in pressures lower than the minimal recommended pressures hence a risk of micro-aspiration. (27) Manometers are used to measure cuff pressures directly. The use of a manometer is the most accurate method. (6,26,28)

Rafael et al using a tracheal simulator consisting of 2cm internal diameter plastic cylinder assessed the ability of randomly selected staff to estimate the cuff pressure by palpation. Estimation of high pressure was 69% accurate, normal pressure were 50% accurate, low pressure was 75% accurate. He noted that an endotracheal tube cuff inflated outside the trachea required more volume of air to attain a certain pressure than when inflated in the trachea. While the cuff was in the trachea initial pressure rise was slow up to 10cmH<sub>2</sub>O after which small volumes resulted in substantial increases in cuff pressure. (24)

Using 20-30cmH<sub>2</sub>O as the recommended range, Trivedi et al observed that 40% of cases of patients intubated with a HVLP cuff ETT had a pressure that was out of range. The patients that were intubated with a HPLV cuff had 100% of pressures greater than 30cmH<sub>2</sub>O. In this study endotracheal cuff pressures were taken as a single measurement after intubation before nitrous oxide gas was switched on. (3)

Khan et al assessed the ability to inflate a cuff within the recommended range of 20-30cmH<sub>2</sub>O. The anesthesiologist inflated the cuff with either a 10cc syringe or a 20cc syringe. Adequacy of inflation was assessed by palpation or by minimal occlusive technique. Cuff pressures were measured within an hour of induction. With the 10cc syringe 52% of the pressures were above the recommended range while 86% were higher than the recommended range in the 20cc group P (0.013). The use of a manometer to monitor cuff pressures was recommended. (28)

In a study by Sengupta et al 50% of the endotracheal tube cuff pressures exceeded 30cmH<sub>2</sub>O, 27% exceeded 40cmH<sub>2</sub>O with use of finger palpation. Nitrous oxide was not used in the duration of the study. Cuff pressures were measured once during the study with a manometer. The measured cuff volume averaged 4.4 ± 1.8ml. There was no statistically significant difference of cuff pressures as a function of the care provider. The providers in the study included anaesthesia faculty, registrars and certified nurse anesthetists. <sup>(29)</sup>

Al-metwalli et al demonstrated that a sealing cuff pressure resulted in a lower cuff pressure than the control group. The sealing cuff pressure was defined as a pressure that prevented air leak at 20cmH<sub>2</sub>O. The study comprised a control group with cuff inflation guided by a manometer, a group with cuff inflation via a minimal occlusive technique and a finger palpation group. The minimal occlusive technique group had significantly lower cuff pressures (p<0.001), while the finger palpation group had significantly high cuff pressures (p<0.01). The volume of air required to inflate the cuff was significantly high in the finger palpation group (p<0.001). <sup>(30)</sup>

### **2.3 Endotracheal tube cuff pressure changes during general anaesthesia**

During the conduct of anaesthesia various factors can influence the endotracheal tube cuff pressure <sup>(8-10,31)</sup>. Anaesthesia with nitrous oxide has been shown to increase endotracheal tube cuff pressures. The volume of the cuff increases due to diffusion of nitrous oxide into the cuff. 76- 88% of cuff volume changes are due to inward diffusion of nitrous oxide. Nitrous oxide is more soluble than nitrogen in blood which results in diffusion of nitrous oxide into the cuff. <sup>(32)</sup> Monitoring of cuff pressures when nitrous oxide is used has been recommended. <sup>(9,31)</sup>

Karaswa et al studied the use of various concentrations of nitrous oxide to inflate the cuff. They compared cuffs filled with air and various percentages of nitrous oxide. The gas mixtures assessed contained; 67%, 30%, 40% and 50% nitrous oxide. The cuff with 67% nitrous oxide resulted in loss of cuff pressures due to diffusion of nitrous oxide from the cuff and a subsequent leak; air resulted in an increase in cuff pressures. With use of 50% nitrous oxide, though there was no significant rise in intra cuff pressure but a leak developed. A concentration of 40% nitrous oxide was recommended. This concentration resulted in a stable

cuff pressure, there were no leaks and the increases in cuff pressure were not significant. It was theorized there was redistribution of nitrous oxide into the pilot balloon and subsequently into air.<sup>(31)</sup>

Nguyen et al performed a study where cuffs inflated with air resulted in increase in cuff pressure and tracheal lesions in patients. In one group the cuff was inflated with air, in the other group a 50% nitrous oxide, 50% oxygen mixture was used. Initial cuff pressures were set at 30- 40 cmH<sub>2</sub>O. The cuffs inflated with nitrous oxide had stable cuff pressures as compared with cuffs inflated with air (P<0.001). Tracheal mucosal lesions were also more common (79%) when the cuff was inflated with air instead of nitrous-oxide/oxygen mixture (39%) (P <0.001) This was explained by the diffusion of nitrous oxide into the cuff in the air group with nitrogen unable to diffuse out. This results in an increase in volume hence pressure.<sup>(9)</sup>

Raised intra-abdominal pressures during laparoscopy have been associated with raised cuff pressures due to decreased lung compliance.<sup>(10,33,34)</sup> This results in increased airway pressures. Yildirim et al assessed the changes in endotracheal tube cuff pressure during laparoscopic and open abdominal surgery. The endotracheal tube cuff pressures were set below 30cmH<sub>2</sub>O and monitored during the procedure. Nitrous oxide was not used during anaesthesia. The laparoscopy group developed cuff pressures that exceeded the critical pressure of 30cmH<sub>2</sub>O after 5 minutes. The cuff pressures were significantly higher in the laparoscopy group than the open group (p<0.05). The rise in intra-abdominal pressure during insufflation results in a rise in the intra-thoracic pressure due to pressure on the diaphragm. The rise in intra-thoracic pressure results in a rise in the peak inspiratory pressures which may raise the cuff pressures.<sup>(10)</sup> The incidence of sore throat was higher in the laparoscopy group. Pneumo-peritoneum affects the intra thoracic pressure; increase in peak inflation pressure may also cause an increase in cuff pressure.<sup>(10)</sup>

Position has also been shown to increase the cuff pressure. Kim et al studied changes in of the endotracheal tube cuff pressures with change from supine to prone position, flexion and extension of the head. The study revealed an increase in cuff pressure from the supine to the prone position. Extension increased cuff pressures in the prone position while head flexion increased cuff pressures in both supine and prone positions. Movement of the endotracheal

tube was hypothesized to be a contributory factor to the rise in cuff pressures. In the prone position rise in intra-thoracic pressures due to use of the Wilson frame results in higher inspiratory pressures. This may result in higher cuff pressures.<sup>(8)</sup>

Ratnaraj et al studied the effects of neck retraction during spine surgery on cuff pressures. Endotracheal tube cuff pressures increased significantly from baseline after neck retractors were positioned. The pressures increased from 20mmHg to  $32 \pm 9$  in the control group and  $33 \pm 10$  mmHg in the treatment group ( $p < 0.05$ ). Retraction time was a significant risk factor for dysphagia at 24hours postoperatively. The incidence of sore throat was greater in the control than the treatment group 51% vs. 74%. Female patients were associated with a significantly higher rate of sore throat than male patients: 83% vs. 35% ( $p < 0.05$ ).<sup>(35)</sup>

Endotracheal tube cuff pressures have also been shown to increase with increase in altitude. A linear expansion in cuff diameter is known to occur with increase in altitude.<sup>(11)</sup>

#### **2.4 Risk factors that may contribute to post-operative sore throat**

POST is an unpleasant experience to the patient. In the assessment of post-operative surgery preferences, POST was one of the symptoms patients stated they would like to avoid.<sup>(36)</sup> The incidence of POST is highest after the use of an endotracheal tube. Various studies have reported different incidence rates. The rates range from 5 – 100%. Different interview techniques may have contributed to the wide variation. Harding et al demonstrated that direct vs. indirect questioning resulted in different reported rates of post-operative sore throat. With direct questioning; patients were asked if they had a sore throat while with indirect questioning they were asked if they had any aches, pain or discomfort. 28 out of 113 patients reported sore throat with direct questioning while only 2 out of 129 reported sore throat with indirect questioning.<sup>(37)</sup> The incidence of POST decreases progressively with increasing time after extubation. Jaensson demonstrated that at 72 hours, 16.5% of patients still had complaints of post-operative sore throat with a decrease to 11% at 96 hours.<sup>(5)</sup>

Christensen et al reported the incidence of POST to be greater after thyroid surgery 61.8%. The presence of a nasogastric tube was also found to increase the incidence of sore throat 20.7% vs. 13.1%. All the ETTs were lubricated with lidocaine jelly 1-2mls. Minimal occlusive technique was used to fill the cuff; heat moisture exchangers were not used.

Multiple attempts at intubation did not increase the incidence of sore throat significantly 13.9% vs. 16%. In this study, the incidence of sore throat was higher in females than males 17.7% vs. 9.0% ( $p < 0.0001$ ).<sup>(38)</sup>

The endotracheal tube size was noted to have an effect on POST in a study by Jaensson et al. The patients were allocated to groups with ETT size 6.0mm or 7.0mm. The ETTs were inflated with air and the cuff pressure was maintained at 20- 30cmH<sub>2</sub>O. No local anesthetics or lubricants were used on the cuff. Discomfort from sore throat was greater with ETT 7.0 (51.1%) compared with ETT 6.0 (27.1%) ( $p = 0.006$ ).<sup>(13)</sup>

Griffiths et al studied the effect of three types of throat packs on POST. Gauze soaked in sterile saline, gauze soaked in Vaseline<sup>®</sup> and autoclaved tampons in patients undergoing wisdom teeth extraction under general anaesthesia. The incidence of sore throat in the study was 70%. There was no statistical difference in the incidence of sore throat in the 3 groups.<sup>(14)</sup>

Elhakim et al studied the effect of topical tenoxicam applied on pharyngeal packs on POST. The gauze packs were soaked in either 100ml saline or 100ml saline with addition of 20mg of tenoxicam. Patients requiring more than one attempt at intubation were excluded. The cuffs were filled with air to a minimal occlusive technique. Nitrous oxide was used in the maintenance of anaesthesia. There were no cuff pressure recordings during anaesthesia. The control group had an incidence of sore throat of 40% while the tenoxicam group had an incidence of 10% ( $p < 0.01$ ).<sup>(39)</sup>

In a study by Jones et al comparing the glide scope video laryngoscope to direct laryngoscopy for naso tracheal intubation; there was a significant reduction in sore throat in the glide scope group with 9% vs. 34%. This was thought to be due to avoidance of use of the Magill forceps hence less pharyngeal trauma. There was also less contact with the oropharynx with the glide scope. All patients had oral suctioning performed with a Yankauer to qualitatively grade the amount of blood in the tubing.<sup>(40)</sup>

A study comparing POST after laryngoscopy with a Macintosh vs. Glide scope video laryngoscope blade in normal patients revealed a higher incidence of sore throat in the Macintosh laryngoscope group than the glide scope video laryngoscope group. At 6 hours the incidence of sore throat was 28% for the Glide scope group and 54% for the Macintosh group

( $p < 0.001$ ). There was no information on the maintainance agents used. Cuff pressure was inflated to 20-25mmHg at induction, there is no information on subsequent readings.<sup>(41)</sup>

## **2.5 Effect of pharmacologic agents on post-operative sore throat**

The use of pharmacologic agents to attenuate POST has been studied. (42–44) In a study assessing the effect of lidocaine and K.Y jelly<sup>®(45)</sup> on sore throat, Doukumo et al demonstrated a lower mean score of sore throat in the K.Y jelly<sup>®</sup> group compared to the lidocaine group, the difference was significant at 12 hours post- extubation ( $p < 0.02$ ). In this study endotracheal cuffs were inflated until there was no audible leak. There was no nitrous oxide administered during the conduct of anaesthesia. The lidocaine jelly and K.Y<sup>®</sup> jelly were applied from the tube tip to a point 15cm from the tip. Patients whose procedures took greater than 240 minutes were excluded.<sup>(45)</sup>

Siji et al studied the effect of dexamethasone 8mg intravenous on postoperative sore throat. In this study sealing cuff pressure was used and a pressure gauge to limit nitrous oxide related intra cuff pressure increase. POST was 20% in the dexamethasone group in comparison to 56.3% in the control group ( $P < 0.01$ ). The ideal time for dexamethasone administration was not investigated.<sup>(43)</sup>

Navarro et al studied the effect of intra cuff alkalized 2% lidocaine on emergence cough, sore throat and hoarseness in smokers. The endotracheal tubes were inflated with saline or lidocaine with sodium bicarbonate. Intra cuff lidocaine was superior to saline. In PACU the incidence of sore throat was significantly lower in the lidocaine group than in the saline group ( $p = 0.02$ ). At 24hrs the incidence was similar in was similar. ( $p = 0.07$ ). The serum levels of lidocaine were measured and did not vary significantly throughout the study period.<sup>(46)</sup>

Sumathi et al in a controlled comparison studied the effect of betamethasone and lidocaine on POST. The betamethasone or lidocaine jelly was applied on the ETT from the distal tip to 15cm from the tip. The endotracheal tubes were inflated with air to prevent an audible leak. A heat moisture exchanger was not used. Anaesthesia was conducted with nitrous oxide. There was no monitoring of cuff pressures. Betamethasone decreased the incidence more than

lidocaine ( $p < 0.05$ ). The incidence of sore throat was lower in the lidocaine group than the control group.<sup>(47)</sup>

Shaaban et al demonstrated that betamethasone gel and a ketamine gargle decreased incidence of sore throat when compared to a control group. Patients were asked to gargle ketamine 40mg mixed with 30ml saline for 60 seconds, 5 minutes before anaesthesia. 2.5ml of 0.05% betamethasone was applied up to 15cm from the tube tip. The minimal leak technique was used to inflate the cuff. Cuff pressure was monitored with a manometer. There was no significant difference between the ketamine and the betamethasone group ( $P > 0.05$ ).<sup>(48)</sup>

Ketamine spraying on the endotracheal tube cuff in parturient patients was studied by Nasrin et al. 1ml of ketamine or normal saline was sprayed on the cuff from a distance of 15cm. Ketamine decreased the incidence of sore throat in the patients at all points of assessment ( $p < 0.05$ ) Nitrous oxide 50% was used in the anesthetic technique there was no adjustment of cuff pressures during the procedure.<sup>(49)</sup>

In our local setup the most common method of endotracheal tube cuff pressure estimation is the palpation method. Wangaka et al found that 94.7% of participants inflated cuffs to high pressures.<sup>(50)</sup> The average endotracheal tube cuff pressure was 91cmH<sub>2</sub>O. The minimal leak technique is also utilized especially in pediatric patients. Nitrous oxide is widely utilized in our theatres. The neurosurgical theatres and cardiac theatres have the option of medical air. The utilization of nitrous oxide is not accompanied by intermittent or continuous cuff pressure monitoring. Follow up of patients to assess for complications such as POST, dysphagia is not routinely done. A study done in Aga Khan revealed an incidence of POST ranging from 37.5% to 92%. Diclofenac did not have a statistically significant effect on the incidence of POST.<sup>(42)</sup>

KNH is the largest referral hospital in East and Central Africa. It has a bed capacity of 1800. It has twenty three main operating theatres, twelve of which are in the main theatre block. There is a PACU available in each theatre block where patients are monitored briefly post-operatively before being discharged to their respective wards.

## CHAPTER THREE

### 3.0 RESEARCH METHODOLOGY

The study was a prospective observational study

#### 3.1 Study population

The study was conducted on ASA 1 and 2 patients greater than 12 years of age undergoing general anaesthesia with a cuffed endotracheal tube.

#### 3.2 Study site

The study was conducted at the KNH main theatre operating rooms. The patients were followed up post-operatively in the PACU and in the wards for twenty four hours.

#### 3.3 Sampling

Consecutive convenience sampling was utilized.

##### 3.3.1 Sample size

Between the months of July to September 2016 an estimated 1000 patients underwent anaesthesia in KNH main theatre monthly. This study will be done over a period of 5 months. The accessible population during the period will be 2113 patients, excluding pediatric and maxillofacial procedures. A representative sample was drawn from this fixed population and the sample size calculation was obtained using a formula for finite population (less than 10,000). The calculation was as follows:

$$n' = \frac{NZ^2P(1-P)}{d^2(N-1) + Z^2P(1-P)}$$

Where

n' = sample size with finite population correction,

N = size of the target population = 2113

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion of patients with difficult airway = 92% (42).

d = margin of error = 5%

$$= \frac{2113 \times 1.96^2 \times 0.92 \times 0.08}{0.05^2 (2113-1) + 1.96^2 \times 0.92 \times 0.08}$$

n = 107

A minimum of 107 patients were sampled to estimate the prevalence of POST within 5% level of precision. The sample was increased by 10% to compensate for attrition giving the total sample size of 118 patients.

### **3.4 Eligibility**

#### **3.4.1 Inclusion criteria**

- American Society of Anesthesiologists class 1 and 2 patients.
- Patients who underwent general anaesthesia with a cuffed endotracheal tube
- Patients greater than 12 years of age who consented to the study

#### **3.4.2 Exclusion criteria**

- Patients under 12 years of age
- Patients who did not consent to the study
- Patients who had a sore throat or throat pain pre-operatively
- Patients who were received in theatre already intubated or with a tracheotomy tube inserted
- Patients who were scheduled for nose, throat and neck surgeries.
- Patients who were not extubated after the procedure
- American Society of Anesthesiologists class 3 and 4 patients

### **3.5 Recruitment and Study procedure**

Patients were assessed upon arriving in the operating theatre complex. The study was explained to patients and/or their guardians. A written consent was obtained from eligible participants. Patients between 12 – 17 years signed an assent form after explanation. An assessment of the mallampati score was done by the interviewer and recorded.

In the operating room the anesthetist anaesthetized the patient as per their plan. After intubation cuff pressures were measured at minute zero (immediately after cuff inflation). Subsequently cuff pressures were measured every 10 minutes for the first hour, every 15 minutes for the second hour and every 30 minutes for the third hour and after. If the cuff pressure was above the recommended physiological range, 20-30cmH<sub>2</sub>O, the anesthetist was

informed. The first recorded elevated cuff pressure and the time of occurrence was used as the incidence of high cuff pressure.

A manometer was used to assess cuff pressures during the study period. The manometer could measure cuff pressure from 0-120cmH<sub>2</sub>O. If pressures were above 30 cmH<sub>2</sub>O the anaesthesia provider was informed for appropriate action. After reversal the patient was assessed with the Ramsay Sedation Scale for wakefulness. Once the patient was responsive, cooperative and tranquil (Ramsay 2); assessment for POST began. The assessment for POST sought a yes or no response. While in PACU assessments were done every 30 minutes. When discharged to the ward, the patient was followed up at 6, 12 and 24 hours. The first complaint of sore throat by the patient was used in the calculation of incidence of sore throat. Patients who complained of sore throat at 6, 12 and 24 hours were advised appropriately.

### **3.6 Measurement tool**

The Covidien Hi-LO manometer<sup>®</sup> was used. It has a color coded gauge to highlight the normal range (20-30cmH<sub>2</sub>O) cuff pressure. The accuracy of the manometer was +/- 2cmH<sub>2</sub>O. It was connected directly to the pilot balloon for cuff pressure measurement or via an extension line.

### **3.7 Outcome**

The primary outcome was to assess the incidence of POST in relation to intra-operative endo-tracheal cuff pressures (High versus normal cuff pressure) as the explanatory variable. POST was assessed every thirty minutes in the post anaesthesia care unit and at 6, 12 and 24 hours while in the ward. Assessment of POST sought a yes or no response.

The ETT cuff pressures were recorded using a manometer (Covidien hi-lo manometer<sup>®</sup>) at 10 minute intervals during the first hour of anaesthesia, 15minute intervals during the second hour and half hourly from the third hour. The secondary outcome was to assess the risk association between POST and intraoperative variables such as: size of ETT used, use of adjunct airways, airway suctioning, use of water based jelly, use of local anaesthesia jelly/spray and positioning during anaesthesia.

### **3.8 Data management and analysis**

The questionnaires were coded, entered and managed in Microsoft Access 2013 database designed for the study. Data cleaning was performed continuously in the course of data entry and the cleaned data exported to SPSS version 21.0 for statistical analysis. Descriptive data that included demographic variables of the patients was summarized into means and percentages for continuous and categorical data respectively. Incidence of POST was presented as percentage with 95% confidence interval. Cuff pressures were categorized as high and normal pressures then presented as percentages. POST was associated with socio-demographic and clinical characteristics. Chi square test was used to test associations between categorical variables and presence of POST. Means such as that of age of the patients will be compared between patients with POST versus those without using independent t test. All statistical tests were done at 5% level of significance (p value less or equal to 0.05). The study findings were presented using tables and graphs.

### **3.9 Ethical considerations**

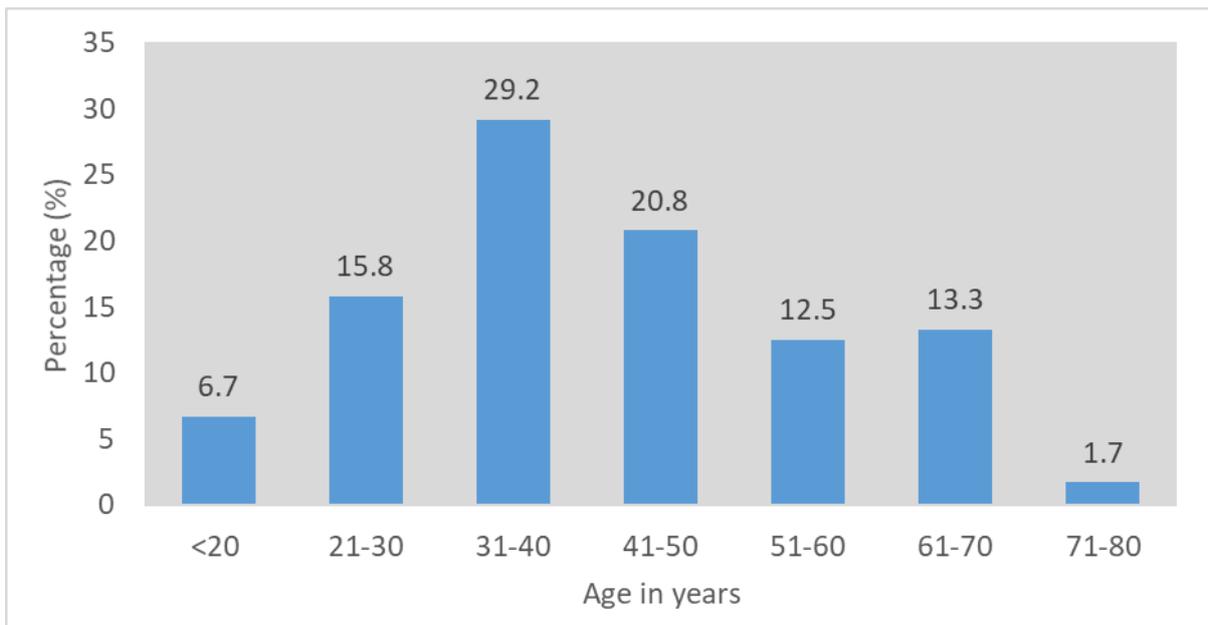
- Permission to carry out the study was sought from the Kenyatta National Hospital-University of Nairobi research and ethics committee.
- Participation was on a voluntary basis, withdrawal from the study was allowed at any point.
- Anonymity of the participants was ensured. There was no use of names or subject identifiers.
- The costs of the study were not transferred to the patient.
- Elevated endotracheal tube cuff pressures were corrected to lie within the normal range. The endotracheal tube cuff pressures were monitored at intervals for the duration of the procedure.
- The study findings were availed to the Kenyatta National Hospital Ethics and Research Committee and The University of Nairobi Department of Anaesthesia

## CHAPTER FOUR

### 4.0 RESULTS

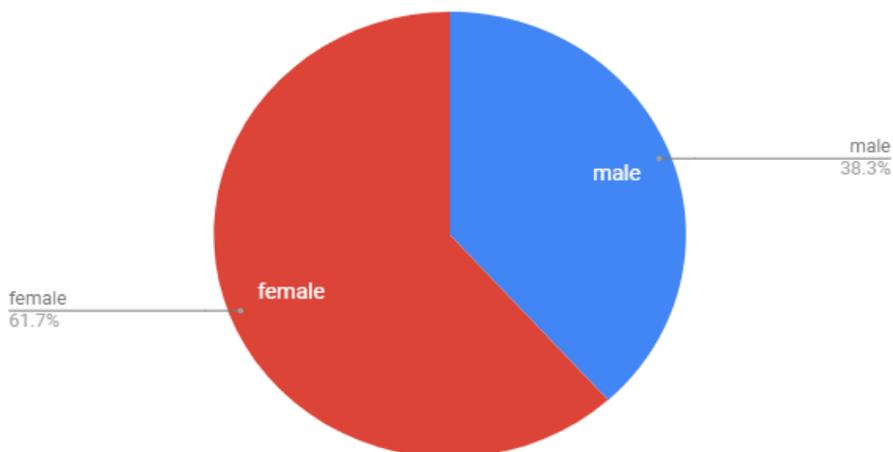
#### Demographic Characteristics

A total of 120 patients were sampled. The maximum age was 75 years while the minimum age was 13 years. Majority of the patients were between 31- 40 years (29.2%). 61.7% of the patients were female, 38.3% male.



**Figure 1: Age distribution**

#### Gender Distribution



**Figure 2: Gender Distribution**

### Distribution of procedures

Patients undergoing gynaecologic surgical procedures constituted 33.3% of the sampled population. 30% of the patients were undergoing exploratory laparotomies. Orthopaedic procedures were 6.7%, Urologic surgical procedures were 11.7%, tympanoplasty 1.7%, plastic surgical procedures 1.7% and other surgeries were 2.5% of the sampled population.

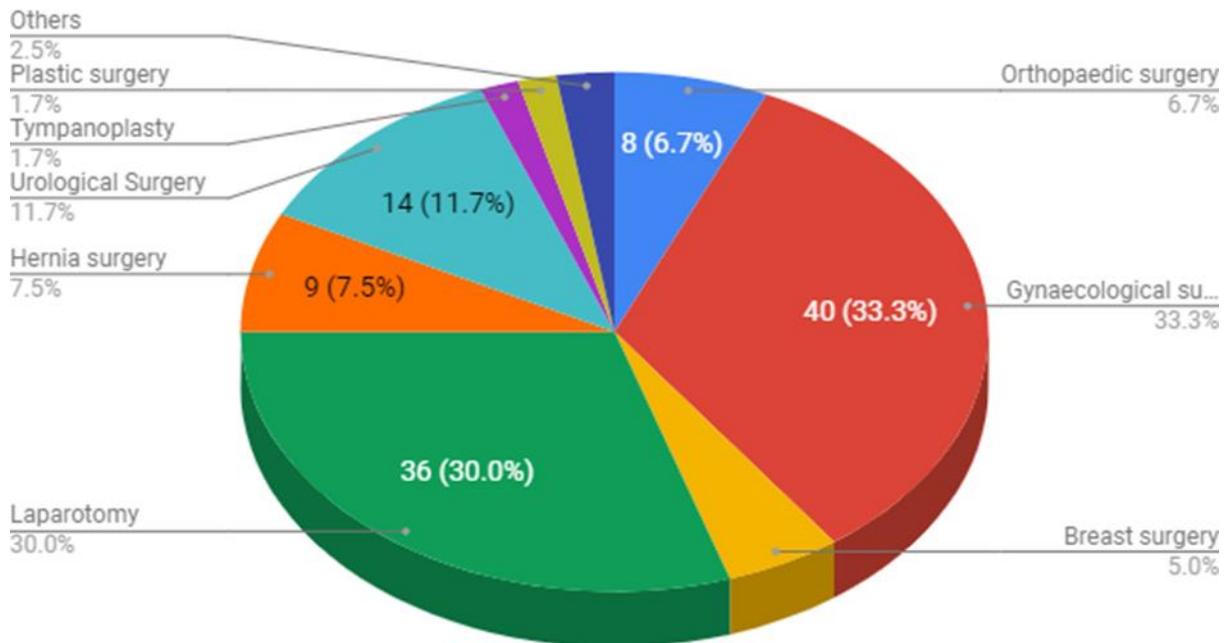


Figure 3: Distribution of Procedures

### Intubation Characteristics

Using the ASA Mallampati scoring system a majority of patients were mallampati 1 (75%), 25% mallampati 2 and 3.3% mallampati 3. ETT size 7.0 was the most commonly used (58.3%), only 1.7% of patients were intubated with a 6.0 ETT.

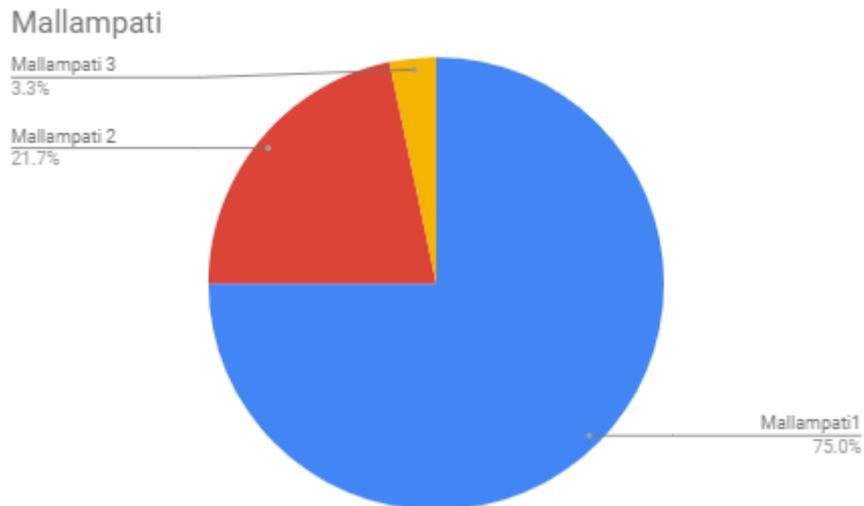


Figure 4: Mallampati

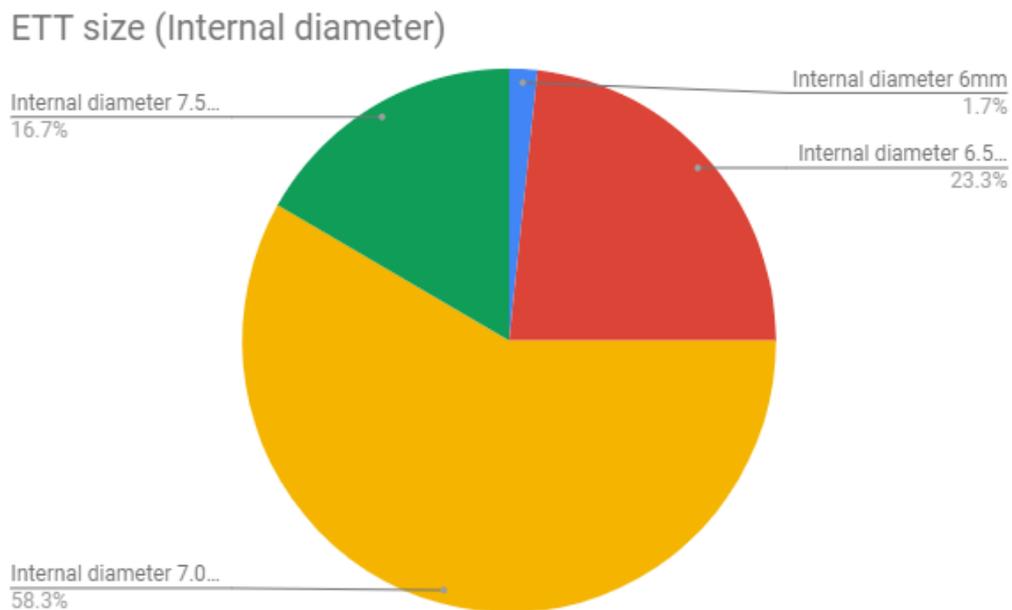
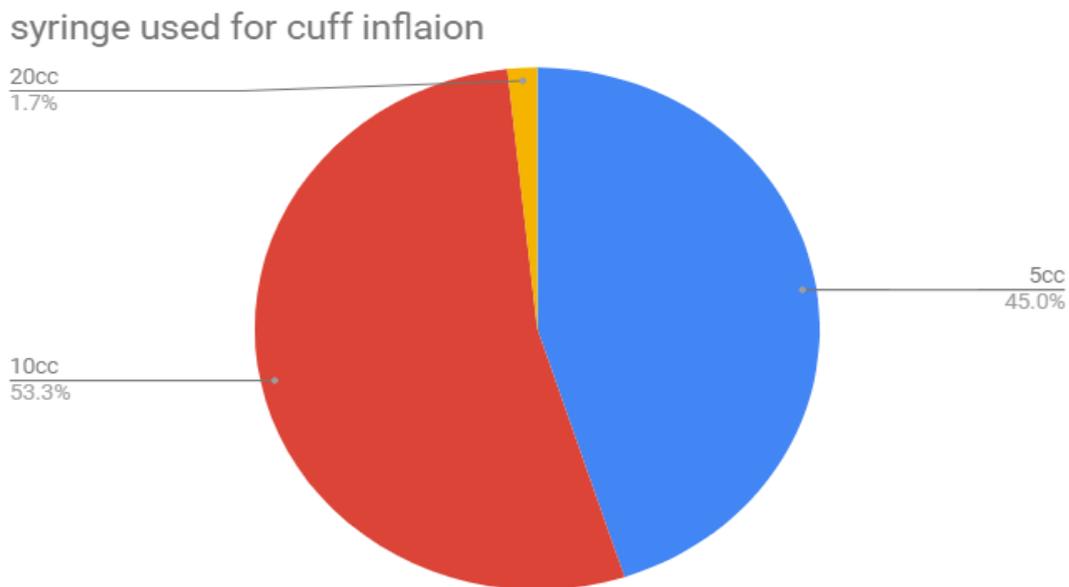


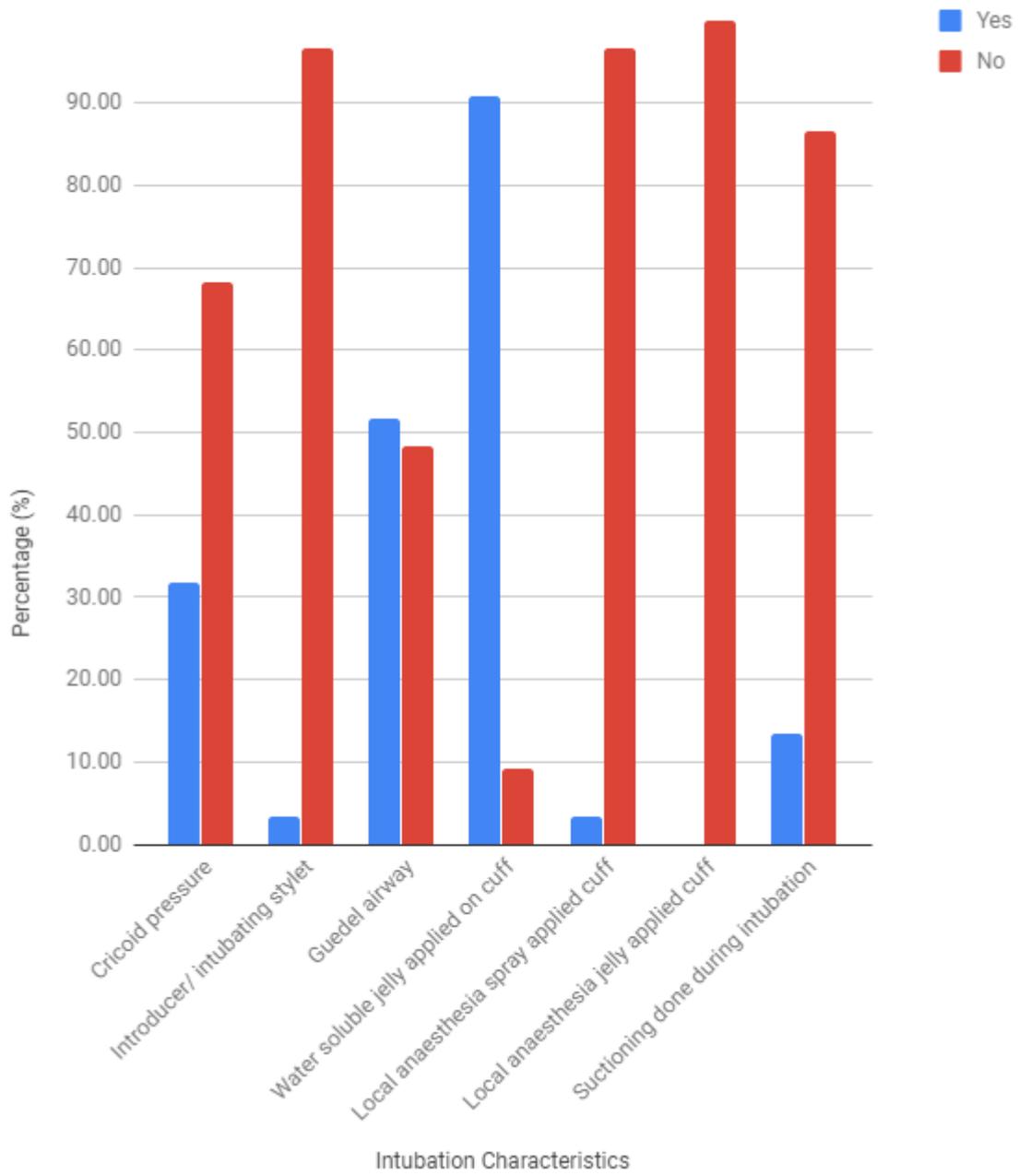
Figure 5: ETT size used

For ETT cuff inflation, 20 cc, 10cc & 5cc syringes were used in 1.7%, 53.3% and 45% of the patients respectively



**Figure 6: Syringe used for ETT cuff inflation**

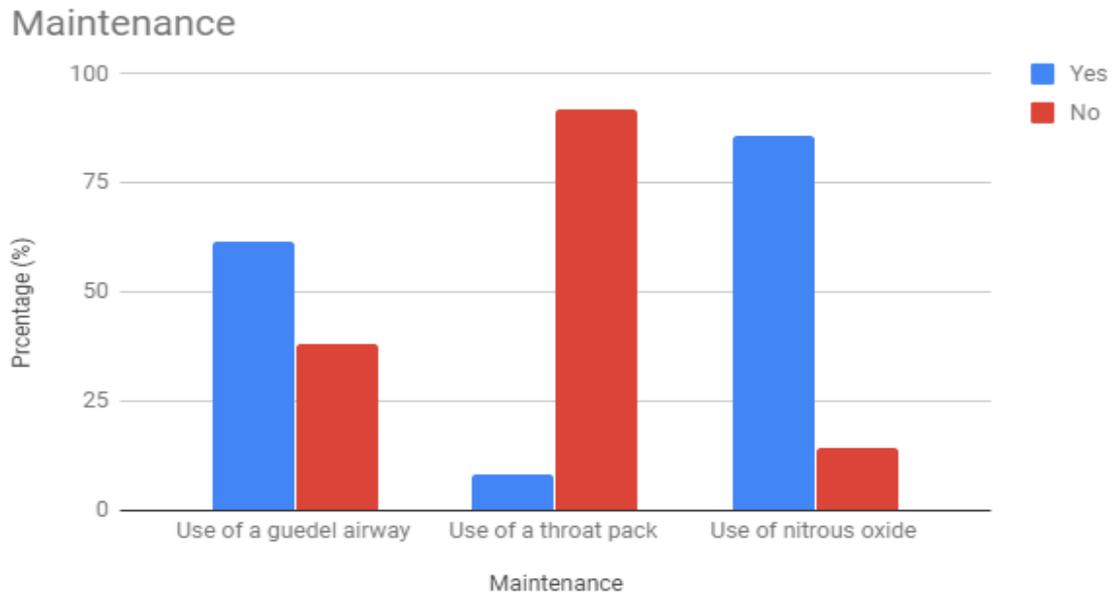
Cricoid pressure was applied in 31.7 % of patients. A stylet aided intubation in 5 % of patients. A guedel airway was inserted at intubation in 51% of patients. In 90% of the patients a water soluble jelly was used to lubricate the ETT. Local anaesthesia jelly was not used to lubricate the ETT in any of the patients. Local anaesthesia spray was used in 3.3% of the patients. 13.3% of patients had suctioning performed during intubation.



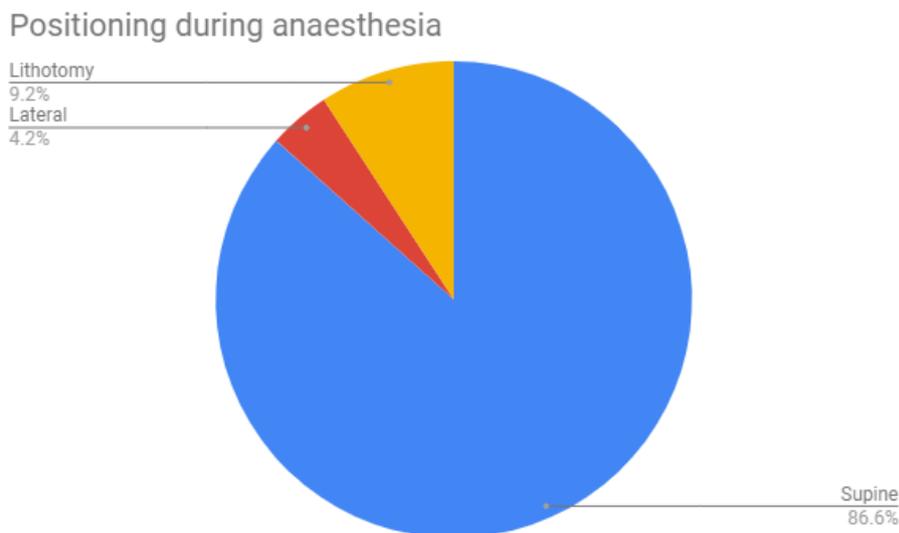
**Figure 7: Intubation Characteristics**

### Maintenance characteristics

A guedel airway was maintained in place in 61.7 % of patients. A throat pack was inserted in 9.2 % of patients. Nitrous oxide was used in 85.8 % of patients sampled. 86.6% of the patients had the procedure done while in the supine position, 9.2% of patients were in the lithotomy position and 4.2% were in the lateral position.



**Figure 8: Maintenance Characteristics**



**Figure 9: Positioning**

### Emergence and extubation

During emergence 95% of patients had a guedel airway inserted. 24.2% of patients bucked on the ETT. 21.7% of patients coughed after extubation. Blood on the ETT was noted in 31.7% of patients after extubation. 97.5% of patients were suctioned at emergence.

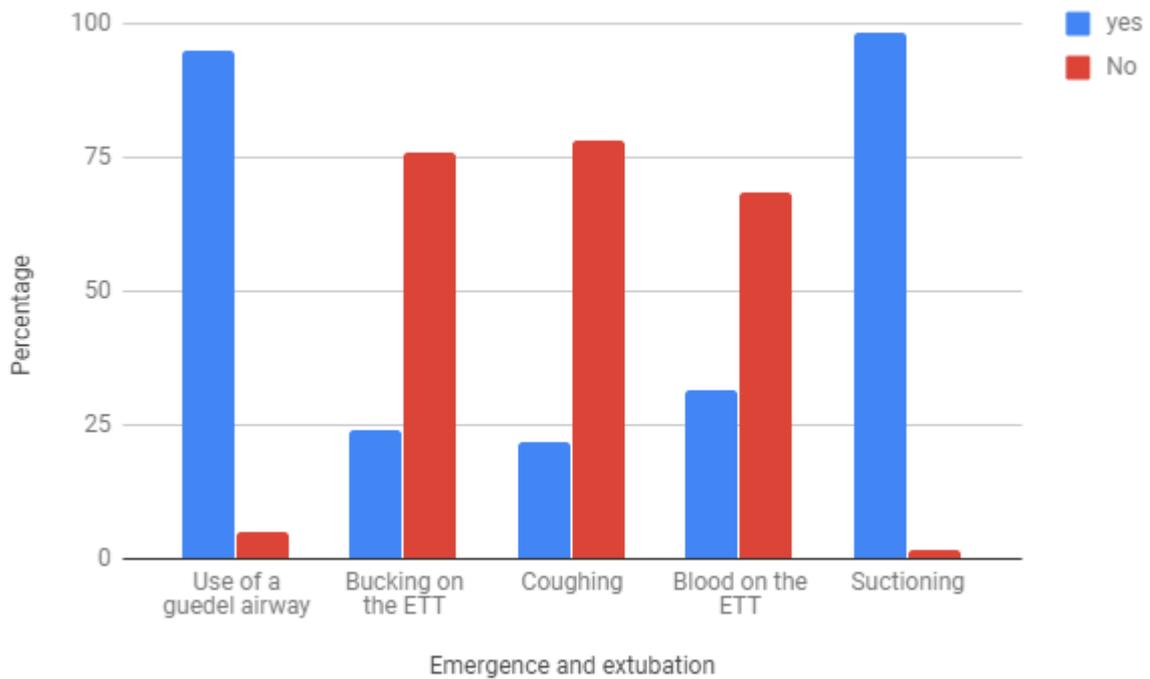
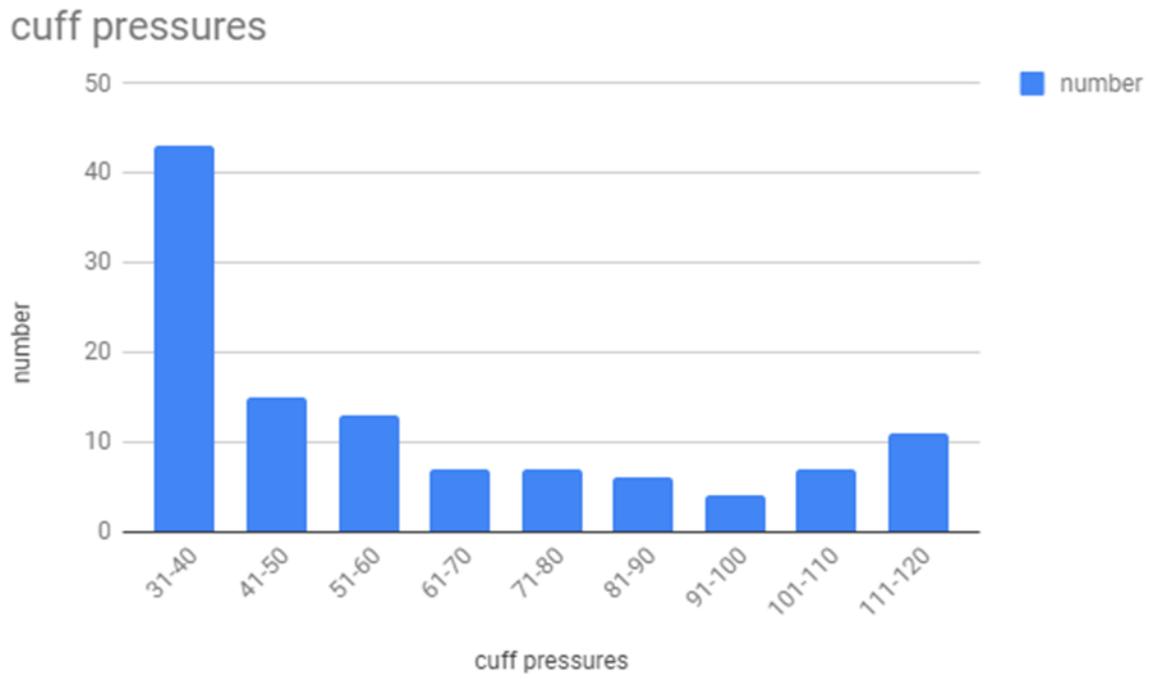


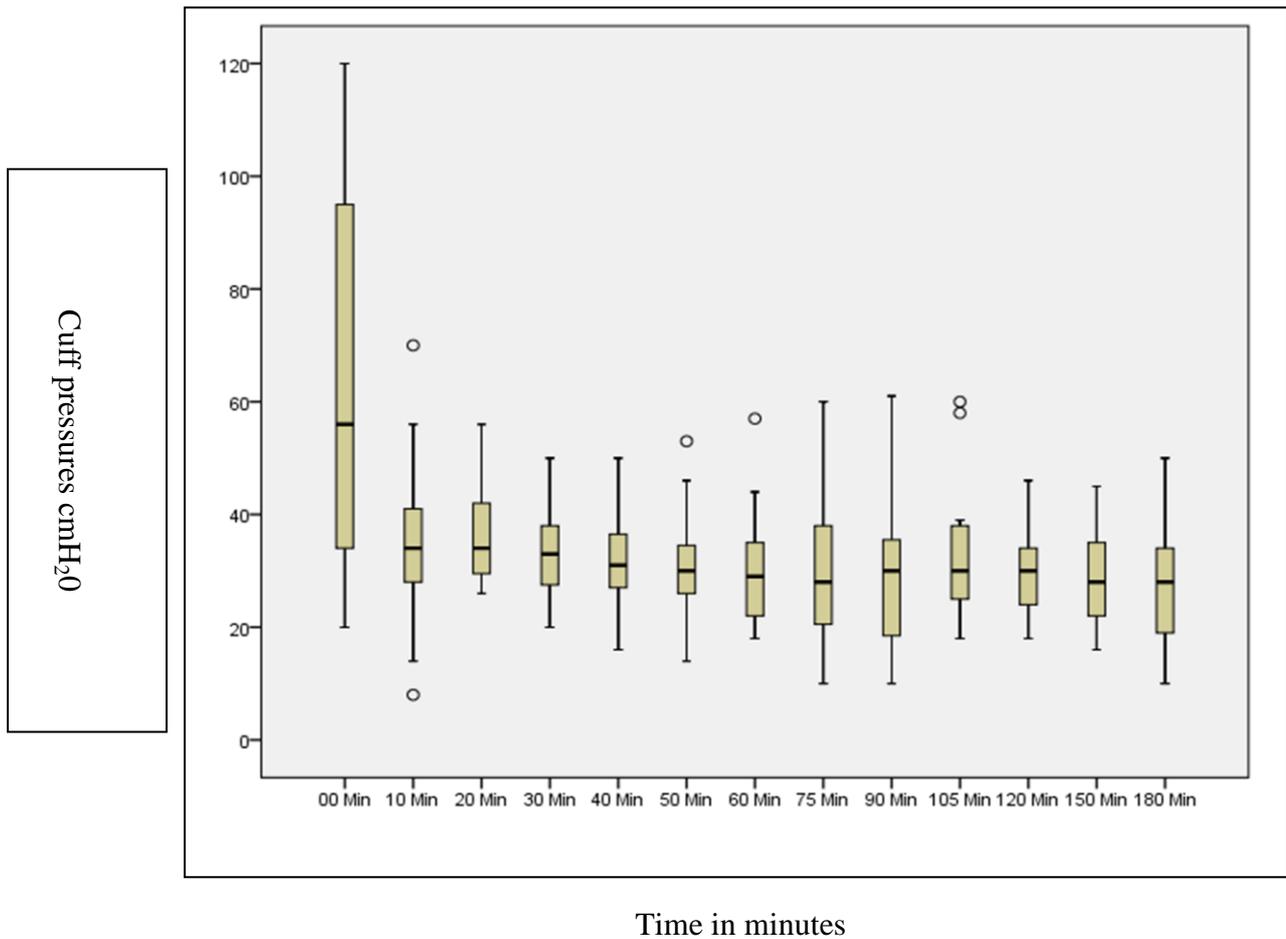
Figure 10: Emergence and extubation characteristics

## CUFF PRESSURES

113 patients (94.2%) of patients had high cuff pressures ( $> 30$  cmH<sub>2</sub>O). Of these 43 (35.8 %) patients had cuff pressures between 31 -40 cmH<sub>2</sub>O, 11 (9.2%) patients had pressures between 111-120 H<sub>2</sub>O. Mean cuff pressures at minute zero was 59.1 with a standard deviation of 31.5.



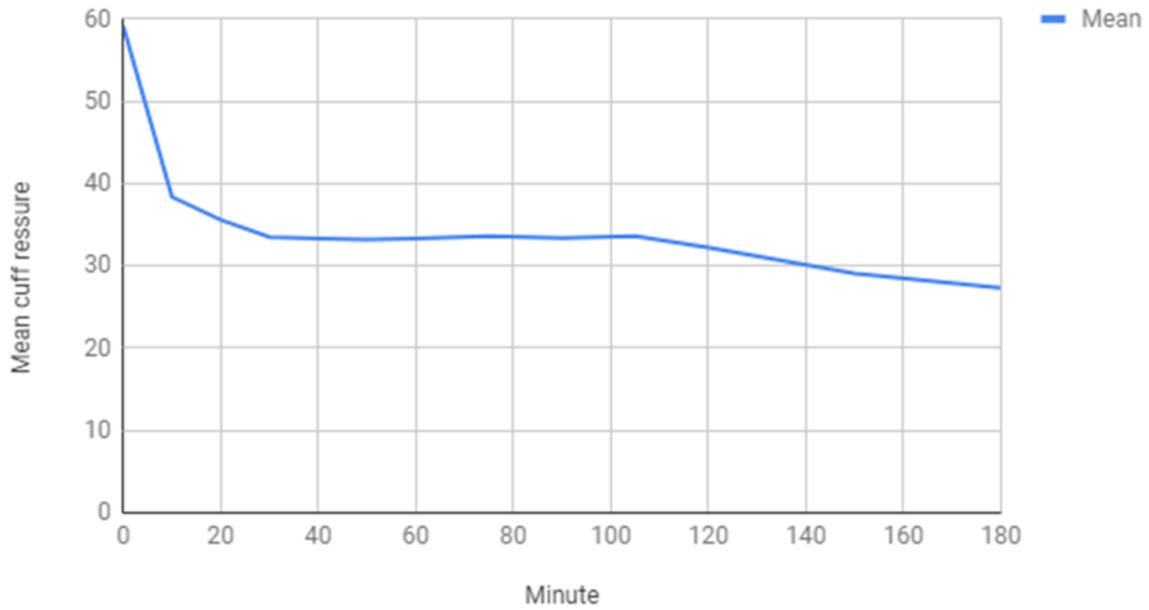
**Figure 11: patients with cuff pressures above 30 cmH<sub>2</sub>O**



**Figure 12: Box Plot of cuff pressures from minute zero to 180**

Cuff pressures varied over a wide range at minute zero. Median pressure was 50 (IQR 32.3 – 80). The maximum cuff pressure was 120 cmH<sub>2</sub>O. At minute 105 there is the least variation in cuff pressures with a median of 29.5 and (IQR 28-40)

Mean cuff pressures vs. time

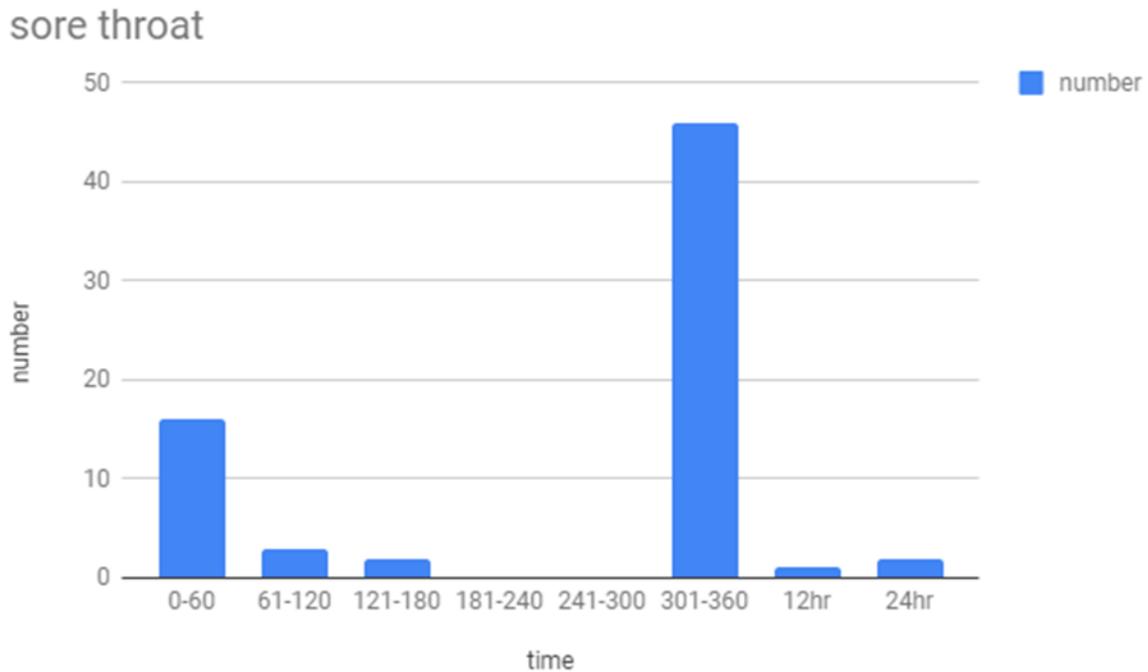


**Figure 13: Mean cuff pressures (cmH20) at time intervals**

Mean cuff pressures at minute zero were 59.1 with a standard deviation of 31.5. At minute 10 the mean cuff pressure was 38.4 with a standard deviation of 15.9. Mean cuff pressure at minute 150 was 29.1 with a standard deviation of 7.9 and at minute 180 was 27.3 with a standard deviation of 10.7

### Incidence of Postoperative Sore throat

61.9% of patients developed sore throat (70 patients). The greatest reporting of sore throat was at hour 6 (46 patients).



**Figure 14: Number of patients reporting sorethroat at time intervals**

### Factors associated with general incidence of postoperative sore throat (POST)

Variable	Yes	No	RR (95% CI)	P value
<b>Sex</b>				
Male	29 (63.0)	17 (37.0)	1.1 (0.8-1.5)	0.409
Female	41 (55.4)	33 (44.6)	1.0	
<b>Mallampati</b>				
1	52 (57.8)	38 (42.2)	1.0	0.296
2	18 (69.2)	8 (30.8)	1.6 (0.7-4.2)	
3	0	4 (100.0)	-	
<b>Cricoid pressure</b>				
Yes	24 (63.2)	14 (36.8)	1.1 (0.8-1.5)	0.466
No	46 (56.1)	36 (43.9)	1.0	

<b>Use of an introducer / intubating stylet</b>				
Yes	1 (25.0)	3 (75.0)	0.4 (0.1-2.3)	0.307
No	69 (59.5)	47 (40.5)	1.0	
<b>Use of a Guedel airway</b>				
Yes	35 (56.5)	27 (43.5)	0.9 (0.7-1.3)	0.713
No	35 (60.3)	23 (39.7)	1.0	
<b>Cuff inflation with</b>				
5cc	32 (59.3)	22 (40.7)	1.0	0.741
10cc	36 (56.3)	28 (43.8)	0.9 (0.4-1.8)	
20cc	2 (100.0)	0	-	
<b>Water soluble jelly applied on cuff</b>				
Yes	65 (59.6)	44 (40.4)	1.3 (0.7-2.6)	0.523
No	5 (45.5)	6 (54.5)	1.0	
<b>Local anesthesia spray applied on the cuff</b>				
Yes	1 (25.0)	3 (75.0)	0.4 (0.1-2.3)	0.307
No	69 (59.5)	47 (40.5)	1.0	
<b>Suction done</b>				
Yes	9 (56.3)	7 (43.8)	0.9 (0.3-2.6)	0.856
No	61 (58.7)	43 (41.3)	1.0	
<b>Positioning during anesthesia</b>				
Supine	58 (55.8)	46 (44.2)	1.2 (0.2-7.4)	0.852
Lateral	3 (60.0)	2 (40.0)	3.4 (0.7-17.3)	
Lithotomy	9 (81.8)	2 (18.2)	1.0	
<b>Nitrous oxide</b>				
Yes	64 (62.1)	39 (37.9)	1.8 (0.9-3.4)	0.038
No	6 (35.3)	11 (64.7)	1.0	
<b>Guedel airway</b>				
Yes	42 (56.8)	32 (43.2)	0.9 (0.7-1.3)	0.657
No	28 (60.9)	18 (39.1)	1.0	
<b>Throat pack</b>				
Yes	6 (60.0)	4 (40.0)	1.0 (0.6-1.8)	1.000
No	64 (58.2)	46 (41.8)	1.0	

<b>Guedel airway</b>				
Yes	68 (59.6)	46 (40.4)	1.8 (0.6-5.6)	0.233
No	2 (33.3)	4 (66.7)	1.0	
<b>Bucking on the ETT</b>				
Yes	14 (48.3)	15 (51.7)	0.8 (0.5-1.2)	0.207
No	56 (61.5)	35 (38.5)	1.0	
<b>Coughing after extubation</b>				
Yes	15 (57.7)	11 (42.3)	1.0 (0.7-1.4)	0.940
No	55 (58.5)	39 (41.5)	1.0	
<b>Blood on the ETT</b>				
Yes	19 (50.0)	19 (50.0)	0.8 (0.6-1.2)	0.236
No	51 (62.2)	31 (37.8)	1.0	
<b>Suction done</b>				
Yes	69 (58.5)	49 (41.5)	1.2 (0.3-4.7)	1.000
No	1 (50.0)	1 (50.0)	1.0	

**Table 1: Association of cuff pressures and various factors**

Nitrous oxide was found to be significantly associated with POST ( $p= 0.038$ ). Other variables assessed were not found to be significantly associated.

Variable	POST		OR (95% CI)	P value
	Yes	No		
<b>Cuff pressure</b>				
<30	68 (60.2)	45 (39.8)	3.8 (0.7-20.3)	0.127
>30	2 (28.6)	5 (71.4)	1.0	

**Table 2: Cuff pressure association with POST**

The odds of developing sore throat with cuff pressures greater than 30(1.51) was greater than with cuff pressures below30 (0.4). Odds ratio 3.78. This was not statistically significant ( $p= 0.127$ .)

## CHAPTER FIVE

### 5.0 Discussion

A total of 120 patients were recruited. There were 61.7% female patients and 38.3% male patients. Gender did not influence the occurrence of POST in this current evaluation. This is in contrast to a study by Christensen where females had significantly higher predisposition POST than male patients<sup>(38)</sup>.

The incidence of POST during the study period was 61.9%, with highest reporting at the sixth hour post operatively. A local study found a 92 % incidence of throat discomfort in the second hour with a reduction at the sixth and eighteenth hour<sup>(42)</sup>. The effect of analgesics and time of interview may have contributed to the difference in incidence between the two studies.

Indirect questioning was used in the assessment of sore throat; this has been shown to result in a lower reported incidence than direct questioning. This may influence the incidence of sore throat in this study<sup>(37)</sup>. Consistent with other studies the reporting of sore throat decreased progressively over time<sup>(13)(42)</sup>.

From this study there are higher odds (O.R 3.78) of developing sore throat when the cuff was inflated to a pressure above the recommended high limit (30cmH<sub>2</sub>O). Statistically this was not significant (p = 0.127). Clinically, however, the significance of this finding is seen as a patient is 3.78 times more likely to develop sore throat if intubated with an ETT with high cuff pressures. It has been thought that elevated cuff pressures have an untoward or adverse effect on mucosal perfusion<sup>(6)</sup>. Our findings are in keeping with Nguyen et al observations that high cuff pressures resulted in more tracheal lesions than cuff pressures maintained within the normal range<sup>(9)</sup>. Importantly, high cuff pressures add no value as micro aspiration was still detected even at cuff pressures of 100cmH<sub>2</sub>O<sup>(6)</sup>.

Mean cuff pressures during the study period were 59.1 cmH<sub>2</sub>O, with significantly high endotracheal cuff pressures in 94.2% of patients. This is consistent with a local study by Wakaba et al where 94.7% of cuff pressures were out of range with average cuff pressures of 91cmH<sub>2</sub>O<sup>(50)</sup>.

In both studies the method used to assess cuff inflation by the anaesthesiologist attending was palpation which has been proven to be inaccurate. The difference in mean cuff pressures seen between this and Wakaba's review may be because of the use of a tracheal simulator which may not fully reflect the natural tracheal elasticity resulting therefore in

higher mean cuff pressures.

Sengupta found that 50% of pressures were greater than 30 cmH<sub>2</sub>O and 27% greater than 40 cmH<sub>2</sub>O with use of palpation(29). The lower percentage of patients with high cuff Pressures may have resulted from the use of low volumes for cuff inflation in their study(4.4± 1.8mls). Palpation generally results in the use of a greater air volume for cuff inflation. Indirectly this is seen in choice of syringes for use in cuffing endotracheal tubes seen in this study . The 10cc syringe was the most popular syringe used for cuff inflation (53.3%) with a 5cc (45.5%) second and a 20cc the least popular (1.7%). Khan et al found that use of a 10cc syringe for cuff inflation resulted in 52% of patients developing high cuff pressures, while a 20cc resulted in 86% of patients developing high cuff pressure(28).

Nitrous oxide was found to be significantly associated with sore throat (p= 0.038). The use of nitrous oxide has been associated with increase in cuff pressures by diffusion of into the cuff. Cuff inflation with a nitrous oxide air mixture has been recommended to prevent this pressure changes. Inflation with air is commonly used. Nguyen et al demonstrated higher cuff pressures with use of air vs a nitrous oxide air mixture to inflate cuffs<sup>(9)</sup>. They demonstrated tracheal lesions were more when cuffs were inflated with air. The tracheal mucosal lesions may contribute to sore throat.

Blood on the endotracheal tube after extubation though not significantly associated with POST is concerning. This may point to trauma and should be further investigated.

## **5.1 Conclusions**

The incidence of POST during the study period was 61.9%.

The average ETT cuff pressure during the study period was 59.1cmH<sub>2</sub>O which is above the recommended maximum pressure.

Nitrous oxide was significantly associated with POST (p= 0.038).

## **5.2 Recommendations**

Manometers should be used to measure cuff pressures in all intubated patients.

Quality control studies should also be carried out to assess cuff pressures.

All post-operative visits should interrogate for postoperative sore throat.

Medical air should be used in all theatres instead of nitrous oxide.

Conduct of a randomized control trial to investigate the effect of nitrous oxide on post-operative sore throat.

### **5.3 Limitations**

This was an observational study hence bias may have affected the results.

Being an observational study, there was no blinding of participants.

## REFERENCES

1. Of HEP. Endotracheal Anesthesia and Its Historical Development\*. 1933;
2. Israel B, Medical D. Endotracheal Tube Cuffs : :51–8.
3. Trivedi L, Jha P, Bajiya NR, Tripathi DC. We should care more about intracuff pressure: The actual situation in government sector teaching hospital. *Indian J Anaesth*. 2010;54(4):314–7.
4. Loeser EA, Orr DL, Bennett GM, Stanley TH. Endotracheal tube cuff design and postoperative sore throat. *Anesthesiology* [Internet]. 1976;45. Available from: <http://dx.doi.org/10.1097/00000542-197612000-00023>
5. Oliver B. Endotracheal tube cuff pressure monitoring: a review of the evidence. *J Perioper Pract*. 2011;21(11):379–87.
6. Seegobin RD, van Hasselt GL. Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large volume cuffs. *Br Med J (Clin Res Ed)* [Internet].1984;288(6422):965–8.Available from: <http://dx.doi.org/10.1136/bmj.288.6422.965>
7. Nordin U. Blood Flow in the Rabbit Tracheal Mucosa under Normal Conditions and under the Influence of Tracheal Intubation. 1977;(1967):81–94.
8. Kim D, Jeon B, Son J-S, Lee J-R, Ko S, Lim H. The changes of endotracheal tube cuff pressure by the position changes from supine to prone and the flexion and extension of head. *Korean J Anesth* [Internet]. 2015 Feb;68(1):27–31. Available from: <http://synapse.koreamed.org/DOIX.php?id=10.4097%2Fkjae.2015.68.1.27>
9. Duvaldestin P, Tu HN, Saidi N, Leiutaud T, Bensaid S, Menival V, et al. Nitrous Oxide Increases Endotracheal Cuff Pressure and the Incidence of Tracheal Lesions in Anesthetized Patients. *Anesth Analg* [Internet]. 1999;89(1):187–90. Available from: [http://journals.lww.com/anesthesia-analgesia/Fulltext/1999/07000/Nitrous\\_Oxide\\_Increases\\_Endotracheal\\_Cuff\\_Pressure.33.aspx](http://journals.lww.com/anesthesia-analgesia/Fulltext/1999/07000/Nitrous_Oxide_Increases_Endotracheal_Cuff_Pressure.33.aspx)
10. Yildirim ZB, Uzunkoy A, Cigdem A, Ganidagli S, Ozgonul A. Changes in cuff pressure of endotracheal tube during laparoscopic and open abdominal surgery. *Surg Endosc*[Internet].2012;26(2):398–401.Available from: <http://dx.doi.org/10.1007/s00464-011-1886-8>
11. Smith RPR, Mcardle BH. Pressure in the cuffs of tracheal tubes at altitude. 2002;
12. Biro P, Seifert B, Pasch T. Complaints of sore throat after tracheal intubation: a

- prospective evaluation. *Eur J Anaesthesiol* [Internet]. 2005;22. Available from: <http://dx.doi.org/10.1017/S0265021505000529>
13. JAENSSON M, OLOWSSON LL, NILSSON U. Endotracheal tube size and sore throat following surgery: a randomized-controlled study. *Acta Anaesthesiol Scand* [Internet]. 2010;54(2):147–53. Available from: <http://dx.doi.org/10.1111/j.1399-6576.2009.02166.x>
  14. Griffiths DPG, Lindop MJ, Samuels SI, Roberts GDD. Pharyngeal packs and the incidence of post-operative sore throat. *Anaesthesia* [Internet]. 1973 May 1;28(3):320–30. Available from: <http://dx.doi.org/10.1111/j.1365-2044.1973.tb00456.x>
  15. Cirilla DJ, Ngo J, Vaisman V, Daly C, Ata A, Sandison M, et al. Does the incidence of sore throat postoperatively increase with the use of a traditional intubation blade or the GlideScope? *J Clin Anesth*. 2015;27(8):646–51.
  16. Monroe MC, Gravenstein N, Saga-Rumley S. Postoperative sore throat: effect of oropharyngeal airway in orotracheally intubated patients. *Anesth Analg*. 1990;70:512–6.
  17. McHardy FE, Chung F. Postoperative sore throat: cause, prevention and treatment. *Anaesthesia* [Internet]. 1999;54(5):444–53. Available from: <http://dx.doi.org/10.1046/j.1365-2044.1999.00780.x>
  18. Haas CF, Faarc MLSR, Rn RMER, Konkle MA, Rrt MPA, Blank R. Endotracheal Tubes : Old and New. :933–55.
  19. Hofmann HS, Rettig G, Radke J, Neef H, Silber RE. Iatrogenic ruptures of the tracheobronchial tree. *Eur J Cardio-thoracic Surg*. 2002;21(4):649–52.
  20. Lewis FR, Schlobohm RM, Thomas AN. Prevention of complications from prolonged tracheal intubation. *Am J Surg*. 1978;135(3):452–7.
  21. Conti M, Pougéoise M, Wurtz A, Porte H, Fourrier F, Ramon P, et al. Management of postintubation tracheobronchial ruptures. *Chest*. 2006;130(2):412–8.
  22. Jensen PJ, Hommelgaard P, Søndergaard P, Eriksen S. Sore throat after operation: influence of tracheal intubation, intracuff pressure and type of cuff. *Br J Anaesth* [Internet]. 1982;54(4):453–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/7066143>
  23. Hoffman RJ, Dahlen JR, Lipovic D, Stürmann KM. Linear correlation of endotracheal tube cuff pressure and volume. *West J Emerg Med*. 2009;10(3):137–9.
  24. FERNANDEZ R, BLANCH L, MANCEBO J, BONSONS N, ARTIGAS A.

- Endotracheal tube cuff pressure assessment: Pitfalls of finger estimation and need for objective measurement. *Crit Care Med* [Internet]. 1990;18(12). Available from: [http://journals.lww.com/ccmjournal/Fulltext/1990/12000/Endotracheal\\_tube\\_cuff\\_pressure\\_assessment\\_.23.aspx](http://journals.lww.com/ccmjournal/Fulltext/1990/12000/Endotracheal_tube_cuff_pressure_assessment_.23.aspx)
25. Faris C, Koury E, Philpott J, Sharma S, Tolley N, Narula A. Estimation of tracheostomy tube cuff pressure by pilot balloon palpation. *J Laryngol & Otol* [Internet]. 2007;121(9):869–71. Available from: <https://www.cambridge.org/core/article/div-class-title-estimation-of-tracheostomy-tube-cuff-pressure-by-pilot-balloon-palpation-div/A530D9D0CEAE6A450861027D3AAF773A>
  26. Rose L, Redl L. Minimal occlusive volume cuff inflation: A survey of current practice. *Intensive Crit Care Nurs*. 2008;24(6):359–65.
  27. Petring OU, Adelhøj B, Jensen BN, Pedersen NO, Lomholt N. Prevention of silent aspiration due to leaks around cuffs of endotracheal tubes. *Anesth Analg* [Internet]. 1986;65(7):777–80. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/3717617>
  28. Khan MU, Khokar R, Qureshi S, Al Zahrani T, Aqil M, Shiraz M. Measurement of endotracheal tube cuff pressure: Instrumental versus conventional method. *Saudi J Anaesth* [Internet]. 2016;10(4):428–31. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044728/>
  29. Sengupta P, Sessler DI, Maglinger P, Wells S, Vogt A, Durrani J, et al. Endotracheal tube cuff pressure in three hospitals, and the volume required to produce an appropriate cuff pressure. *BMC Anesthesiol*. 2004;4(August 2016):8.
  30. Al-metwalli RR, Al-Ghamdi AA, Mowafi HA, Sadek S, Abdulshafi M, Mousa WF. Is sealing cuff pressure, easy, reliable and safe technique for endotracheal tube cuff inflation?: A comparative study. *Saudi J Anaesth* [Internet]. 2011;5(2):6–10. Available from: <http://dx.doi.org/10.4103/1658-354X.82795>
  31. Karasawa F, Ohshima T, Fukuda I, Uchihashi Y, Takamatsu I, Ehata T, et al. The Effect on Intracuff Pressure of Various Nitrous Oxide Concentrations Used for Inflating an Endotracheal Tube Cuff. 2000;708–13.
  32. Patel R, Oh T EB. Effect of nitrous oxide on pressure changes of tracheal tube cuffs following inflation with air and saline. *Anaesthesia*. 1983;38:44–6.
  33. Wu C-Y, Yeh Y, Wang M-C, Lai C-H, Fan S-Z. Changes in endotracheal tube cuff pressure during laparoscopic surgery in head-up or head-down position. *BMC*

- Anesthesiol [Internet]. 2014;14(1):75. Available from: <http://dx.doi.org/10.1186/1471-2253-14-75>
34. Geng G, Hu J, Huang S. The effect of endotracheal tube cuff pressure change during gynecological laparoscopic surgery on postoperative sore throat: a control study. *J Clin Monit Comput* [Internet]. 2015;29(1):141–4. Available from: <http://dx.doi.org/10.1007/s10877-014-9578-2>
  35. Louis S, Ratnaraj J, Todorov A, McHugh T, Cheng MA, Laurysen C. Effects of decreasing endotracheal tube cuff pressures during neck retraction for anterior cervical spine surgery. *J Neurosurg*. 2002;97(Spine 2):176–9.
  36. Jenkins K, Grady D, Wong J, Correa R, Armanious S, Chung F. Post-operative recovery : day surgery patients ' preferences. 2001;86(2):272–4.
  37. Harding CJ, McVey FK. Interview method affects incidence of postoperative sore throat. *Anaesthesia* [Internet]. 1987;42(10):1104–7. Available from: <http://dx.doi.org/10.1111/j.1365-2044.1987.tb05179.x>
  38. Christensen AM, Willemoes-larsen H, Lundby L, Jakobsen KB. Postoperative throat complaints after tracheal intubation. *Br J Anaesth*. 1994;73(6):786–7.
  39. Elhakim M, Siam A, Rashed I, Hamdy MH. Topical tenoxicam from pharyngeal pack reduces postoperative sore throat. *Acta Anaesthesiol Scand* [Internet]. 2000 Jul 1;44(6):733–6. Available from: <http://dx.doi.org/10.1034/j.1399-6576.2000.440612.x>
  40. Jones PM, Armstrong KP, Armstrong PM, Cherry RA, Harle CC, Hoogstra J, et al. A Comparison of GlideScope® Videolaryngoscopy to Direct Laryngoscopy for Nasotracheal Intubation. *Anesth Analg* [Internet]. 2008;107(1):144–8. Available from: [http://journals.lww.com/anesthesia-analgia/Fulltext/2008/07000/A\\_Comparison\\_of\\_GlideScope\\_\\_Videolaryngoscopy\\_to\\_Direct\\_Laryngoscopy\\_for\\_Nasotracheal\\_Intubation.24.aspx](http://journals.lww.com/anesthesia-analgia/Fulltext/2008/07000/A_Comparison_of_GlideScope__Videolaryngoscopy_to_Direct_Laryngoscopy_for_Nasotracheal_Intubation.24.aspx)
  41. Najafi A, Imani F, Makarem J, Khajavi MR, Etezadi F, Habibi S, et al. Postoperative sore throat after laryngoscopy with macintosh or glide scope video laryngoscope blade in normal airway patients. *Anesthesiol pain Med* [Internet]. 2014;4(1):e15136. Available from: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3961026&tool=pmcentrez&rendertype=abstract>
  42. Thang P, Kanya D, Mung V. Effects of intravenous diclofenac on postoperative sore throat in patients undergoing laparoscopic surgery at Aga Khan University Hospital ,

- Nairobi : A prospective , randomized , double blind controlled trial. :999–1006.
43. Thomas S, Beevi S. Dexamethasone reduces the severity of postoperative sore throat. *Can J Anaesth* [Internet]. 2007;54:897–901. Available from: <http://dx.doi.org/10.1007/BF03026793>
  44. Ebneshahidi A, Mohseni M. Strepisils(R) tablets reduce sore throat and hoarseness after tracheal intubation. *Anesth Analg*. 2010;111.
  45. Doukumo DM, Faponle AF, Bolaji BO, Adenekan AT, Olateju SOA. EFFECTS OF LIDOCAINE AND K-Y JELLIES ON SORE THROAT, COUGH, AND HOARSENESS FOLLOWING ENDOTRACHEAL ANAESTHESIA. *J West African Coll Surg* [Internet]. 2011;1(3):44–61. Available from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4170275/>
  46. Navarro LHC, Lima RM e, Aguiar AS, Braz JRC, Carness JM, Módolo NSP. The effect of intracuff alkalized 2% lidocaine on emergence coughing, sore throat, and hoarseness in smokers. *Rev Assoc Med Bras*. 2012;58:248–53.
  47. Sumathi PA, Shenoy T, Ambareesha M, Krishna HM. Controlled comparison between betamethasone gel and lidocaine jelly applied over tracheal tube to reduce postoperative sore throat, cough, and hoarseness of voice. *Br J Anaesth*. 2008;100(2):215–8.
  48. Shaaban AR, Kamal SM. Comparison between betamethasone gel applied over endotracheal tube and ketamine gargle for attenuating postoperative sore throat, cough and hoarseness of voice. *Middle East J Anaesthesiol* [Internet]. 2012 Feb;21(4):513—519. Available from: <http://europepmc.org/abstract/MED/23327023>
  49. Faridi Tazeh kand N, Hosseini L, Yazarlu K, Eslami B, Ghorbany Marzony S. The Relation between Ketamine Spraying on the Endotracheal Tube Cuff and Reduced Postoperative Sore Throat, Cough and Hoarseness in Parturient Patients. *Arch Anesthesiol Crit Care*; Vol 1, No 1 Winter [Internet]. 2015 Oct 3; Available from: <http://aacc.tums.ac.ir/index.php/aacc/article/view/7>
  50. Att KENY, Hospital N. A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF. 2006;

## APPENDICES

### Appendix I: Budget

ITEM	UNIT COST	QUANTITY	TOTAL
Manometer	20000	20000	20000
Stationery	5000	5000	25000
Printing	10000	10000	35000
Research assistant	40000	40000	75000
Statistician	25000	25000	100000
ERC fee	1000	1000	101000
Miscellaneous	10000	10000	111000

## Appendix II: Data Collection Tool

### A PROSPECTIVE OBSERVATIONAL STUDY ON THE INCIDENCE OF POSTOPERATIVE SORE THROAT IN RELATION TO ENDOTRACHEAL TUBE CUFF PRESSURES IN KENYATTA NATIONAL HOSPITAL

Participant number .....

#### A. Biodata

1. Age .....
2. Sex: male  female

#### B. Procedure

3. ....
4. Mallampati 1  2  3  4

#### C. Intubation

5. ETT size ..... Internal diameter
6. Laryngoscope type Macintosh  miller  other
7. Number of attempts at intubation .....
8. Cricoid pressure  yes  no
9. Use of an introducer/ intubating stylet  yes  no
10. Use of a Guedel airway  yes  no
11. Cuff inflation with  5cc  10cc  20cc
12. Water soluble jelly applied on cuff  yes  no
13. Local anaesthesia spray (e.g. Lidocaine) applied on the cuff  yes  no
14. Local anaesthesia jelly (e.g. Lidocaine) applied on the cuff  yes  no
15. Suctioning done  yes  no

#### D. Maintenance

16. Positioning during anaesthesia:  Supine  Prone  Lateral  
 Trendelenburg  Reverse Trendelenburg  Lithotomy  Decubitus  other
17. Guedel airway  yes  no
18. Throat pack  yes  no
19. Nitrous oxide  yes  no

**20. Cuff pressures**

Minute	00	10	20	30	40	50	60	75	90	105	120	150	180
Cuff pressures(cmH <sub>2</sub> O)													

**E. Reversal**

21. Guedel airway yesno

22. Bucking on the ETT yesno

23. Coughing after extubation yesno

24. Blood on the ETT yesno

25. Suctioning done yesno

**26. PACU**

Minute	00	30	60	90	120	150	180	210	240
Sore throat (yes/no)									

**27. POSTOPERATIVE (IN THE WARD)**

Hour (postoperative)	6	12	24
Sore throat (yes/no)			

### **Appendix III: Explanation and Consent for the Patient/Next of Kin**

#### **A COMPARATIVE OBSERVATIONAL STUDY ON THE INCIDENCE OF POST OPERATIVE SORE THROAT IN RELATION TO ENDOTRACHEAL TUBE CUFF PRESSURES**

##### **Study site**

Kenyatta National Hospital

##### **Background**

My name is Killian Kariuki Wanyoro, a postgraduate student studying anaesthesia at the University of Nairobi. I am conducting a study on the incidence of postoperative sore throat.

##### **Purpose**

The purpose of the study is to assess factors that may contribute to sore throat in patients undergoing surgery. This will help us improve the quality of care.

##### **Participation**

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

##### **Risks of participation**

We will not alter your planned treatment. The measurement of cuff pressures will not add on to the risks associated with treatment.

**Confidentiality**

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

**Sharing of results**

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

**Consent form**

I.....of.....

OR I ..... next of kin to..... of ..... hereby give written consent for the participation in the prospective observational study assessing the incidence of postoperative sore throat in relation to endotracheal tube cuff pressures.

I have understood the information regarding the study. I have had my questions addressed.

I have the right to withdraw at any point

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

I have explained to the patient/ next of kin about the study. I have addressed all their questions and concerns to the best of my knowledge.

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

## **FOMU YA MAKUBALIANO YA KUJIUNGA NA UTAFITI**

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

### **A COMPARATIVE OBSERVATIONAL STUDY ON THE INCIDENCE OF POST OPERATIVE SORE THROAT IN RELATION TO ENDOTRACHEAL TUBE CUFF PRESSURES**

Jina langu ni Killian Kariuki Wanyoro nafanya utafiti wa shahada ya juu katika anaesthesia kwenye Chuo Kikuu cha Nairobi.

Utafiti huu unalenga kuchunguza kinacho sababisha koo kuwa na uchungu na sauti kubadilika wagonjwa wanapotoka katika chumba cha upasuaji. Maswali kuhusu uchungu kwa koo na sauti yataulizwa baada ya kutoka chumba cha upasuaji na kabla ya kupelekwa huko.

Utafiti huu utaweza kuboresha wagonjwa wanavyohisi wakitoka chumba cha upasuaji. Kusajiliwa kwa utafiti huu ni kwa hiari yako . Hakuna malipo utakayo lipa zaidi ya malipo ya hospitali. Hakuna pesa utakayo pewa kwa kushiriki. Hakuna hatari inayotokana na kushiriki katika utafiti huu. Uko na ruhusa kujiondoa kwa utafiti wakati wowote. Majina yako hayatatumika katika utafiti na usiri mkubwa utatumiwa katika utafiti. Kama jamaa/mgonjwa utahitajika kuelewa kuhusu utafiti na kutia sahihi kubalio ili jamaa/ wewe asajiliwe katika utafiti

Baada ya utafiti, uchambuzi wa takwimu utafanywa. Habari itachapishwa katika kitabu kitkachowekwa kwa maktaba ya Chuo Kikuu Cha Nairobi. Usiri mkubwa utatumika kwakuziweka taarifa hizi.Sasa nitakupa nafasi ya kuuliza maswali yoyote uliyo nayo kuhusu utafiti huu. Ikiwa umekubali kushiriki katika utafiti huu, tia sahihi yako kwenye nafasi iliyotolewa. Maswali yoyote kuhusu utafiti huu yanaweza kuelekezwa kwa KNH-ERC, Hospitali ya Rufaa ya Kenyatta, Sanduku la Posta20723, Nairobi. Simu: 2726300-9

## **FOMU YA IDHINI**

Nambari ya Usajili.....

Mimi ni.....Kutoka.....

Ama mimi ni jamaa wa karibu wa.....

Kutoka.....

Nimekubali kushiriki katika utafiti wa

A prospective observational study on the incidence of post-operative sore throat in relation to endotracheal tube cuff pressures

Ninaelewa ya kwamba uchunguzi utafanyika bila madhara yoyote kwa magonjwa.

Nina uhuru wa kujiuzulu kutoka kwa utafiti huu wakati wowote.

Sahihi..... Tarehe.....

Nina thibitisha kwamba nimemwelezea mgonjwa kwa ukamilifu kuhusu utafiti huu na amekubali bila kushurutishwa

Sahihi..... Tarehe.....

**Appendix IV: Assent Form**

My name is Killian Kariuki Wanyoro. I am doing a research on the relationship between endotracheal tube cuff pressures and postoperative sore throat. We want to find out how common sore throat is after going to theatre and what may contribute to it.. The information we obtain will be confidential. Your name will not be included in the information. When the study is completed we will write a report on what we have learnt. You will not be harmed during the study. Participation is voluntary. If you decide not to participate after we start the study it is ok. Your parents know about the study. If you decide you want to be in this study please sign your name.

I..... want to be in this research study.

Sign..... Date.....

**Fomu ya kibali kwa watoto wenye umri wa miaka 12-17 years**

Jina langu ni Killian Kariuki Wanyoro. Nafanya utafiti kuhusu. The relationship between endotracheal tube cuff pressures and postoperative sore throat. Utafiti ni njia ya kuchunguza njia za matibabu ili kutuwezesha kutibu watu vizuri zaidi. Utafiti utatufahamisha matukio ya watu kuwashwa koo baada ya kutoka katika chumba cha upasuaji. Hautaadhirika kwa jinsi yeyote kutoakana na utafiti huu. Baada ya utafiti matokeo yatachapishwa katika ripoti. Jina lako halitatumiwa katika utafiti. Hakuna atakayejua kwamba umeshiriki katika utafiti huu. Unaweza kujiondoa katika utafiti wakati wowote hata kama ulikubali hapo mbeleni. Wazazi wako wameelezwa kuhusu utafiti huu.

Mimi..... ningependa kushiriki kwa utafiti huu

Sahihi yako..... Tarehe.....

## **Appendix V: Ramsay Sedation Scale**

<b>Level of Activity</b>	<b>Points</b>
Patient conscious, agitated, restless	1
Patient co-operative, oriented, tranquil	2
Patient responds to verbal commands	3
Patient with brisk response to light glabella tap or loud auditory stimulus	4
Patient with sluggish response to light glabella tap or loud auditory stimulus	5
Patient with no response to light glabella tap or loud auditory stimulus	6

## Appendix VI: Approval Letter

 <p>UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES P O BOX 19676 Code 00202 Telegrams: varsity Tel: (254-020) 2726300 Ext 44355</p>	<p>KNH-UON ERC Email: <a href="mailto:uonknh_erc@uonbi.ac.ke">uonknh_erc@uonbi.ac.ke</a> Website: <a href="http://www.erc.uonbi.ac.ke">http://www.erc.uonbi.ac.ke</a> Facebook: <a href="https://www.facebook.com/uonknh.erc">https://www.facebook.com/uonknh.erc</a> Twitter: @UONKNH_ERC <a href="https://twitter.com/UONKNH_ERC">https://twitter.com/UONKNH_ERC</a></p>	 <p>KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202 Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi</p>
Ref: KNH-ERC/A/330		3 <sup>rd</sup> November, 2017
Dr. Killian Wanyoro Kariuki Reg. No. H58/74585/2014 Department of Anaesthesia School of Medicine College of Health Sciences University of Nairobi		
Dear Dr. Kariuki,		
<b>REVISED RESEARCH PROPOSAL –AN OBSERVATIONAL STUDY ON THE INCIDENCE OF POSTOPERATIVE SORE THROAT IN RELATION TO ENDOTRACHEAL TUBE CUFF PRESSURES IN KENYATTA NATIONAL HOSPITAL MAIN THEATRE (P362/07/2017)</b>		
This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and <b>approved</b> your above proposal. The approval period is from 3 <sup>rd</sup> November 2017 –2 <sup>nd</sup> November 2018.		
This approval is subject to compliance with the following requirements:		
<ol style="list-style-type: none"><li>Only approved documents (informed consents, study instruments, advertising materials etc) will be use</li><li>All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-U ERC before implementation.</li><li>Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within hours.</li><li>Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse event whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.</li><li>Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period (<i>Attach a comprehensive progress report to support the renewal</i>).</li><li>Submission of an <i>executive summary</i> report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing relate research studies so as to minimize chances of study duplication and/ or plagiarism.</li></ol>		
Protect to discover		

## Appendix VII: Antiplagiarism certificate

### AN OBSERVATIONAL STUDY ON THE INCIDENCE OF POSTOPERATIVE SORE THROAT IN RELATION TO ENDOTRACHEAL TUBE CUFF PRESSURES IN KENYATTA NATIONAL HOSPITAL MAIN THEATRE

#### ORIGINALITY REPORT

<b>12%</b>	<b>2%</b>	<b>9%</b>	<b>4%</b>
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

#### PRIMARY SOURCES

<b>1</b>	<b>Submitted to University of Nairobi</b> Student Paper	<b>2%</b>
<b>2</b>	Prerana P Shroff. "Efficacy of cuff inflation media to prevent postintubation-related emergence phenomenon: air, saline and alkalized lignocaine", European Journal of Anaesthesiology, 06/2009 Publication	<b>1%</b>
<b>3</b>	R D Seegobin. "Endotracheal cuff pressure and tracheal mucosal blood flow: endoscopic study of effects of four large volume cuffs.", BMJ, 03/31/1984 Publication	<b>1%</b>
<b>4</b>	F. E. McHardy. "Postoperative sore throat: cause, prevention and treatment", Anaesthesia, 5/1999 Publication	<b>1%</b>