

**RISK FACTORS FOR EARLY  
COMPLICATIONS OF TRACHEOSTOMIES  
AT KENYATTA NATIONAL HOSPITAL**

**A dissertation submitted in part fulfillment for the degree of Master of  
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## **DECLARATION**

This dissertation is my original work and has not, to the best of my knowledge, been presented for approval in any other University.

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## **DEDICATION**

I dedicate this work to my late sister, Dr Joyce Nyathaa Karuga. I know you'd have loved to see its completion. I thank you for all the support you gave me throughout my postgraduate study. Rest in Peace.

To my parents, Mary Njeri and Bernard Karuga for their prayers, support and encouragement.

To my brothers Joseph and Arthur and my sister Edith for their understanding and shoulders to lean on.



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I Acknowledge the Almighty for bringing me this far. It is by God's Grace that I have seen this study to completion.

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## **ABBREVIATIONS AND ACRONYMS**

KNH	Kenyatta National Hospital
ENT/HN	Ear Nose Throat and Head and Neck.
ICU	Intensive Care Unit
Ip	Inpatient
No	Number.
TOF	Tracheo-oesophageal fistula
ENT	Ear Nose and Throat

## **ABSTRACT**

**Background:** A tracheostomy is a surgical intervention that can mean the difference between life and death. It has been practiced for thousands of years. The operation is associated with various complications the commonest of which are haemorrhage, surgical emphysema and pneumothorax. The aim of this study was to identify risk factors that contribute to complications following tracheostomies.

**Research Question:** What are the determinants of early complications in patients undergoing tracheostomy in Kenyatta National Hospital (KNH)?

**Objective:** To establish the determinants of early complications following tracheostomies in KNH.

**Study Design:** This was a prospective cohort study. The study followed up for 7 days all in-patients who had undergone tracheostomy to determine the risk and risk factors for complications amongst this inpatient group.

**Study site:** This study was conducted in KNH situated in the city of Nairobi. KNH is a teaching hospital that sits at the apex of the pyramidal referral system in the Kenyan health sector.

**Study population:** All patients undergoing tracheostomy in KNH during the study period of October 2010 to March 2011, a total of 100 patients were recruited.

**Outcome Variables:** The outcome variables of each patient were the occurrence of complications following tracheostomy. These were related to the presumed risk factors.

**Data collection and analysis:** Data was collected by the principal investigator and research assistants using a questionnaire. Descriptive statistics and prevalence estimates (with 95%

confidence intervals). The data was analyzed using logistic regression for the various outcomes (intraoperative, post operative whether intra/post operative complication). Variables that were significant at 5% level from the univariable analysis were entered into the respective final multivariable models. Sex and age of patient, whether surgery was elective or emergency, whether surgery was performed under general or local anaesthesia, whether the condition was obstructive or not, site where surgery was performed and, the surgeon who performed the surgery were included in all the final models appropriately.

**Discussion:** One hundred patients who underwent tracheostomy in Kenyatta National Hospital were recruited into the study. The age ranged from one year old to eighty nine years old. In the study, 7/100 patients died; 4 of these patients' deaths were as a result of decannulation of their tracheostomy tube peri-operatively. Prevalence of intraoperative complications was 23% (95 % CI 14.61, 31.39) while that of post operative complications was 42% (95% CI 32.16, 51.84). These estimates were higher than those previously obtained in a retrospective study in the same institution. Excessive bleeding during the operation was the most common complication (21/100). The most common complications postoperatively were: pneumonia (17/100), emphysema (15/100) and infection of the tracheostomy site (10/100).

Interestingly, the study found a significant increase in morbidity with increasing age of the patient and in patients who had neck masses. Tracheostomies done in the operating room and those performed in ICU had no significant difference in complications. Moreover, no significant difference in complications was seen in patients whose tracheostomy was performed by residents visa vie consultants.

**Conclusion and Recommendations:** The prevalence of complications following tracheostomies in this study was comparable with the findings from other studies. The study put to rest fears of higher risks to the patients undergoing tracheostomy in ICU as no significant difference was noted in this group. It was also encouraging to note that the learning curve for residents learning and performing the surgery was not as steep as expected.

The importance of properly trained staff in perioperative care of patients post tracheostomy cannot be over emphasized. This is both in the operating room and ICU setting. The introduction of percutaneous dilatational tracheostomy technique in our setup is also likely to decrease complications and also improve the performance of tracheostomies in the institution.

## **INTRODUCTION**

*“The word Tracheostomy is used to describe the creation of a stoma at the skin surface which leads into the trachea”* (1). This surgical intervention has been described in the last few millennia and is a simple and life saving surgery. Before the nineteenth century it was rarely performed nor generally accepted by most physicians. In the last two decades a revolution of sorts has taken place for its acceptance into day to day medical management in critical care. Today it is widely used not only in treatment of upper airway obstruction, but also in Intensive care Units (I.C.U) to aid in artificial ventilation, which now constitute its main uses.

## **HISTORICAL PERSPECTIVE**

It is difficult to believe that dating as far back as 4000 years ago, *‘Rig Veda’*, a sacred Hindu handbook contains descriptions resembling a tracheostomy. Hundreds of years prior, the ancient Egyptians’ papyrus reeds, documented a technique that has been interpreted as a tracheostomy. This was one of the contributions made by this civilization that was advanced in medical and surgical techniques for their time. They also documented the use of surgical incisions to drain abscesses and cautery to control bleeding. One of the greatest and well known physicians of the time was Imotep, who is regarded by many to have been a genius in many fields. Up to the time of the Roman Empire, many physicians were still skeptical about tracheostomies. This did not deter *‘Asclepiades of Bithynia’* who, in 100AD, went ahead and performed the first tracheostomy that was properly documented (2,3). Literature is scant in the Dark Ages on the development of tracheostomies though Indian and Arabic texts still contain

some literature on the surgery. Guidi developed a new method of performing tracheostomies in the 16<sup>th</sup> century (2).

Literature has been obtained identifying a tracheostomy procedure in 1546 by Antonio Musa Brasavola. This is thought to be the 1<sup>st</sup> case in which a patient successfully recovered from the procedure. A peculiar case of a boy who '*tried to hide a bag of gold by swallowing it*' brought to the light the possible use of tracheostomies for the alleviation of upper airway compromise in children (2). However, it was not until 1765 when the surgical procedure was deemed safe as an emergency intervention for children who had severe difficulty breathing due to swelling in their airway (3). Indeed the diphtheria epidemic pushed the consideration of paediatric tracheostomies further. The technique was improved to save children from eminent death as a last resort and the dramatic effect it had was such that Fabricius would write in the 17th century, "*This operation redeems the honor of the physician and places him on a footing with the gods*" (4).

One of the greatest figures in history who is thought to have died of upper airway obstruction was George Washington, the first president of The United States of America, in 1799. He is thought to have had acute supraglottitis or a laryngeal abscess. It is said that his physician knew of a tracheostomy as a surgical option but had not done one previously. He was therefore not keen on performing one on the president himself and this led to a fatal outcome (5)

The word tracheostomy as we know it today was introduced in 1718 by Lorenz Heister (2). Chavalier Jackson is rightfully credited with the modern day technique of tracheostomy. He developed this technique during the height of the polio epidemic of the 1940's and the procedure has remained largely unchanged to date. (6).

## **BACKGROUND**

### ***TYPES OF TRACHEOSTOMY***

#### **Temporary tracheostomy**

*'This may be either elective or emergency'*. Temporary tracheostomy is done to secure an airway or to allow for prolonged ventilator use. In a temporary tracheostomy, the larynx is still present though may not be functional in the patient. Sometimes it is necessary to use a temporary tracheostomy for long term airway control when the primary lesion cannot be treated. (1).

#### **Permanent tracheostomy**

A permanent tracheostomy is made when the entire larynx is surgically removed as occurs in a laryngectomy or laryngopharyngectomy. In these patients, the lower airway is exteriorized through a tracheostome sutured on to the skin (1).

### ***INDICATIONS***

In the ABC's of resuscitation, an airway must be secured first. The level of airway obstruction will determine the intervention used. Tracheostomies are often used in patients with obstruction above the subglottis. During resuscitation it is always important to look for and manage other medical problems that may make breathing difficult despite a tracheostomy (1).

In developing countries tracheostomy is still predominantly being done for upper airway obstruction conditions.

In adults the most common indication is secondary to tumors. Macharia's study in 1990 over five years found that tumors accounted for 72.2% of adult upper airway obstruction (7). In children,



Swift et al (8) found congenital anomalies of the head and neck as the leading cause of upper airway obstruction accounting for 75%. Neoplasms of the head and neck can lead to upper airway obstruction and these include tumors of the larynx, hypopharynx, nasopharynx, oropharynx, oral cavity, thyroid amongst others (7).

Foreign body impaction of the airways is a rare indication in our set up. Macharia's study (7) did not find any patient requiring tracheostomy due to an inhaled foreign body. Okafor's study in 1983 (9) showed a high rate of 39% of tracheostomies performed secondary to foreign bodies.

Acute infection of the airways can cause upper airway obstruction. Such infections include Ludwig's Angina, severe tonsillitis and Diphtheria. In studies done by Okafor in Nigeria (9) and Soni in India (10), tracheostomies were performed in patients with severe laryngotracheobronchitis and acute epiglottitis. Today the trend is towards the use of intubation for severe cases.

Radiotherapy, inhalational burns and laryngeal instrumentation can result in laryngeal mucosal swelling with airway compromise. Paralysis of vocal cords following injury is a common occurrence in our setup following thyroid and neck surgery (7). The above may need a tracheostomy to secure the airway.

Maxillofacial trauma and laryngeal trauma, may lead to upper airway obstruction requiring a tracheostomy (7,11,12). Macharia's study (7) found an incidence of 6.1%.

Tracheostomies are often used in patients with excess bronchiopulmonary secretions to assist in tracheobronchial toilet. This is especially found in patients with chest injury secondary to trauma, bronchopneumonia, chronic bronchitis and other chest infections which lead to excess secretions secondary to an inflammatory process. Patients who are confined to their beds especially in I.C.U also accumulate chest secretions and tracheostomies aid in their aspiration (12,13).

The options available for patients on artificial ventilation are intubation and tracheostomy. Though patients are initially intubated, in cases where prolonged ventilator support is anticipated, a tracheostomy has been found to be safer and is thus preferred (1,11,12,14). Some particular advantages have pushed for the greater acceptance of tracheostomy tube over endotracheal intubation for ventilator support in I.C.U. It's been found that the patient is more comfortable with a tracheostomy tube and the cough reflex is less stimulated thus less sedation is required. It is easier to achieve oral and bronchial hygiene when using a tracheostomy. The dead space is reduced in a tracheostomy tube as compared to intubation and thus reduces the work of breathing in a patient with spontaneous respiration. It has also been found that patients with tracheostomies have less long term complications of subglottic stenosis as compared to patients with prolonged endotracheal intubation (1,7,10,11,12). Despite this, however, it still remains controversial over how long a patient should remain intubated before a tracheostomy is performed in I.C.U. This is especially so because of the current use of low pressure cuff tubes for intubation that is thought to be less deleterious than previously used tubes (10).

Many surgeries of the oral cavity and or pharynx as well as maxillofacial procedures are best performed after a prerequisite tracheostomy. An example of this is major tongue or floor of the mouth surgeries. This allows for a clearer and less cumbersome surgical field.

## **REVIEW OF LITERATURE**

As with any surgery, there are some complications associated with tracheostomies. The complications arising from this procedure have previously been reported to range from 6 to 66 % (7,13,15,16).

Complications of tracheostomy fall into the following categories: Early, which includes immediate and those within one week, and late complications.

Early complications are complications that occur within 1 week postoperatively (7,17,18,19).

Immediate complications are part of early complications that occur during the surgical procedure and include haemorrhage, apnoea, cardiac arrest, local injury; such as injury to thyroid cartilage, cricoid cartilage, and recurrent laryngeal nerve. Early post surgical complications include: Displacement of the tube, surgical emphysema, pneumothorax, haemorrhage, infection, tube obstruction by secretions or crusts, tracheal necrosis, tracheoarterial fistula, and dysphagia.

Late complications occur after one week post operatively and include: decannulation, tracheocutaneous fistula, disfiguring scar, tracheal stenosis and tracheomalacia.

### **Early complications of tracheostomies.**

Macharia, (7) in a retrospective study done at Kenyatta National Hospital of 115 patients over 5 years found a morbidity rate of 39% in adults undergoing tracheostomies and 78.3% of paediatric patients. Intraoperative complications were 7%. The commonest early complications noted during the study were: Surgical emphysema at 33.3%, infection at 27.8%, and tube displacement at 19.5% (7).

A retrospective study done by Zeitouni (20) found a complication rate of about 14% and a mortality rate of 2%. Very comparable was a study done by Lewis (21) that found a morbidity rate of 15% and mortality of 1%. A met analysis by Sicard (22), found an overall complication rate of 14%.

Bruno (23), conducted an Intensive care Unit (I.C.U) based study. He observed a complication rate of 30% after a 6 month follow-up. He also found that 22% of patients had developed a complication related to the tracheostomy during their admission. A retrospective study in the I.C.U of The Federal University of Sao Paulo was conducted for patients undergoing tracheostomy. Early complications such as haemorrhage were observed in 2.7% of the patients. However, the study had a relatively small sample size of 73 patients (24).

### **Anaesthetic complications related to the surgery.**

The anaesthetic options available for a tracheostomy are general anaesthesia and local anaesthesia. Whenever possible, intubation of the patient and subsequent tracheostomy is preferred in order for the surgeon to take his time and reduce complications. However in patients with upper airway obstruction that prevents intubation then that option is obliterated. Beatrous (14) reviewed 1000 tracheostomies and found that only 91 were done under general anaesthesia. This contrasts with Newlands study (15) that found 54 of the 57 tracheostomies were performed under general anaesthesia. Macharia (7) found that 79% of tracheostomies in KNH were done under general anaesthesia. Some of the anaesthetic complications include, drug reactions aspiration cardiac arrest and hypoventilation.

## **Haemorrhage.**

Most texts report haemorrhage as the most common complication. Many authors find this debatable (12). Tracheostomies performed electively have been found to have a low rate of haemorrhage as a complication. This is because in these cases the surgeon has an opportunity to maintain a bloodless field by paying particular attention to bleeders. This is more so if the patient has been intubated prior to the surgery. This is not so when the patient is undergoing an emergency tracheostomy where the priority is then to secure an airway. In these cases, the thyroid vessels and the thyroid isthmus are often injured with resultant haemorrhage (1,13).

Macharia's study at K.N.H found that 7.8% of patients had haemorrhage severe enough to be documented (7). This was comparable to a study done by Bruno (8) that obtained 7%. However the frequency of this complication in the latter study may be limited to the fact that all the tracheostomies were done electively. A met analysis on the complications of tracheostomies done by Durbin (26) also obtained a rate of 7% for haemorrhage. Dane's prospective study (16) found a 10% rate of haemorrhage post tracheostomy. Intraoperative haemorrhage was considered to be more than 200ml blood loss (6 soaked gauzes), whereas post op haemorrhage was considered as any bleeding postoperatively that warrants intervention (7).

This study seeks to obtain the rate of haemorrhage in our setup and compare between elective and emergency cases.

## **Pneumothorax and pneumomediastinum**

These are common complications encountered following a tracheostomy. The incidence in adults has been reported at 2 to 5%. Children are not only more likely to develop this complication, but also more likely to die from it (20). Various authors have offered different possible mechanisms for this injury. The most accepted theory is that it occurs due to tracking of air within the subcutaneous tissues brought about by forceful inspiration in patients with airway obstruction. The incision made during the tracheostomy provides a pathway for aspiration of air into the mediastinum. This exerts pressure that leads to rupture of the pleura leading to pneumothorax. It is also possible that direct injury of lung apex can occur during the surgery, especially in children where the apex is higher placed than in adults (27). This was especially indicated in Rabuzzi's study (28) in which 70% of children between 6 months and 2 years were observed to develop these complications. To avoid these complications, it is imperative that the surgeon maintains a strict midline dissection during the tracheostomy procedure.

## **Surgical emphysema.**

This complication results from entry of air into the subcutaneous tissues through a pathway created by the neck incision. If the skin is tightly closed thereafter, the air cannot leak out. This is exacerbated if the tracheostomy tube is obstructed by mucous or other secretions. Subcutaneous emphysema can be mild or severe. In severe cases, it can extend superiorly to the upper face and inferiorly to the chest wall. This can cause a mass effect that can lead to decannulation of the tracheostomy tube. The incidence of this complication is very high, and Macharia's study (7) in KNH reported it as 33.3%.

## **Tracheal-oesophageal fistula**

This complication results from either: Surgical injury of the posterior wall of the trachea and anterior wall of the oesophagus during the procedure or secondary to long term pressure of a tracheostomy tube on the posterior wall of the trachea. The main complaint from the patient is aspiration despite cuffing the tube. If it is secondary to direct surgical trauma, it usually appears earlier. The incidence in literature is reported to be about 0.01%. However, Macharia (7) found a higher incidence in KNH of 6.1%.

## **Decannulation and Tracheostomy Tube obstruction.**

A tracheostomy tube can be obstructed by thick secretions, blood clots or due to poor placement of the tube leading to obstruction of the lumen by soft tissues. It can also be too long, especially in children, and end up in one principle bronchus. This complication carries serious consequences especially in children and more so in the first 24 hours after the surgery. The mortality rate associated with this complication is up to 25% (22). The incidence in KNH of tube displacement or decannulation was up to 19.5% (7). It is important to ensure that the tube used has a curvature that is suitable for the patient and that the correct size is used. It is also important to suction the tube whenever necessary and to moisten inspired air to prevent crusting. In children this is even more critical. Decannulation is prevented by ensuring that any soft tissue that can herniate into the stoma is divided. This includes the thyroid isthmus. In our setup, the plate of the tracheostomy tube is sutured on to the skin of the anterior neck and the ties provided, properly applied. In patients where the risk of decannulation is high, a Bjork flap is used. In



children, stay sutures are inserted on either side of the tracheostome to aid in recannulation if necessary (1).

### **Wound infection.**

A tracheostomy is considered a '*clean contaminated wound*' (1). Different studies use different ways of diagnosing and classifying wound infection. Stauffer (13) found cases of stomal wound infection to be as high as 36%. However, his study found only 3-8% of patients had cellulitis and/or purulent wounds. Stomal infection has thus been reported in studies as a '*mild indolent infection, cellulitis or granulation tissue.*' However it can rarely manifests as a more serious infection such as mediastinitis, fasciitis or a frank abscess. In some severe cases, clavicular osteomyelitis has been reported. The colonizing bacteria have been shown to vary over the time of infection. Initially *streptococcus* and *staphylococcus* species are predominant but in chronic infections *pseudomonas* and other gram negative rods predominate (17). There is still no consensus on the use of prophylactic antibiotics. The contaminated wound produced following a tracheostomy may result in ulceration of laryngeal mucosa. This can lead to granulation tissue formation and later a stricture. Infection influences the amount of scar tissue or granulation tissue formed (1). Sasaki (29) performed an animal study with the use of prophylactic antibiotics and povidine iodine applied to the wound and showed a reduction in infection and laryngeal sequelae. His study demonstrated the positive effects of a topical antiseptic in wound infection control. However, there is a risk for selection of resistant organisms by the use of perioperative antibiotics. The sequelae of serious wound infection are wound closure, tube fixation and neurologic injury. In our set up, prophylactic antiobiotic cover is given to all patients after a

tracheostomy. The study in KNH found an incidence of wound infection post tracheostomy of 27.8% (7).

### **Pneumonia**

In some centres it is one of the most common complications. Gunawardana (30) observed a rate of 24.5% of pneumonia in patients post tracheostomy. The longer a patient is on a ventilator the more the risk of developing pneumonia. In this study the diagnosis was clinical, and backed by radiological features of chest infection. It was strengthened by positive cultures of pathogenic organisms in tracheal aspirates. These cultures mainly grew *Staphylococcus aureus*, *Escherichia coli* and *Pseudomonas aeruginosa* (30).

## ***Presumed risk factors for Complications***

### **Biographical data**

Age has been found to be a risk factor in the occurrence of complications. For example Pneumothorax and pneumomediastinum commonly documented complications following tracheostomy. A range of 2 - 5% has been found in adults and in children, the occurrence is as high as 17% and is a major contributor to mortality in this age group (20). Chest complications are more common in children due to the higher placement of the lung apex. Rabuzzi (28) found that children between half a year to 2 years old had a high incidence of this complication of up to 70%. Other complications are also higher in children to the reduced size of the structures and thus more easily injured (1).

No significant differences have been reported between males and females undergoing tracheostomies. This study assessed if indeed any significant differences occur in the complications between the sexes.

### **Indications**

Indications can be divided broadly as obstructive and non obstructive. Obstructive indications in our set up are mainly secondary to tumors and are more likely to be performed as emergencies. Bruno (23) found a complication rate of 20.9% in a study on elective tracheostomies whereas a study done by Morphy (31) found a complication rate of 35% in an emergency setting. Macharia (7) found a complication rate of up to 33.3% in a study that had both emergency and electively performed tracheostomies. Indications also include head and neck surgery, ventilator support and intractable aspiration. This study sought to compare the complications following tracheostomies for obstructive and non obstructive causes.

### **Intensive care Unit vs Operating room**

Up to 10% of patients in I.C.U undergo tracheostomy to assist in mechanical ventilation. No other surgical procedure is performed more commonly in I.C.U (32). The world wide trend is to perform these tracheostomies at the bedside. This avoids the risks involved in transporting a patient on ventilator support to busy operating theatres. The general complication rate for tracheostomies ranges from 6 to 66%. Bruno's study (23) of patients undergoing tracheostomies in I.C.U found a complication rate of 20.9% for early complications. This is within the range for complications observed in Operating rooms (7). This study found it useful therefore to compare the complication rates to assess if indeed bedside tracheostomies should be encouraged in the I.C.U.

### **Elective versus Emergency tracheostomies**

In general it has been noted that emergency tracheostomies have a higher complication rate than elective tracheostomies (7,31). This study compared the outcome from the two types of surgeries. It is also of note that elective cases are predominantly done under general anaesthesia whereas emergency cases under local anaesthesia. This study also sought to assess if the complications arising from each method of anaesthesia.

### **Surgeons experience.**

Few studies have been done to assess the learning curve in surgeons performing tracheostomies. A met analysis done by Kevin et al (33) shows an intraoperative complication rate of 10% for

percutaneous tracheostomies performed by residents in first year of practice versus 6% in the second year. The study further favors percutaneous dilation tracheostomy to open tracheostomy and the former is emerging as the method of choice. This study aimed to document the possible differences in complication rate of tracheostomies done depending on surgical experience.

## **STUDY JUSTIFICATION**

Tracheostomy is a common emergency surgical procedure carried out by ENT and head and neck surgeons, yet no previous prospective study had been done in our setup to assess the early complications of tracheostomies.

The study also related common risk factors with complications seen post tracheostomy with the aim of modification or improvement of the procedure to reduce the incidence of complications.

The study also aimed to determine the high risk patients for complications following tracheostomy in order to aid in prevention of the same.

## **RESEARCH QUESTION**

Are there risk factors which determine the prevalence of early post operative complications in patients following tracheostomy in KNH?

## **BROAD OBJECTIVE**

To determine the role of the presumed risk factors in causation of early post operative complications following tracheostomy.

## ***SPECIFIC OBJECTIVES***

1. To determine the prevalence of early complications following tracheostomies in KNH
2. To determine the indications for tracheostomies in KNH.
3. To assess the influence of presumed risk factors in early post op complications following tracheostomies in KNH.
4. To compare the complication rate of tracheostomies done in I.C.U and operating room and assess if bedside tracheostomies should be encouraged in the I.C.U.

## **METHODOLOGY**

### **Study design**

This was a prospective cohort study. The study followed up for 7 days all in-patients who had undergone tracheostomy to determine the risk and risk factors for complications amongst this inpatient group.

### **Study site**

This study was conducted in KNH situated in the city of Nairobi. KNH is a teaching hospital and sits at the apex of the pyramidal referral system in the health care sector in Kenya.

## **Study population**

All patients undergoing tracheostomy in KNH during the study period of October 2010 to March 2011.

## **Inclusion Criteria**

All patients undergoing tracheostomy in KNH (I.C.U, operating room, ward or casualty) were included in the study after obtaining informed consent. For those in I.C.U, consent was obtained from the next of kin as at the time of obtaining consent for the tracheostomy

## **Exclusion criteria**

These included the following:

1. Patients who declined to give informed consent
2. Patients who were undergoing permanent tracheostomies after laryngectomy

## **Consent**

Informed consent was obtained from all adult patients or from the guardians or next of kin for children and patients in ICU before induction into the study.

## **Recruitment**

The principle investigator with the help of his research assistants (ENT-HN surgery ) residents identified the patients to be recruited into the study and filled their details into a proforma designed for the study. Standard management of the patients was maintained during the study period.



## Sample size calculation

A complication prevalence of 14% has been used for sample size calculations, informed by Michael W. Sicard (22). Approximately 4 tracheostomies took place weekly at KNH thus it was expected that a total of 100 patients would be recruited in the six months of the study, Assuming power of 80% and  $\alpha=0.05$ (the corresponding  $z=1.96$ ) ,the precision of our estimate given the fixed sample size of 100 and a postulated prevalence of 0.14 can be found from the equation:

$$n = z^2 X p(1 - p)/d^2 \text{ Fisher et al(1998)} \quad \text{EQ 1}$$

$$d = \sqrt{\frac{1.96^2 X 0.14(1 - 0.14)}{n}} \approx .068 \quad \text{EQ2}$$

Thus a fixed sample size of 100 will sufficiently estimate the prevalence with 95% Confidence intervals at an acceptably high precision of +/- 6%.

The analysis strategy for the determinants of complications was analyzed as a **nested case-control**, with the resulting measures of effect being Odds Ratios (OR). Assuming a  $\alpha=0.05$ , varying prevalence of the exposure/risk in the control group, and with a fixed sample size of 100, the power (ability to reject the null hypothesis that OR=1) for different effect sizes are shown on table 1

Table 1: Power calculations

Prevalence of exposure controls	in	Odds Ratio			
		1.5	2.0	3.0	5.0
2%		0.153	0.397	0.834	0.997
5%		0.303	0.745	0.994	1.000
8%		0.432	0.897	1.000	1.000
10%		0.503	0.943	1.000	1.000
20%		0.729	0.995	1.000	1.000
30%		0.822	0.999	1.000	1.000
50%		0.856	0.999	1.000	1.000

Elective vs emergency – 10%

ICU vs operating room- 50%

Adult vs children - 70%

Indication: obstructive vs non obstructive-90%

### Sampling procedure

All eligible patients were sequentially recruited into the study and followed up for seven days by the principle investigator. The findings were documented in the standard proforma.

## **PROCEDURE**

All patients who met the inclusion criteria were recruited into the study and informed consent obtained from the patient, guardian or next of kin.

The biographic data, and the indication for the tracheostomy were recorded in the data collection sheet.

A thorough medical history was taken from the patient or their parents/guardians. This included obtaining a history of bleeding or coagulation disorders, a history of previous laryngeal or thyroid surgery and any history that defined the indication for the tracheostomy. All the information obtained was entered into the questionnaire.

A complete physical examination was done before surgery. This included a general as well as a thorough ENT examination. This included an assessment for previous surgery or gross malformation of the neck.

Intra-operative complications and intra-operative diagnosis was recorded by the principle researcher or by recruited research assistants.

### **Surgical Procedure**

Most of the tracheostomies were performed in the operating room or in I.C.U. Others were rarely performed in casualty or in the ward in dire emergencies. In the I.C.U, Operating room conditions were reproduced as much as possible. Adequate light, suction, instruments and assistance were provided.

The procedure was performed with the patient supine and neck extended using a sand bag and head stabilized using a head ring. The skin was prepared then infiltrated with a mixture of lignocaine and adrenaline and diluted with normal saline in a ratio of 2: 0.1: 17.9. A transverse

incision was used in this study. It was placed 2 finger breaths (approximately 3 centimeters) above the sternal notch. The incision was made up to the cervical fascia, cutting through the platysma. Any bleeders were identified, coagulated or ligated. The midline was identified visually or by palpation. Blunt dissection was performed on the midline thus retracting the strap muscles laterally. The thyroid isthmus was identified and either divided after cautery or retracted superiorly. The next structure encountered was the pretracheal fascia. This was dissected off the trachea over the first 3 to 5 tracheal rings. The prepared solution of local anaesthetic and adrenaline was then infiltrated into the membrane of the intended site for the tracheal window. This prevented bleeding, anaesthetized and reduced the cough reflex in patients whose tracheostomy was performed under local anaesthesia.

Stabilization of the trachea was done using a tracheal hook. A tracheal window was made on the second and third tracheal rings. This was the technique used for tracheostomies in this study. In children, 2 vertical stay sutures were placed on either side of the midline alongside the third and fourth tracheal cartilages. The trachea is then opened via a vertical incision through the third and fourth rings in between the stay sutures. The tracheostomy tube used was equivalent to the recommended endotracheal tube for the patient's age, sex and body size. It was ensured that the tube occupied two thirds to three fourths of the tracheal lumen. In children, the tracheostomy tube used was none cuffed.

Prior to insertion the tubes were lubricated with jelly to prevent mucosal laceration or injury. The position of the tracheostomy tube within the trachea was ascertained and then cuffed in adults. In large incisions, loose sutures were placed on either end of the incision, otherwise it was left open. The tube was secured using the provided ties around the neck and by suturing the

tracheostomy plate to the skin on either side. The wound was dressed with iodoform soaked gauze (1,7,12,22).

Thereafter, the patient was reviewed daily and assessment made for any complications that may have arisen in the first 7 days. Any complications that occurred were recorded as well as the investigations done and treatment given. A daily general examination and ENT examination was carried out by the principal investigator to assess for any complications.

The complications were investigated and managed as was required. For example chest X rays – for suspected chest infections or pneumothorax, culture and sensitivity for infections.

## **STATISTICS/ DATA MANAGEMENT**

Data collected was initially entered in a pretested data collection sheet. These were then entered into a customized Microsoft Access database with checks to minimize error in entry. Analysis were then conducted in Stata v 11.0

Descriptive statistics were calculated including tabulation of the patient characteristics, presenting complaints, physical examination findings, and characteristics of the tracheostomy surgery (site, surgeon, reason). These are also presented cross tabulated against the various complications. Complications were aggregated into intraoperative and post operative by counting those patients with at least one complication.

The prevalence estimates and their 95 % confidence intervals were calculated using large sample formula in Stata's proportion command. Where the events were few and the estimated proportion outside the acceptable range (0-100%), truncation was done; values below zero are reported as zero while those above 100 are reported as 100.

To investigate association between the complications and various patient and surgery characteristics, a series of univariable logistic regression were fitted. Variables that did not have a positive event were left out and included: cough and hotness of body. Variables that were significant at 5% level were entered into the respective final multivariable models. Sex and age of patient, whether surgery was elective or emergency, whether surgery was performed under general or local anaesthesia, whether the condition was obstructive or not, site where surgery was performed and, the surgeon who performed the surgery were included in all the final models appropriately. In the multivariate models the casualty and ward as sites where tracheotomy was

performed were dropped, as the limited number (n=4) caused problems with convergence. Age was centered at the grand mean (i.e. grand mean minus individual patient's age ).

The results are presented as odds ratios with 95% confidence intervals. Statistical significance is at the nominal value of 5%. An odds ratio less than 1 indicates that the odds of having a complication were lower for a given characteristic than for the reference level, whereas an odds ratio of 1 or more indicates that the odds of a complication were greater. Since age is centered at the grand mean, the interpretation of the odds ratio is the increase/decrease in the odds of a complication for one year increase in age for a patient with the mean age for the population studied.

## **ETHICAL ISSUES**

Approval was sought and obtained from the Standards and Ethics committee of Kenyatta National Hospital prior to beginning the study.

Informed consent was taken from the participating patients or their parents or guardians.

Those who declined to consent for the study received the same management as those participating in the study.

There was no extra cost to the patient for participating in the study.

Confidentiality of the participating subjects was maintained at all times. Names, and numbers obtained on the questionnaires were to be used only for purposes of follow-up if there was need.

The results of the study will be published and made available for use by members of the medical fraternity.

## **BUDGET ESTIMATES**

Table 2: Budget

<b>Description</b>	<b>Quantity</b>	<b>Unit cost</b>	<b>Amount</b>
Research fee		1500	1,500
Data analysis		20,000	20,000
Stationery + printing	5 reams printing paper+ printing	400x 5 + 5000	7,000
Books and Journals			15,000
Contingencies			10,000
Miscellaneous			10,000
<b>Total</b>			<b>63,500</b>



## PROPOSED STUDY PERIOD

Table 3: Timelines

Protocol presentation	July 2010
Ethics approval	July-October 2010
Data collection	October 2010 – March 2011
Data analysis	March- 2011
Dissertation Writing	April – 2011
Presentation and Submission of Dissertation	April – 2011

## RESULTS

### *Descriptive*

One hundred patients were recruited into the study between October 2010 and February 2011. The characteristics and presenting complainants of the patients are shown in table 4. Of the 100 patients, 24/40(24%) of the patients were female. A majority of the patients (65%) reported being in some form of employment, either formal or informal. About a half of the patients were first seen in casualty. The median age was 40 years (range 1.5 – 89 years). The distribution of age is shown in figure 1.

**Table 4: Characteristics and presenting complaints of the patients tabulated against the various complications (N=100)**

<b>Variable</b>	<b>n(%)</b>
Age(median, range)	40 , 1.5-89
Sex(female)	24(24.0)
Occupation	
Student	16(16.0)
Unemployed	19(19.0)
Working	65(65.0)
Department of first visit	
Casualty	52(52.0)
ENT	38(38.0)
Missing	10(10.0)

n=number of patients in that category. Total number of patients=100

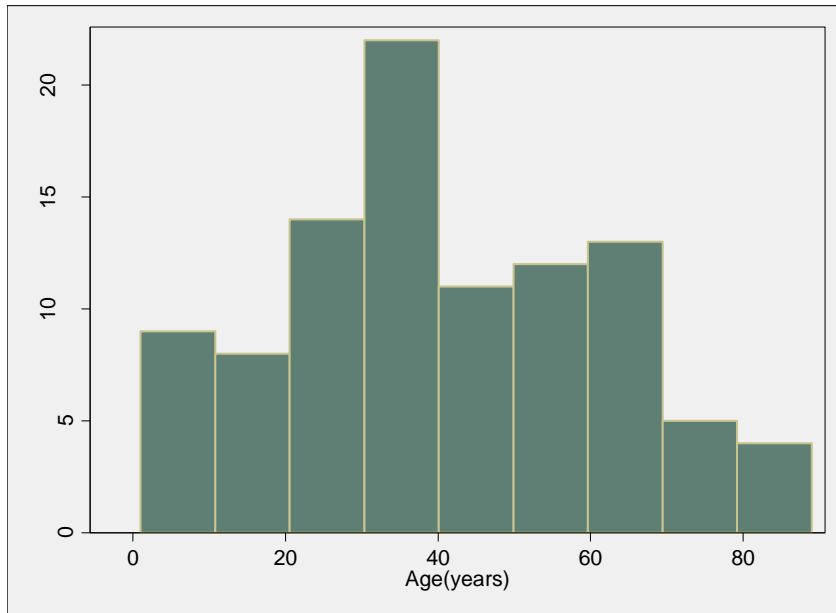


Figure 1: Graph of age distribution of patients undergoing tracheotomy during the study period

The main presenting complaints were difficulty in breathing (46%), stridor (42%) and difficulty in swallowing (12%) as seen in table 5.

Table 5: presenting complaints of patients undergoing tracheostomies.

Main presenting complaints	n(%)
Difficulty in breathing (yes)	46(46.0)
Stridor (noisy breathing) (yes)	42(42.0)
Cough(yes)	0(0)
Foreign body inhalation(yes)	1(1.0)
Hotness of body (yes)	0(0)
Trauma	5(5.0)
Difficulty in swallowing(yes)	12(12.0)
Neck swelling(yes)	8(8.0)

n=number of patients in that category. Total number of patients=100

Table 6 shows the findings of the physical examination. The most common positive findings on examination were presence of pallor (17%), cervical adenopathy (13%).

Table 6: Clinical examination findings(N=100)

<b>Variable</b>	<b>n(%)</b>
Pallor (yes)	17(17.0)
Cervical adenopathy (yes)	13(13.0)
Mass on indirect laryngoscopy (yes)	9(9.0)
Mouth (mass/trauma)	7(7.0)
Nose (mass/trauma)	6(6.0)
Widened laryngeal framework(yes)	6(6.0)
Neck mass(yes)	5(5.0)
Previous surgical scar(yes)	3(3.0)
Ear (mass/trauma)	2(2.0)
Trachea displacement (yes)	1(1.0)

n=number of patients in that category. Total number of patients=100

The characteristics of the surgery are tabulated in table 7. A majority of the tracheotomies were conducted in the operating room (61%). The tracheostomies were distributed approximately equally into those due to obstructive and non obstructive causes. About 7 in 10 of the tracheotomies were conducted under general anaesthesia while the majority of surgeries (9/10) were conducted by were conducted by a registrar.

Table 7: Characteristics of the surgery(N=100)

<b>Variable</b>	<b>n(%)</b>
Site where tracheostomy is performed	
Casualty	3(3.0)
I.C.U	35(35.0)
Operating room	61(61.0)
Ward	1(1.0)
Obstructive	47(47.0)
Non Obstructive	53(53)
Emergency	46(46.0)
Elective	54(54)
General anaesthesia	71(71.0)
Local Anaesthesia	29(29)
Surgeon	
Consultant	10(10.0)
Registrar	90(90.0)

n=number of patients in that category. Total number of patients=100

Table 8 shows the prevalence (and the corresponding 95% confidence intervals) for the various complications observed. Overall, 56% experienced at least one complication either intraoperative or post operatively. 9/100 had both intra and post operative complications. Twenty three patients experienced at least one intraoperative complications (prevalence: 23%, 95% CI: 14.61, 31.39). One patient had 2 intraoperative complications (haemorrhage and decannulation). Excessive bleeding during the operation was the most common complication (21/23).

Seven patients enrolled in this study died: - 4/7 of the patients' deaths were as a result of decannulation of their tracheostomy tube peri operatively; The decannulation leading to death all occurred within minutes to 2 hours after the surgery 1/7 of the patients' died as a result of the severe head injury they had sustained; 1/7 of the patients' died as a result of pneumonia while in intensive care unit; 1/7 patients' developed a cardiac complication immediately postoperatively.

4/7 of the deaths occurred in patients whose tracheostomies were performed in the operating room and all were emergencies while 2/7 of the deaths occurred in ICU in elective surgery for prolonged intubation. One of seven of the deaths occurred in casualty after an emergency tracheostomy.

Complication directly related to the tracheostomy procedure observed over a 7 day post operative period are also shown in table 7. Overall 42/100 patients enrolled in this study experienced at least one post operative complication. The most common complications were:- pneumonia, emphysema and infection of the tracheostomy site. 12 patients had 2 contemporaneous complications. Five of these patients had both an infection at the site of tracheostomy and emphysema; three had an infection at the site of tracheostomy and pneumonia; one had emphysema and pneumonia and; one had emphysema and tube obstruction; one had haemorrhage and tube obstruction; one had pneumonia and tube obstruction.

Table 8: Prevalence estimates for the various complication and 95% Confidence intervals

<b>Variable</b>	<b>n/N (%)</b>	<b>95% Confidence intervals</b>
<b>Intraoperative</b>	<b>23(23.0)</b>	<b>14.6, 31.4</b>
Haemorrhage	21(21.0)	12.9 , 29.1
Decannulation	3(3.0)	0, 6.4
Injury to structures	1(1.0)	0, 3.0
Tube displaced	1(1.0)	0, 3.0
<b>Post-operative complication</b>	<b>42(42)</b>	<b>32.7 , 51.8</b>
Death	7(7.0)	1.9, 12.1
Pneumonia	17(17.0)	9.5, 24.5
Emphysema	15(15.0)	7.9, 22.1
Decannulation	5(5.0)	0.7 , 9.4
Infection	10(10.0)	4.0 , 16.0
Tube obstruction	5(5.0)	0.7 , 9.3
Haemorrhage	2(2.0)	0, 4.8
TOF	2(2.0)	0 , 4.8
Pneumothorax	0(0)	-
Pneumomediastinum	0(0)	-

n=no with complication; N= total number of patients (100); ¶Note that this totals represent the occurrence of at least one complication. 3/23 and 14/42 patients with intraoperative and postoperative complications had 2 complications occurring together respectively.

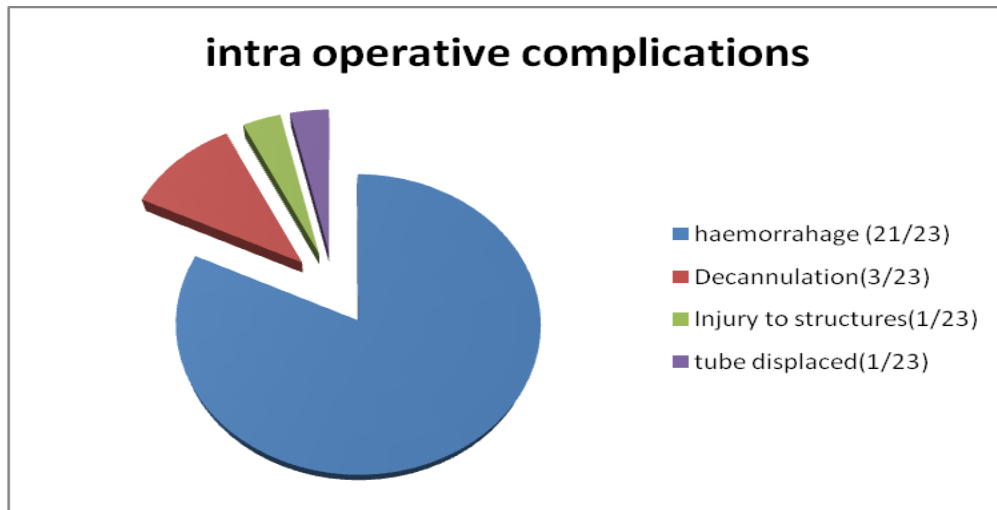


Figure 2: intra operative complications

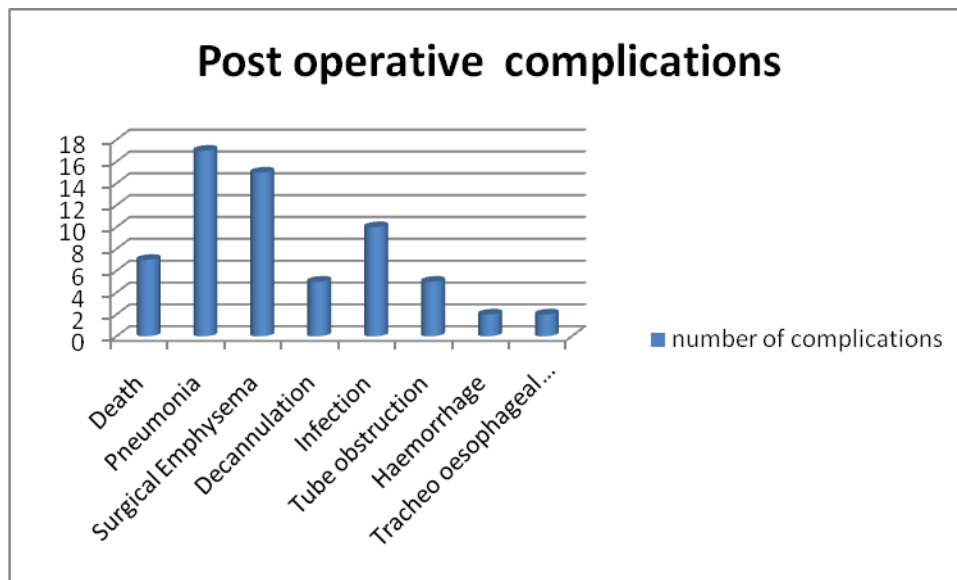


Figure 3: graph of post operative complications.

### ***Logistic regression***

The results of the univariable logistic regression are presented in table 9. Patients occupation, history of difficulty in breathing, stridor and trauma, pallor, neck mass, site of surgery, whether surgery was elective or emergency, whether the patient had an obstructive cause or not and, type of anaesthesia were all independently associated with occurrence of intraoperative complications. No variables were significantly associated with post operative complication at the 5% level.

The results of the final models are shown in table 10. The estimates comparing the odds of an intraoperative complication between those with an obstructive or non obstructive cause and, those who had the surgery done as an emergency or as an elective case were poorly estimated by the model and the results have been excluded. The odds of any complication increase by 2% ( $p=0.026$ ) for every one year increase in age. Compared to those who had their tracheostomy performed in ICU, those who had it performed in the operating room were at approximately four fold odds of post operative complications( $p=0.017$ ).



Table 9: Results of univariable logistic regression

Variable	Intraoperative complications				Post operative complications			
	n/N (%)	OR	95% CI	<i>p value</i>	n/N (%)	OR	95% CI	<i>p value</i>
<b>Demographic characteristics</b>								
Age(centered)	-	1.02	0.99, 1.04	0.144		1.01	0.99, 1.03	0.179
Gender:								
Female	7/24(29.2)	Ref			8/24(33.3)	Ref		
Male	16/76(21.1)	0.65	0.23, 1.83	0.41	34/76(44.7)	1.62	0.62, 4.24	0.326
Occupation								
Student	1/16(6.3)	Ref			4/16(25.0)	Ref		
Unemployed	3/19(15.8)	2.81	0.26, 30.09	0.39	10/19(52.6)	3.33	0.78, 4.16	0.103
Employed	19/65(29.2)	<b>6.2</b>	<b>0.76, 50.27</b>	<b>0.09</b>	28/65(43.1)	2.27	0.66, 7.79	0.193
<b>Clinical signs</b>								
Nasal mass								
No	21/95(22.1)	Ref			35/83(42.2)	Ref		
Yes	2/5(40.0)	2.35	0.37, 15.00	0.37	7/17(41.2)	0.33	0.04, 3.06	0.329
Oral mass								
No	22/93(23.7)	Ref			41/93(44.1)	Ref		
Yes	1/7(14.3)	0.54	0.06, 4.71	0.58	1/7(14.3)	0.21	0.02, 1.83	0.158
Pallor								
No	16/83(19.3)	Ref			35/83(42.2)	Ref		
Yes	7/17(41.2)	<b>2.93</b>	<b>0.97, 8.89</b>	<b>0.06</b>	7/17(41.2)	0.96	0.33, 2.77	0.94
Cervical adenopathy								
No	20/87(23.0)	Ref			34/87(39.1)	Ref		
Yes	3/13(23.1)	1.01	0.25, 4.01	0.99	8/13(61.5)	2.49	0.75, 8.26	0.135
Widened laryngeal framework								
No	21/94(22.3)	Ref			39/94(41.5)	Ref		
Yes	2/6(33.3)	1.74	0.30, 10.16	0.54	3/6(50.0)	1.41	0.27, 7.36	0.683
Neck mass								
No	20/95(21.1)	Ref			39/95(41.1)	Ref		
Yes	3/5(60)	<b>5.62</b>	<b>0.88, 35.99</b>	<b>0.07</b>	3/5(60.0)	2.15	0.34, 3.50	0.413

Mass on indirect laryngoscopy									
No	2/9(22.2)	Ref				41/99(41.4)	Ref		
Yes	21/91(23.1)	0.95	0.18, 4.94	0.95		1/1(100)	1.12	0.28, 4.43	0.876
Surgical scar									
No	21/97(21.7)	Ref				40/97(41.2)	Ref		
Yes	2/3(66.7)	7.24	0.63, 83.76	0.11		2/3(66.7)	2.85	0.25,32.51	0.399
<b>Characteristics of surgery</b>									
Site where tracheotomy is performed									
ICU	4/35(11.4)	Ref				12/35(34.2)	Ref		
Casualty/ward	3/4 (37)	<b>0.04</b>	<b>0.00, 0.52</b>	<b>0.01</b>		2/4(50.0)	0.52	0.07, 4.18	0.54
Operating room	16/61(26.2)	<b>0.12</b>	<b>0.01, 1.22</b>	<b>0.07</b>		28/61(45.9)	0.85	0.11, 6.42	0.874
Type of surgery									
Elective	18/48(37.5)	Ref				22/52(42.3)	Ref		
Emergency	5/47(9.6)	<b>5.64</b>	<b>1.89, 16.80</b>	<b>0.0001</b>		20/48(41.7)	0.97	0.44, 2.16	0.948
Reason for surgery									
Non obstructive	15/46(32.6)	Ref				22/54(40.7)	Ref		
Obstructive	8/54(14.8)	<b>2.78</b>	<b>1.05, 7.35</b>	<b>0.04</b>		20/46(43.5)	1.12	0.50, 2.48	0.782
Anaesthesia									
General	11/29(37.9)	Ref				29/71(40.9)	Ref		
Local	12/71(16.9)	<b>3</b>	<b>1.13, 7.95</b>	<b>0.03</b>		13/29(44.8)	1.18	0.49, 2.81	0.714
Surgeon									
Registrar	22/90(24.4)	Ref				5/10(50)	Ref		
Consultant	1/10(10)	2.91	0.35, 24.29	0.32		37/90(41.1)	0.7	0.19, 2.58	0.59

Notes: n=number of patients in the specific category with complication; N=total number of patients in the category; OR = odd ratio; 95% CI= 95% confidence interval; ref= reference category, category with which other categories are being compared to.

Table 10: Results of Multivariate logistic regression.

Variable	Intraoperative			Post operative		
	OR	95% CI	<i>p</i> value	OR	95% CI	<i>p</i> value
Age (centered)	1.02	0.97, 1.06	0.468	<b>1.02</b>	<b>1.00, 1.05</b>	<b>0.072</b>
Gender: male vs female	<b>0.04</b>	<b>0.00, 0.33</b>	<b>0.003</b>	1.99	0.67, 5.94	0.218
Occupation: unemployed vs student	0.12	0.01, 2.23	0.155			
Occupation: working vs student	<b>0.02</b>	<b>0.00, 0.50</b>	<b>0.018</b>			
Pallor: yes vs no	2.49	0.37, 16.64	0.347			
Neck mass: yes vs no	31.34	1.17, 836.89	0.04			
Site where tracheotomy is performed: operating room vs I.C.U	0.11	0.00, 5.74	0.27	<b>4.27</b>	<b>1.07, 17.07</b>	<b>0.04</b>
Emergency vs elective	<sup>a</sup>	<sup>a</sup>	0.986	0.17	0.01, 2.16	0.171
Obstructive vs non obstructive	<sup>a</sup>	<sup>a</sup>	0.989	1.49	0.13, 17.18	0.748
Anaesthesia: local vs general	0.87	0.15, 5.19	0.878	0.89	0.26, 3.09	0.854
Surgeon: registrar vs consultant	8.85	0.26, 301.13	0.226	0.97	0.21, 4.49	0.965

N=total number of patients in the category; OR = odd ratio; 95% CI= 95% confidence interval. <sup>a</sup> poorly estimated and results thus unreliable

## DISCUSSION

In this prospective study at Kenyatta National Hospital, 100 patients who underwent tracheostomy were recruited into the study. Review of literature found that the range of complications post tracheostomy was 6% to 66% (7,13,15). In this study, intraoperative complications were found to be 23% (95% CI 14.61, 31.39) and early postoperative complications found to be at 42% (95% CI 32.16, 51.84). Some patients experienced both intraoperative and post operative complications (56%). The prevalence estimates are higher than those obtained by Prabhat et al (34), and Zeitouni (20) who found a complication rate of 18.36%, and 14% respectively. However these studies data were collected retrospectively and thus the probability of missing out on cases or recall bias is high. In these two studies no differences in complications were found in elective versus emergency surgeries. These findings are in agreement with those of the present study.

In a retrospective study by Macharia (7) in 1990 at Kenyatta National Hospital, the prevalence of intra operative complications was only 7%. Again this may have arisen from poor documentation of complications as data in that study were collected by reviewing medical charts retrospectively. The foregoing underscores the importance of proper medical record keeping a problem observed in both low and high income countries. The medical records required for Macharia's study (7) was also long at 5 years. This negatively affects the quality of data obtained.

In the present study the most common intraoperative complication found was haemorrhage at 21% (95% CI 12.88, 29.12). This estimates are consistently higher than those observed by Macharia et al (7.8%), Bruno et al (7%) and Dane et al (10%) (7,8,16). However the study by Bruno et al was only on elective tracheostomies and therefore well stabilized before the surgery. If one considered elective tracheostomies only in this study the prevalence of hemorrhage intra

operatively is comparable to that of Bruno et al (8) (7.4%, 95% CI 0.20, 15.18). Majority of cases with intraoperative hemorrhage were therefore among patients whose surgery was an emergency (Prevalence 35.41, 95% CI 21.38, 49.4)

Zero point five percent to 1.6% of patients post tracheostomy die, mostly due to displacement of the tracheostomy tube. In this study intraoperative decannulation of the tracheostomy tube was found to be at 3% and 5% intraoperative and postoperatively respectively. The mortality from decannulation was 4 out of 8 patients. This is a mortality rate of 50%. Worldwide studies have also found a high mortality rate for this complication of up to 25% (22). Failure to recognise the complication early may explain the high rates of death experienced in the present study. Health workers are either inadequately trained to quickly identify the complication and manage it in a timely fashion or inadequate in number to properly monitor the patients postoperatively. Zeitouni et al found a mortality rate of 2% in elective tracheotomies (20). Similarly 2/7 of deaths occurred after elective tracheotomy in our study.

Surgical emphysema was one of the common complications noted in this study and the rates were found to be at 15%. Previously found to be at 33.3% in Macharia's study. This complication varies from mild to severe. In severe cases, the tracheostomy tube can be displaced. Other studies, such as that done by McClelland (36), found 16 patients with surgical emphysema out of 389 patients in whom tracheostomies were performed, a rate of about 4%. The reason for the marked differences is not easily perceivable. The technique of closure of the incision may have a role or in some studies mild emphysema may go unreported.

A total of 10 patients were found to develop wound infection. Of these, one patient's stoma cultured pseudomonas while one cultured staph aureus. Both patients were in ICU. The other 8

did not culture any organisms on the swabs taken. No significant difference was noted in the number of wound infections in patients whose tracheostomies were done in ICU and those done in the Operating room. Of the 10 patients with wound infection 6 were done in the Operating room. All the infections were mild ranging from mild cellulitis to granulation tissue. The incidence in Macharia's study was 27.8%.which was much higher compared to this study. This may be attributed to the current practice of prophylactic antibiotic cover for patients post tracheostomy.

Patients found to develop pneumonia post tracheostomy in this study were 17%. This approaches the values obtained by Gunawardana (30) which were at 24.5%. however it is important to note that 8 out of 35 patients whose tracheostomy was done in I.C.U were already on treatment for pneumonia while the other 8 patients developed pneumonia after tracheostomy in the Operating room and 1 after the surgery in the ward. Ventilation associated pneumonia is a confounder related to these figures. Studies show approximately 40% of patients on respirator develop pneumonia and this could have contributed to the higher figures obtained especially in I.C.U (32). Gunawardana's study (30) was based on patients undergoing tracheostomies in ICU, and the high incidence of pneumonia in his study emphasizes the high rates of ventilation associated pneumonia.

In this study it was found that 71% of the tracheostomies were done under general anaesthesia. This was close to the figure of 79% obtained by Macharia (7). In contrast the study done by Newlands (15), 54 of 57 patients were done under general anaesthesia. This is probably due to the fact that, in our setup, the patients operated under local anaesthesia had advanced disease limiting the possibility of intubation compared to those done by Newlands (15). The only

anaesthetic complication noted in this study could attribute to the development of cardiac complications and subsequent death of one of the patients recruited for the study.

### ***Presumed risk factors of complications.***

#### **Biographic data**

Age has been found to be a risk factor in the occurrence of complications. In this study no patients were found to have pneumothorax or pneumomediastinum post tracheostomy. In contrast, Rabuzzi (28) found a rate of 70% with this complication in children between the age of 6 months and 2years. In this study, however, only 2 patients were below the age of two years and therefore may have been insufficient to review this trend. None the less what was found was that the odds of post operative complication increase by 2% (95% Confidence Interval and p value of 0.026) for every one year increase in age from the grand mean of 41.5 years (table 9). However, after adjusting for other variables the risk was not found to be significant.

Males were at 96% lower odds of intraoperative complications compared to females (p = 0.03). This significant difference in complications could be attributed to the difference in anatomy between males and females with an increased likelihood of females having a shorter and fatter neck. However a larger sample size maybe necessary to make this a definitive conclusion.

Patients who were working had a 2% increased risk of developing complications as compared to students. This is likely to be due to the fact that the working group were older and were admitted with obstructive symptoms as compared to the student group. More than half of the students' tracheostomies were performed in I.C.U (9/15).

## **Indications**

These were broadly divided into obstructive and non obstructive indications for the tracheostomy. Patients with obstructive symptoms are likely to have tracheostomies done under local anaesthesia and also as emergencies. This could lead to the higher rate of complications. In this study there was no significant increase in complications in patients with obstructive symptoms.

Tracheostomies done as emergencies were found to have a higher rate of complications. It was found that these surgeries had a complication rate of 73.9%.of all patients with complications. When this is compared with elective tracheostomies in a multivariate analysis, the difference was not significant. However the high incidence of complications in emergency tracheostomies is in keeping with other studies done where Morphy (31) found a complication rate of 35% in emergency setting while Bruno (21) found a complication rate of 20.9% in electively done tracheostomies. In our setup, this rate is much higher possibly because patients undergoing emergency tracheostomies have advanced disease in comparison to those in more developed countries.

A predominant use of general anaesthesia was noted in this series just as in that of Macharia (7) with 71% and 79% of tracheostomies done under general anaesthesia respectively. Tracheostomies done under local anaesthesia had a complication rate of 11 out of 23 patients who had complications or 47.8% of the complications intra - operatively. Multivariate analysis found no significant increase in risk of complications in cases done under general anaesthesia compared to local anaesthesia (table 10). The fact that a large number of patients have their tracheostomies done under local anaesthesia in our setup may aid in the development of the



surgeon's skill thus no significant differences in complications when corrected for other variables.

### **Intensive care versus Operating room**

The complications seen in patients whose tracheostomies were performed in Intensive care unit were 4/23 for intra – operative complications (17.4%) and 12/42 for postoperative complications (28.57%). As compared to complications encountered in patients whose tracheostomy was performed in the operating room there was a reduced risk of complications of tracheostomies performed in ICU. There was a 5 times increased risk of complications in the Operating room tracheostomies compared to those performed in I.C.U in the multivariate analysis (table 10). This is an encouraging result as it was also noted that all tracheostomies performed in I.C.U were done by residents. It also shows that there is a reduced risk of complications in intubated patients and electively done tracheostomies. The incidence of 24.6% of early complications also closely compares with that of Gunawardana's study (30) which had an incidence of 24.5%, in an ICU based study.

### **Surgeons Experience**

In this study 90 of the 100 tracheostomies performed were done by residents. One of the 10 patients whose tracheostomy was done by a consultant developed an intraoperative complication. Four of the 10 patients developed post - operative complications. Twenty two of the patients whose tracheostomy was performed by a resident developed an intraoperative complication, while 38 patients had a postoperative complication. After multivariate analysis, no significant increase risk for complications was found in patients whose tracheostomy was performed by a consultant or a resident. However it is important to note that the tracheostomies performed by a

consultant were those which were perceived to be difficult or expected to be challenging. An example of this is children under 5 years old and patients in poor general condition. The meta-analysis done by Kevin et al (33) did show a difference in complication rates of 6% for 2nd year residents versus 10% for 1st year residents in percutaneous tracheostomies. The study by Kevin et al (33) does not control for variables that may have been present. It is also worth noting that the learning curve may not be revealed in this study as residents assist their seniors until they are ready to perform the tracheostomies on their own.

### **Clinical state of the patient**

A surprising significant finding was that the odds of intraoperative complications was increased 31 fold for patients who had a neck mass ( $p=0.04$ ). This could be due to the distortion in the anatomy of the neck as a result of the mass. Other studies encountered did not account for the presence of a neck mass in their analysis.

### **CONCLUSION**

The overall intraoperative complication rate was found to be 23% (table 8). Early post operative complications were found to be 42%. Patients who had either intraoperative, postoperative complications or both, were 52% (some patients had both intraoperative and postoperative complications). This finding was in concurrence with other studies that obtained a range of 6-66% (7,13,15). An increase in risk for complications was seen in this series in patients who are older and in emergency cases as well as those performed under local anaesthesia and for those performed by residents vis a vis consultants. However these were not found to be significant after

multivariate analysis. A significant risk was noted for patients whose tracheostomy was performed in the Operating room compared to those performed in I.C.U and for those patients who presented with a neck mass.

## **LIMITATIONS**

Some of the limitations to the study were obtaining consent from patients or their relatives for those in I.C.U especially because most of the patients requiring tracheostomy were quite ill.

Routine Chest X Rays post tracheostomy especially for I.C.U patients would have helped rule out pneumothorax and haemothorax.

A larger sample size would help in evaluating those variables with borderline results.

It is difficult to compare with results from other parts of the world if the techniques used for performing tracheostomies are different.

## **RECOMMENDATIONS**

1. The emerging trend in the world is the use of percutaneous dilatation tracheostomy. This can be performed at the bedside especially in I.C.U. Studies have shown a decrease in complications as compared to open tracheostomy as seen in the met analysis by Kevin et al (33). One of the currently practiced methods is one developed by Ciaglia (37). Dilators of increasing size are used to enlarge an opening into the trachea into which a tracheostomy tube can be passed in. Ciaglia also pioneered the use of a '*single tapered dilator.*' As a result, seasoned surgeons can now perform the procedure much faster. An

introduction of single use kits and the use of bronchoscopy to assess the placement of the tube have made the procedure even safer. Freemans met analysis (38) of prospective studies on Ciaglia's technique found that the technique was easier to perform than previously described techniques and had less potential for complications especially bleeding and infection.

2. It would also be useful to contemplate early tracheostomy for patients who have obstructive symptoms if encountered in our set up. As the study has shown, those patients in whom tracheostomy is done as an emergency and also under local anaesthesia due to failure of intubation have had a worse outcome.
3. Bedside tracheostomies in I.C.U have been found to be useful and not fraught with increase risk. The procedure could be improved by; improved lighting, and better qualified assistants and by improving perioperative monitoring of patients. The introduction of percutaneous dilatation tracheostomy could improve on safety and outcome of the surgery.
4. The need for properly trained staff to manage patients undergoing tracheostomies perioperatively cannot be over emphasized. This would help in reducing complications and also prevent some mortality that was noted in this study.

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# **APPENDIX 1**

## ***GENERAL PATIENT INFORMATION AND CONSENT FORM***

### **General patient information**

We would like to seek your consent to participate in a study aimed at understanding the various aspects of the complications resulting from tracheotomies. This will include the rate, timing and the various risk factors associated with these complications. This will enable us to improve on the surgery wherever it is performed.

### **How to participate**

1. We will ask you questions seeking to know how the disease started, investigations done, any treatment given and the response to it.
2. We shall record any findings of examinations done, any investigations done for diagnosis and for surgery, how and where the surgery is done.
3. We shall monitor your progress closely during and after surgery, and note any complications that may occur. In case of any complications, they shall be managed accordingly. We shall review the patient over one week to monitor the progress.
4. Similar findings from all participants will be used to compute the rate, timing and the factors associated with the complications arising from this procedure.

### **How does your participation affect you?**

It does not adversely affect you in any way because:

1. You will receive the same treatment without participating in the study.

2. No treatment will be given to you in addition to what you require and you would ordinarily get were you not participating in the study.
3. All information given by you will be accorded confidential treatment.

**Are there any hidden dangers?**

1. Not at all.
2. Refusing to consent will not affect the management you receive either.

**How does your participation help us?**

1. The findings in the study will help us improve management of similar patients in the future.
2. We shall share the findings of the study with other professional colleagues elsewhere. Thus the findings can be published in scientific journals or be presented at scientific conferences without divulging specific patient information.
3. You are free to discuss this with family members and we shall be ready to answer any questions raised. If you understand everything said and have accepted it then you can sign the consent form provided.

## APPENDIX II

### ***CONSENT FORM Patients less than 18years (English)***

I Mr./Mrs./Ms.....the parent /guardian of  
master/miss..... agree to enroll him/her into the  
study as explained to me by Dr.....

My signature is confirmation that I have understood the nature of the study and that whatever  
information that I give will remain confidential.

I also confirm that no monetary or material gains have been promised or given to me for  
participating in the study.

Signed.....(patient/guardian's signature).

Relationship..... Date:.....

Signature of principal investigator..... Date:.....

### ***Consent for patients more than 18 years***

I Mr./Mrs./Ms ..... agree to enroll into the study as explained to me  
by Dr ..... My signature is confirmation that I have understood the  
nature of the study and that whatever information that I give will remain confidential.

I also confirm that no monetary or material gains have been promised or given to me for  
participating in the study.

Signed ..... date: .....

Signature of principle investigator .....date: .....

## ***MAELEZO YA UTAFITI KWA MGONJWA NA KIBALI CHA UTAFITI***

Tungependa kukuomba ruhusa (kwa hiari yako) kukuhusisha kwenye utafiti huu. Utafiti huu ni juu ya madhara yanayoweza kutokana na upasuaji huu. Kutokana na utafiti huu, tutafaidika kwa kuwa tutaweza kujua ni nini kinachosababisha madhara haya na ni njia gani zinazoweza kutumika kuzuia au kukumbatana na madhara haya. Zaidi ya hayo, tutaweza kujua mbinu za kutumia za kuzuia madhara haya.

### **Jinsi ya Kushiriki**

1. Tutakuuliza maswali kutaka kujua ni lini ugonjwa ulianza na ni matibabu gani uliyopewa na kama ilikusaidia au la.
2. Tutakupima na kurekodi ugonjwa ulio nao na kujua ni upasuaji gani utakayofanywa.
3. Baada ya upasuaji tutakutunza vilivyo kwenye wadi na iwapo kutatokea madhara yoyote itatibiwa papo hapo. Tutakufuatilia kwa muda ya wiki moja kwa minajili ya utafiti huu.
4. Habari hii itakusanywa kutoka kwa wagonjwa wengine walio na shida kama yako na itatumiwa kujua zaidi juu ya upasuaji huu na ni nini kinachoweza kufanywa kuzua au kutibu madhara haya.

### **Kushiriki kunakudhuru vipi?**

Hakukudhuru kwa njia yoyote ile kwasababu:

1. Utapata matibabu sambamba na wale wasioshiriki.
2. Hakuna chocote utakachopewa kukusawishi kushiriki kwenye utafiti huu.

3. Habari yoyote utakayotoa itawekwa siri.

**Kuna madhara yoyote iliyofichwa yanayoweza kutokana na utafiti huu?**

1. La hasha.
2. Hata kukataa kushiriki hakutabadili matibabu utakayopewa.

**Kushiriki kwako kutatufaidi vipi?**

1. Kushiriki kwako ni muhimu kwa sababu matokea ya utafiti huu utasaidia kujua jinsi ya kuzuia au kutibu madhara yanayotokana na upasuaji huu kwenye siku za usoni.
2. Matokeo haya yatatumika hata na madaktari wenzetu walioko kwengine.
3. Uko huru kujadiliana na watu wa familia yako kabla ya kukubali kushiriki na maswali yoyote mutakayouliza yatajibiwa.

Iwapo umeridhika na maelezo haya yote, na umekubali kushiriki, basi utatia sahihi kwenye kibali cha utafiti kudhibitisha kwamba umekubali.

## ***KIBALI CHA UTAFITI***

### **Watoto chini ya miaka 18/wasiojifahamu:**

Mimi, Bi/Bwana ..... mzazi wa.....Nimekubali

kushiriki katika utafiti huu baada ya kuelezwa na daktari .....

Sahihi yangu ni thibitisho ya kwamba nimeelewa umuhimu wa utafiti huu na kwamba habari yoyote nitakayotoa itawekwa siri.

Pia nathibitisha ya kwamba sijapewa au kuahadiwa pesa au chochote kile, kukubali kushiriki kwenye utafiti huu.

Sahihi ..... Uhusiano .....tarehe .....

Sahihi ya mtafiti ..... Tarehe .....

### **Watu wazima/zaidi ya miaka 18**

Mimi, Bi/Bwana ..... nimekubali kuandikikshwa

kwa utafiti huu baada ya kuelezwa na daktari .....

Sahihi yangu ni thibitisho ya kwamba nimeelew umuhimu wa utafiti huu na kwamba habari yoyote nitakayotoa itawekwa kwa siri. Pia nathibitisha kwamba sijapewa au kuhahidiwa pesa au chochote kile kukubali kushiriki kwenye utafiti huu.

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

Sahihi ya mtafiti ..... Tarehe .....

## APPENDIX III

### ***DATA COLLECTION SHEET FOR COMPLICATIONS OF TRACHEOSTOMIES***

#### 1. BIOGRAPHICAL DATA:

Date: ..... Study Number: .....

Hospital Ip No: ..... Age: .....

Sex(tick)            ( ) Male            ( ) Female

Telephone number.

Wt ..... kilograms

Occupation:

#### 2. CLINICAL DETAILS: (patient in Casualty/ENT clinic/ Ward)

Date first presented to KNH:

Department first presented to:

ENT( )            CASUALTY( )            ICU( )            Other( )

(specify)

Signs and symptoms at presentation:            Yes            No            Duration

- a. Difficulty in breathing ( ) ( ) ( )
- b. Stridor ( ) ( ) ( )
- c. Hoarseness of voice: ( ) ( ) ( )
- d. Cough ( ) ( ) ( )
- e. Foreign body inhalation ( ) ( ) ( )
- f. Hotness of body ( ) ( ) ( )
- g. Neck swelling ( ) ( ) ( )
- h. Difficulty in swallowing ( ) ( ) ( )
- i. Trauma ( ) ( ) ( )
- j. Others(specify)

3. GENERAL EXAMINATION FINDINGS

a. Normal ( ) Pallor( )

b. Cervical Lymphadenopathy Yes( ) No( )

If yes, N Staging.....

Others (specify).....



4. ENT Examination:

a. Ear: normal( )                      Mass( ).....

b. Nose: Normal( )                      Mass( )                      Trauma( )  
Other( )(specify).....

c. Oral cavity: Normal( )                      Mass( )                      Trauma( )

d. Neck: Adenopathy	Yes( )	No( )
Widened laryngeal framework	Yes( )	No( )
Mass	Yes( )	No( )
Displaced trachea	Yes( )	No( )

Previous surgical scar( ) (specify)

e. Indirect laryngoscope:	Normal	( )
	Laryngeal mass	( )
	Hypopharyngeal mass	( )
	Oropharyngeal mass	( )

5. Site where tracheostomy is performed:

ICU [ ]	Operating room [ ]
Ward [ ]	Casualty [ ]
Other [ ] specify.....	

6. Patient in ICU:(Not in ICU go to 7)

a. Intubated Yes( ) No( )

b. Indication for intubation:

Head injury ( )

Chest infection ( )

Metabolic Disease ( ) (specify).....

Other trauma ( ) (specify).....

Others ( ) (specify).....

c. Duration of intubation.....days.

d. Indication for tracheostomy:

Tracheobronchial toilet ( ) Prolonged intubation ( )

Others ( ) (specify).....

7. Anaesthesia used during surgery:

General anaesthesia with patient intubated[ ]

Local Anaesthesia[ ]

Others[ ] (specify)

8. Surgeon:

Consultant[ ] Years of practice: <5( ) 5-10( ) >10( )

Registrar[ ] year of study:.....year 2( ) Year3( ) Year 4( ) Year 5( )

9. Intraoperative Diagnosis:

- Ca larynx ( )
- Ca Hypopharynx ( )
- Ca Oropharynx ( )
- Nasopharyngeal Ca ( )
- Blunt laryngeal trauma ( )
- Penetrating laryngeal trauma ( )
- Facial trauma unable to intubate ( )
- Others Specify.....

10. Intraoperative complications encountered

- Haemorrhage ( )
- Decanulation ( )
- Injury to structures ( ) specify).....
- Displaced trachea ( )
- Others ( ) specify.....

11. Management of intraoperative complications and investigations:

Specify.....

12. Follow-up:

		Day						
		1	2	3	4	5	6	7
<b>Complication</b>	<b>Haemorrhage</b>							
	<b>Infection</b>							
	<b>Emphysema</b>							
	<b>Pneumonia</b>							
	<b>Decannulation</b>							
	<b>TOF</b>							
	<b>Tube obstruction</b>							
	<b>Pneumothorax</b>							
	<b>Pneumomediastinum</b>							
	<b>Others(specify)</b>							

13. In Case of Death of Patient: Cause of death.....

.....Days after tracheostomy: