COMPARISON OF HAEMODYNAMIC RESPONSES TO LARYNGEAL MASK AIRWAY INSERTION AND LARYNGOSCOPY WITH ENDOTRACHEAL INTUBATION IN ADULTS UNDERGOING ELECTIVE SURGERY AT MUHIMBILI

By

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A Dissertation Submitted In Partial Fulfillment of The Requirements For The Degree Of Master Of Medicine (Anaesthesiology) Of Muhimbili University Of Health And Allied Sciences

Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certify that they have read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled***, Comparison Of Haemodynamic Responses To Laryngeal Mask Airway Insertion And Laryngoscopy With Endotracheal Intubation in adults undergoing elective surgery at Muhimbili,*** in fulfillment of the requirements for the degree of Master of Medicine (Anaesthesiology) of Muhimbili University of Health and Allied Sciences.

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DEDICATION

To my loving husband Sabry, my heart warming kids Barka and Muhammad, my inspiring mum Asya and my sweet exemplary sister Farhat. For all that you have been, and all that you will be to me. You are all deeply loved and appreciated.

ABSTRACT

Background

Airway management is of utmost importance during delivery of general anaesthesia. Traditionally, laryngoscopy and endotracheal tube (ETT) insertion has been the mainstay in providing adequate airway management and delivering anaesthesia. The laryngeal mask airway (LMA) offers a much less invasive way of maintaining the airway as it does not pass through the glottis but is placed over the glottis. It does not require the use of the laryngoscope. Laryngoscopy and tracheal intubation or laryngeal mask airway insertion are noxious stimuli which provoke a transient but marked sympathetic response manifesting as hypertension and tachycardia. In susceptible patients particularly those with systemic hypertension, coronary heart disease, cerebrovascular disease and intracranial aneurysm, even these transient changes can result in potentially deleterious effects like left ventricular failure, arrhythmias, myocardial ischaemia, cerebral haemorrhage and rupture of cerebral aneurysm.

Objective

To determine the haemodynamic response elicited by laryngoscopy and endotracheal intubation and compare it with that elicited by laryngeal mask insertion in ASA I and ASA II patients, undergoing elective surgeries at Muhimbili national Hospital (MNH) and Muhimbili Orthopaedic Institute (MOI) in 2011.

Methods

A hospital based prospective randomized comparative study was conducted to determine the haemodynamic response elicited by laryngoscopy and endotracheal intubation and compare it with that elicited by laryngeal mask insertion in ASA I and ASA II patients, undergoing elective surgeries at MNH and MOI . After induction of anaesthesia either an ETT or LMA was inserted. Evaluations included measurement of blood pressure and heart rates before insertion, after insertion of device, 1 minute, 3 minutes and 5 minutes after insertion. Measuments were taken from the Drager infinity gamma XL monitor. Time and ease of insertion was also noted.

Results

There was an increase in HR, SBP and DBP seen after laryngoscopy and ETT insertion as well as after laryngeal mask insertion. The change in haemodynamic parameters after laryngoscopy and ETT insertion were significantly greater than those elicited by LMA insertion ($p<0.0001$). The increase took about 5 minutes to return to pre insertion values in the ETT group, while it took about 3 minutes for the same values to return to pre insertion values in the LMA group. It took a significantly shorter time to insert an LMA (12.63 sec) as compared to time taken to insert an ETT (22.76 sec). Insertion of an LMA was rated easy in 84% of the patients while it was rated easy in 60% of the ETT patients.

Conclusion

The haemodynamic changes elicited by LMA insertion are less and short lived compared to those elicited by laryngoscopy and ETT insertion. It takes a shorter time and is much easier to insert an LMA as compared to laryngoscopy and ETT insertion. These changes might be insignificant in a normotensive patient, but could be harmful in a patient with cerebrovascular or cardiovascular abnormalities. The use of an LMA is recommended in these groups of patients.

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ABBREVIATIONS

ASA	American Society of Anaesthesiologists
LMA	Laryngeal Mask Airway
ETT	Endo tracheal Tube
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure
MAP	Mean Arterial Pressure
HR	Heart Rate
IPPV	Intermittent Positive Pressure Ventilation
MNH	Muhimbili National Hospital
MOI	Muhimbili Orthopaedic Institute
SPSS	Statistical Package for Social Sciences
SD	Standard Deviation
ECG	Electrocardiography

DEFINITION OF TERMS

ASA I: Generally healthy patient with localized pathologic process

ASA II: Patient with stable mild to moderate systemic condition [1]

Cormack and Lehane classification: [35]

This classification describes the best view possible at laryngoscopy. It includes:

Grade I: complete glottis visible. No difficulty

Grade II: anterior glottis not seen. Pressure on the larynx may improve the view. Slight difficulty

Grade III: epiglottis seen, but not glottis. There may be severe difficulty

Grade IV: epiglottis not seen. Intubation may be impossible without special technique

CHAPTER 1

1.0 INTRODUCTION

1.1 BACKGROUND

Airway management is of utmost importance during delivery of general anaesthesia. Patients who have been anaesthetized are unable to maintain an adequate airway on their own and artificial airway maintenance devices are employed.[1]

Traditionally, laryngoscopy and endotracheal intubation has been the mainstay in providing adequate airway management, delivering anaesthesia and avoidance of aspiration in anaesthetized patients. Though intubation has many advantages including provision of a reliable airway, prevention of aspiration and delivery of anaesthetic gases, it is not without complications. These can be seen during insertion, after insertion and during extubation and they include airway trauma, physiological reflexes like hypoxia, tachycardia and hypertension, malposition, laryngospasm, narrowing and increased airway resistance as well as negative pressure pulmonary edema.[1,2]

The laryngeal mask airway offers a much less invasive way of maintaining the airway as it does not pass through the glottis but is placed over the glottis. It does not require instrumentation i.e. use of the laryngoscope. It acts as an intermediate between the endotracheal tube and the oropharyngeal airway and offers some of the advantages of the endotracheal tube while surpassing the disadvantages like stimulation of the laryngopharyngeal reflex.[2]

Laryngoscopy and tracheal intubation or laryngeal mask airway insertion are noxious stimuli which provoke a transient but marked sympathetic response manifesting as hypertension and tachycardia. In susceptible patients particularly those with systemic hypertension, coronary heart disease, cerebrovascular disease and intracranial aneurysm, even these transient changes can result in potentially deleterious effects like left ventricular failure, arrhythmias, myocardial ischaemia, cerebral haemorrhage and rupture of cerebral aneurysm.[3,4,5,6]

There are a number of ways to blunt these haemodynamic changes. They include minimizing the duration of laryngoscopy, the use of intravenous narcotics, lidocaine, vasodilators and beta - blocking agents, but most of these have produce variable results.[6]

Laryngeal mask airway insertion involves lesser mechanical manipulation of upper airway than endotracheal intubation does, but it has its own limitations as it is contraindicated in patients who are at risk for aspiration, those with low pulmonary compliance and those with pharyngeal obstruction.[1,2]

1.1.1 Anatomy of the airway reflexes:

The upper airway extends from nares and mouth to the glottis. Cricoid cartilage is the boundary between the upper and lower respiratory tract.

Oral cavity is supplied by the branches of trigeminal, facial, glossopharyngeal and hypoglossal nerve. Nasal cavity is supplied by anterior and posterior ethmoidal nerves. It is also supplied by anterior-superior alveolar branch and infra orbital branch of maxillary nerve.

Base of the tongue, upper part of epiglottis and pharyngeal walls are supplied by glossopharyngeal nerve. Lower part of the epiglottis and supra glottic parts of the pharynx are supplied by superior laryngeal branch of vagus nerve.[1]

The mucous membrane of the larynx receives its nerve supply from both the superior and recurrent laryngeal nerves. The superior laryngeal nerve arises from inferior ganglion of vagus but receives a small branch from the superior sympathetic ganglion. At the level of greater horn of hyoid it divides into an internal and external branch. The internal branch is purely sensory. The upper branch supplies the mucous membrane of the lower part of the pharynx, epiglottis, vallecula and vestibule of the larynx. The lower branch supplies the aryepiglottic fold and mucous membrane of the posterior part of rima glottidis. The lower part of the larynx below the vocal cords is supplied by the recurrent laryngeal nerve. The external branch of superior laryngeal nerve supplies the cricothyroid muscle and all the rest of the muscles of larynx are supplied by recurrent laryngeal nerve.[1]

1.1.2. Physiology of the airway reflexes

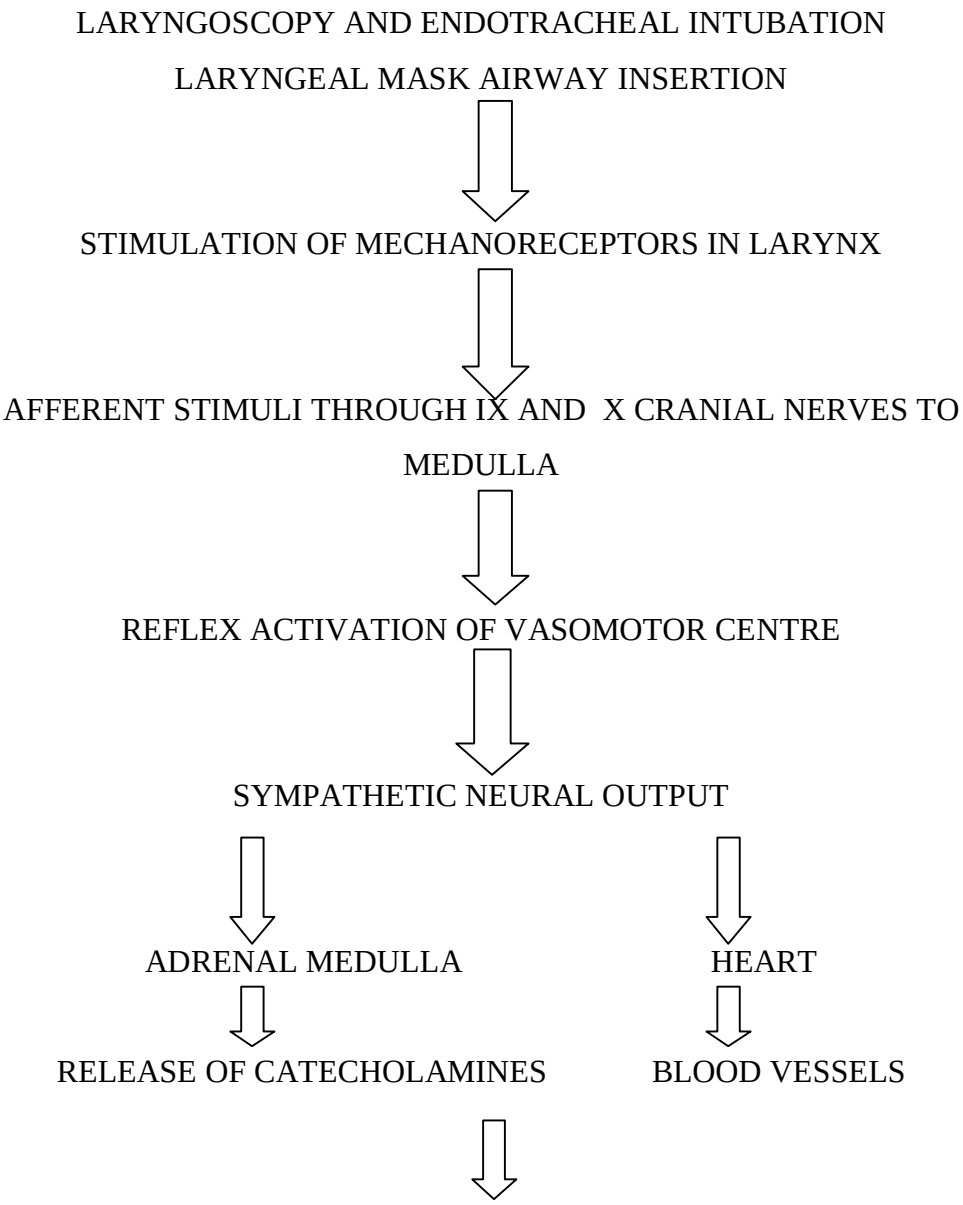
Lower pharynx, epiglottis and larynx contain numerous sensory receptors which respond to chemical, thermal and mechanica1 stimuli. The mechanoreceptors are abundant especially in the lower pharyngeal wall, epiglottis and vocal cords. Stimulation of these mechanoreceptors can produce reflex motor responses like cough, hiccup and also reflex sympathetic stimulation and cardiovascular pressor response.[4]

The sensory unit consists of free nerve endings that lie between the mucosal cells of the airway epithelium. Sensory units appear to be particularly abundant over the arytenoid cartilages and are also found on the laryngeal side of the epiglottis. The superior laryngeal nerve carries a large proportion of small diameter myelinated fibres (group III, A - delta, B sensory fibres) which carry afferent impulses. The recurrent laryngeal nerve also carries sensory fibres mainly from rapidly adapting receptors that are activated by light touch. These receptors are abundant on the inferior surface of the vocal cords.[4, 7]

Afferent fibres in the laryngeal nerves project centrally to the nucleus tractus solitarius particularly caudal and posterior parts. The central reflex site is in medulla. The nucleus tractus solitarius at which the afferent impulses terminate is closely linked with vasomotor centre. Sympathetic activity originates within the reticular formation of the lower third of pons and the upper medulla from regions that are represented bilaterally. Together these areas are referred as the vasomotor centre. The neurons of vasomotor centre are under constant influence of afferent impulses that originate from mechanoreceptors located within the heart, lungs and arteries.[4, 7]

Each efferent sympathetic pathway is composed of a pre-ganglionic neuron. The cell bodies of pre-ganglionic neurons lie within the thoracic and upper lumbar spinal cord. These fibres pass from the cord via anterior routes of each spinal nerve and then via the white ramus to synapse with post ganglionic cell bodies located within the ganglia of the sympathetic chains. From these ganglia post ganglionic sympathetic nerves pass to their effector organs. Pre ganglionic fibres of T8 to T12 synapse in the adrenal medulla. Stimulation of these causes release of catecholamines from the adrenal medulla into the circulation.[7]

1.1.3. Suggested mechanism of haemodynamic response



1.1.4. The laryngeal mask airway (LMA)

The LMA was designed in 1981 by Dr. Archie I.J Brain as a part of a specific search for an airway that was more practical than face mask and less invasive than tracheal tube. It forms an airtight seal by enclosing the larynx rather than plugging the pharynx and avoids airway obstruction in the oropharynx. [2]

Description of a Standard LMA

The laryngeal mask consists of a hollow silicon mask with a large size tube connected with a lumen at 30^0 angle. The elliptical mask is surrounded by an inflatable cuff that has an inflation tube with a pilot balloon and inflation valve. There are two vertical bars at the entry of the tube into the mask to prevent the epiglottis from obstructing the lumen. Proximally the tube is joined to a standard 15mm polysulfone connector.[2]

Standard insertion Technique

This technique involves using a middle or slightly diagonal approach with the cuff fully deflated. The head should be extended and the neck flexed. This position is best maintained during insertion by having the non intubating hand stabilize the occiput. The mouth may be allowed to fall open or may be held open by an assistant during insertion of mask into the mouth.

The tube portion is grasped as if it were a pen, with the index finger pressing on the point where the tube joins the mask. With the aperture facing anteriorly the tip of cuff is placed against inner surface of upper incisors. The mask is pressed back against the hard palate to keep it flattened as it is advanced into oral cavity using the index finger to push upward against the palate. A change of direction can be sensed as the mask tip encounters the posterior pharyngeal wall and follows it downwards. By withdrawing the other fingers as the index finger is advanced and slight pronation of forearm it is often possible to insert the mask fully into position with a single movement, if not the hand position is changed for the next movement. The tube is grasped with the other hand

straightened slightly and then pressed down with a single, quick but gentle movement until a definite resistance is felt.

The mask is now in place resting on the floor of hypopharynx avoiding collision with highly innervated anterior pharyngeal structures. Once in place the cuff should be inflated with correct amount of air as per recommendation. [1]

Fixation

A bite block should normally be used while the laryngeal mask is in place, because biting may damage the tube or cause airway obstruction.

Brain recommends using a roll of gauze (at least 3cm width) as a bite – block, taping it firmly to the tube and fixing both to the face.[2]

Maintenance of anaesthesia

Both spontaneous breathing and intermittent positive pressure ventilation (IPPV) can be achieved through the laryngeal mask. IPPV through the LMA should generally be confined to peak airway pressure of less than 20 cm H2O. Higher airway pressure may be utilized provided there is no leak. Adequate ventilation is usually achievable with no air leak or gastric insufflation at tidal volumes of 8-10 ml/kg. Epigastric auscultation should be performed in all patients to ensure that gastric insufflation is not occurring. Anterior neck auscultation is a valuable procedure for determining oropharyngeal leak pressure. [1]

Physiological effects

When the cuff of the mask is inflated with the recommended maximum volume of air, the calculated pressure transmitted to the pharyngeal mucosa is much higher than the capillary perfusion pressure. However, despite the increases in cuff pressure, the pressure exerted upon the pharyngeal mucosa does not increase because the muscles of the pharynx relax under general anaesthesia.[23]

The laryngeal mask bypasses part of the anatomical dead space. Dead space is less than when the facemask is used, but more than when the trachea is intubated.

The laryngeal mask cause a relatively smaller increase in airway resistance, compared to tracheal intubation, because the diameter of the tube of the laryngeal mask is much larger than that of the tracheal tube and the trachea is not directly stimulated.[1]

Blood pressure and heart rate increases after placement of the laryngeal mask. The increases are similar to those after insertion of a guedel airway and less than those after tracheal intubation. The duration of change in heart rate is shorter than that after tracheal intubation.[8]

The intra ocular pressure increases to a lesser amount after placement of the laryngeal mask than after tracheal intubation.[4]

Advantages and disadvantages of LMA compared to ETT

Advantages

- Avoidance of laryngoscopy
- Easier to place
- Less invasion of respiratory tract
- Minimal cardiovascular response
- Less raise in intraocular pressure
- Avoids oesophageal and endobronchial intubation
- Better tolerated
- Smooth emergence [2]

Disadvantages

- Aspiration risk
- Gastric insufflation more likely.
- Airway not as secure
- Unsuitable for collapsible airway [2]

1.2 REVIEW OF LITERATURE

Following laryngoscopy and tracheal intubation, a cardiovascular reflex which includes tachycardia, hypertension and arrhythmias has been described in anaesthetized patients.[4]

Laryngeal mask airway, originally described by Brain has recently become widely used in airway management. Insertion of the laryngeal mask airway after induction of anaesthesia has been described to cause less haemodynamic changes than tracheal intubation.[8]

Tachycardia and hypertension following laryngoscopy and tracheal intubation in normotensive patients has been documented under a variety of anaesthetic techniques.[9, 10,11]

The reflex circulatory responses to direct laryngoscopy and tracheal intubation has also been described and it was found that laryngoscopy and tracheal intubation in anaesthetized patients causes tachycardia despite the increase in systemic arterial pressure.

It was then established that laryngotracheal stimulation can lead to sympatho adrenal stimulation. This can cause a sudden rise in blood pressure leading to left ventricular failure, cerebral haemorrhage and myocardial ischaemia.[3,4,5,6]

In normotensive patients laryngoscopy and insertion of an endotracheal tube is immediately followed by an average increase of mean arterial pressure of 25 mm Hg. There is no evidence that this effect causes lasting damage in normotensive patients.[12]

In another study it was seen that introduction of a foreign body into the trachea was almost always associated with cardiovascular disturbances, including increase in arterial pressure and ventricular premature beats.[13]

The changes in the arterial pressure and arterial concentration of noradrenaline, adrenaline and dopamine following endotracheal intubation were studied. A significant increase in arterial pressure which was associated with an increase in noradrenaline concentration was found. Adrenaline and dopamine concentrations did not change significantly following intubation.[14]

A comparison between the changes in arterial pressure and plasma catecholamine concentrations in normotensive and hypertensive patients was done. Following induction of anaesthesia, both arterial pressure and plasma noradrenaline concentrations decreased in both the groups. Following laryngoscopy, there was a moderate increase in the

arterial pressure in both normotensive and hypertensive patients. In normotensive patients, laryngoscopy was associated with a moderate increase in plasma noradrenaline concentration. There was no change in adrenaline concentration. By contrast there was marked increase in noradrenaline concentration, a moderate increase in adrenaline concentration and an increased arterial pressure response in the group of hypertensive patients.[15]

The catecholamine and cardiovascular responses to laryngoscopy alone with those following laryngoscopy and intubation were also compared. It was found that there were significant and similar increase in arterial pressure and circulating catecholamine concentrations following laryngoscopy with or without tracheal intubation. However laryngoscopy and intubation was associated with significant increase in heart rate which did not occur in the laryngoscopy only group.[16]

A pilot study done on the laryngeal mask, suggested LMA as an alternative and less invasive airway device compared to endotracheal intubation both for spontaneous and positive pressure ventilation.[17]

The pressor response of tracheal intubation with that of laryngeal mask insertion in normotensive patients was compared. A similar but attenuated pattern of response associated with mask insertion in comparison with laryngoscopy and intubation was found. It was concluded that the use of the laryngeal mask may therefore offer some limited advantages over tracheal intubation in the anaesthetic management of patients where the avoidance of pressor response is of particular concern.[18]

A similar study in the same year, found that the differences between the two groups with respect to mean heart rate and systolic arterial pressure were not significant. However, maximum individual increases in systolic arterial pressure over control values were significantly greater in the endotracheal intubation group.[19]

The cardiovascular effects related to the insertion of Brain laryngeal mask airway compared with those after insertion of Guedel oral airway were also investigated. A significant increase in arterial pressure and heart rate followed insertion of laryngeal mask and Guedel airway, with no difference between the two groups at any time. The

changes in arterial pressure and heart rate returned to 'at insertion' levels within sixty seconds of the stimulus.[20]

A comparison done in healthy patients, compared the cardiovascular responses induced by laryngoscopy and intubation with those produced by insertion of laryngeal mask. The mean maximum increase in systolic arterial pressure after laryngoscopy and tracheal intubation was 51.3% compared with 22.9% for laryngeal mask insertion. Increases in maximum heart rate were similar (22.6% and 25.7% respectively) although heart rate remained elevated for longer after tracheal intubation. They concluded that insertion of laryngeal mask was accompanied by smaller cardiovascular responses than those after laryngoscopy and intubation and that its use may be indicated in those patients in whom a marked pressor response is deleterious.[8]

A study that compared the cardiovascular effects due to the forces applied during laryngoscopy and that of tracheal intubation, concluded that tracheal intubation causes more cardiovascular changes than laryngoscopy in routine uncomplicated procedures. It also suggested that the most important laryngoscopic factor influencing the cardiovascular responses was duration of laryngoscopy, the forces applied having only minor effects.[21]

The afferent pathway responsible for the pressor response were also studied and it was concluded that glossopharyngeal nerve is mainly responsible for the pressor response and both glossopharyngeal and vagus nerves were responsible for the tachycardic response.[22]

Marjot investigated the effects of LMA cuff on the pharyngeal mucosa, and found two distinguishing features of LMA cuff compared to cuffs of endotracheal tubes. First, there was no sustained increase in transmitted lateral wall pressure with increasing cuff volume and secondly the transmitted lateral wall pressure decreased during the time the mask was insitu.[23]

In a review done on the techniques of LMA insertion and its complications it was also found that haemodynamic changes following LMA insertion were lower and of shorter duration compared to endotracheal intubation.[24]

The effects of laryngeal mask airway insertion and tracheal intubation on circulatory responses in normotensive and hypertensive patients were also studied. In both the groups,

heart rate, mean arterial pressure and rate pressure product increased after tracheal intubation or laryngeal mask airway insertion compared with baseline. The haemodynamic changes were greater after intubation than after laryngeal mask airway insertion. Following intubation of the trachea or insertion of the laryngeal mask airway, heart rate increased more markedly in hypertensive patients than normotensive patients. The increase in noradrenaline concentration after tracheal intubation was greater than after laryngeal mask airway insertion. They concluded that insertion of laryngeal mask airway was associated with less circulatory responses than tracheal intubation in both normotensive and hypertensive patients.[25]

A comparison between LMA with other forms of airway management including tracheal tube and facemask was done and many advantages were found in LMA compared with tracheal tube including improved haemodynamic stability at induction and during emergence.[26]

The haemodynamic response after insertion of cuffed oropharyngeal airway and LMA with that of endotracheal intubation was also compared. It was found that the arterial pressure and heart rate changes were similar after cuffed oropharyngeal airway or LMA insertion but endotracheal intubation was associated with a significant increase in heart rate and arterial pressure compared with the other two airway devices.[27]

In a study that compared hemodynamic and catecholamine stress responses to insertion of the combitube, laryngeal mask airway and tracheal intubation, it was found that the hemodynamic response to insertion of the combitube and endotracheal tube was significantly greater than that due to laryngeal mask insertion.[28]

In a more recent study done in Nigeria, which compared the blood pressure and heart rate response to endotracheal intubation and laryngeal mask airway insertion, it was seen that the response to laryngeal mask insertion is less and is short lived.[29]

1.3 PROBLEM STATEMENT

Airway management is of key importance during the delivery of safe anaesthesia. Several methods can be utilized by the anaesthetist to ensure this need is met safely and efficiently.

The main method of airway management during delivery of anaesthesia in our setting is by laryngoscopy and endotracheal intubation. Various studies have shown that this method can cause hypertension and tachycardia which could be non harzadous to a healthy patient but could cause deleterious effects in a patient with underlying cardiovascular or cerebrovascular pathology. These include left ventricular failure, arrhythmias, myocardial ischaemia, cerebral haemorrhage and rupture of cerebral aneurysm. [3, 4, 5]

LMA which has recently gained popularity in the world as an airway management tool is not commonly used in our setting. In studies done elsewhere in the world, it has been shown to cause less haemodynamic disturbance as compared to the conventional method of laryngoscopy and endotracheal intubation.[8] It has also been shown to be easier to insert when compared to the endotracheal tube.[32]

As it is the role of the anaesthetist to ensure safe delivery of anaesthesia, the need to seek better ways of improving the quality of care given to our patients while minimizing any undue complications cannot be overemphasized. Therefore for patients with cardiovascular or cerebrovascular pathology, it is important to find a better way of anaesthesia delivery for our population so as to avoid the haemodynamic response that is seen with laryngoscopy and endotracheal intubation.

1.4 JUSTIFICATION

Although a number of researches comparing the haemodynamic changes seen with either laryngoscopy and intubation and laryngeal mask airway insertion have been done around the world, no such study has been done in Tanzania. Laryngoscopy and endotracheal tube insertion is the main method used for airway management and delivery of anaesthesia in our setting. The technique of laryngoscopy and endotracheal intubation has been associated with the complications of stimulating the cardiovascular reflex and consequential deleterious effects in patients with underlying cardiovascular and cerebrovascular disease.[3, 4, 5] While the laryngeal mask airway is not routinely used in our setting for the same purpose, it has been shown to have positive effects in other populations, with respect to haemodynamic changes and ease of insertion. The same has not been established in our population.

In order to improve the quality of care of our patients and decrease morbidity related with the conventional method of endotracheal intubation for anaesthesia delivery, this study aims at comparing the haemodynamic responses of laryngoscopy and endotracheal intubation versus laryngeal mask insertion in our population.

With the execution of this study, evidence on the effect of the LMA on the haemodynamic parameters in our population will be gathered. This evidence will aid us in developing protocols for improving the quality of the techniques used in delivering anaesthetic services to our patients.

The information generated from this study, will also serve as a basis for further researches to be performed on better ways of delivering anaethesia to our patients.

1.5 OBJECTIVES

1.5.1 Broad objective

To determine the haemodynamic response elicited by laryngoscopy and endotracheal intubation and compare it with that elicited by laryngeal mask insertion, in ASA I and ASA II patients undergoing elective surgeries at MNH and MOI.

1.5.2 Specific objectives

1. To determine the haemodynamic response to laryngoscopy and endotracheal intubation in ASA I and ASA II patients undergoing elective surgeries.
2. To determine the haemodynamic response to laryngeal mask insertion in ASA I and ASA II patients undergoing elective surgeries.
3. To study the difference between the haemodynamic response seen with laryngoscopy and endotracheal intubation and that seen with laryngeal mask insertion in patients undergoing elective surgeries.

CHAPTER 2
2.0 METHODOLOGY

2.1 Study design

A prospective randomized comparative study was conducted

2.2 Study sites

The study was conducted at Muhimbili National Hospital (MNH) and Muhimbili Orthopaedic Institute (MOI) located in Dar-es-salaam, Tanzania between July and December 2011. Both facilities are tertiary hospitals serving as the main referral hospitals. They are also used as the teaching facilities for Muhimbili University of Health and Allied Sciences. There are a total of 9 operating theatres at MNH; 6 are used for elective cases, 1 for general emergencies and 2 for obstetric cases. At MOI, there are a total of 6 operating theatres, 1 for emergencies, 3 for orthopaedic cases, 1 for neurosurgical cases and one for cardiothoracic surgeries. Approximately 1 – 4 elective surgeries are performed per day in each theatre used for elective cases.

2.3 Study period

This study was conducted between July and December, 2011.

2.4 Study population

The study recruited adult between the age of 18 to 60 years who were ASAI and ASAII patients of both sexes presenting for elective surgeries at MNH and MOI.

2.5 Sample size

Using the formula for continuous outcomes[34] and means from a study done in Vienna Austria[28]

$Z_{1-\alpha/2}$ = 1.96 for a p = 0.05 (95% confidence interval)

$Z_{1-\beta}$ = 0.83 for 20% beta error

S = standard deviation

μ_1 = 140±24 mmHg Mean maximal systolic blood pressure increase in endotracheal intubation group

μ0 = 115±33 mmHg Mean maximal systolic blood pressure increase in laryngeal mask group,

$$(Z_{1-\alpha/2} + Z_{1-\beta})^2 = \frac{n(\mu_1 - \mu_0)^2}{S_0^2 + S_1^2}$$

$$(1.96 + 0.83)^2 = \frac{n\,(140-115)^2}{24^2 + 33^2}$$

$$7.7841 = \frac{n \times 255}{244+1089}$$

$$n = \frac{7.7841 \times 1333}{225} = 40.69$$

N= 41 per group

For 2 groups N = 41 x 2 = 82

Adjusting for missing data, loss to follow up and non compliance

Sample size was increased by 20% to be 98.

Total sample size = 100

2.6 Sampling procedure

Patients listed for surgery were enrolled and assessed for eligibility. Those not meeting the inclusion criteria or those refusing to participate were excluded. The patients were then randomly allocated to one of the two groups: ETT group and LMA group. Blocks of 10 sealed opaque envelopes, 5 ETT and 5 LMA were prepared and mixed in a box. An envelope was

picked randomly and opened once an eligible patient had consented. They were then randomly assigned to anesthetists experienced in handling both devices. On average 2-4 patients were enrolled per week. A total of 50 patients in the LMA group and 50 patients in the ETT group were completed in a span of 6 months.

2.7 Selection of study participants

2.7.1 Inclusion criteria

- Patients undergoing elective surgeries
- Aged between 18- 60 years
- Mallampati I and II
- ASAI and ASAII
- Willing to participate in the study by giving written informed consent

2.7.2 Exclusion Criteria

- History of respiratory problems.
- History of angina, palpitations, syncopal attacks.
- Baseline heart rate< 60 per minute.
- Baseline systolic pressure <100mmHg.
- Hepatic, renal problems.
- Regurgitation prone conditions.
- Patients with predetermined difficult airway.
- History of difficult intubation.
- Unwillingness to participate in the study.

Assessment of the patients was done during the pre anaesthetic evaluation. Exclusion of patients with cardiac and renal problems was based on history and preoperative investigation results.

Patients undergoing elective orthopaedic, gynaecological, urological and general surgical procedures of duration between 1-2 hours were selected for the study.

2.8 Training of research assistants

Two nurse anaesthetists who assisted in carrying out the procedures underwent a training program by the principal investigator on the objectives of the study, the method of conducting the anaesthetic technique and filling out the data collection sheets so as to have standardized procedures. Both study assistants were equally skilled and had more than two years experience in the use of both LMA and ETT.

2.9 Pilot study

A 2 weeks pilot study was conducted. The ease of obtaining data was assessed and necessary changes were made.

2.10 Study tools

Instruments that were used in the study included, non invasive BP machine for blood pressure measurement, ECG electrodes and pulse oxymeter probes for ECG and oxygen saturation of the patients respectively. Laryngeal mask airways for airway management in the LMA group and endotracheal tubes with laryngoscopes for the ETT group. I.V. cannulae, drugs including propofol, morphine, suxamethonium, midazolam, oxygen and halothane for the induction and maintenance of anaesthesia. Drager Fabius anaesthetic machines were used for delivery of anaesthesia. Stop watches were used for timing the length of insertion of LMA or intubation. Monitoring of HR, SBP, DBP and MAP of the patients was done using Drager infinity gamma XL monitors.

The data sheets used to collect information contained demographic data, proposed surgery, type of airway management tool, ease of insertion, haemodynamic variables including heart rate, non invasive systolic, diastolic and mean arterial pressure before induction, preinsertion/intubation, immediately after laryngoscopy with intubation or insertion of laryngeal mask, 1, 3 and 5 minutes after intubation or insertion of laryngeal mask. Information on insertion time and any complications was also included in the data sheets.

2.11 Data collection

2.11.1 Initial assessment

Each morning, patients listed for surgery were enrolled and assessed for eligibility by the principal investigator. Those meeting the inclusion criteria were then randomized to either the ETT group or the LMA group.

2.11.2 Anaesthetic technique

The standard anaesthetic machine check was done prior to commencement of any procedure every morning.

The patients were cannulated using 16 or 18G cannula and an infusion of ringer lactate was initiated.

Non invasive blood pressure cuff, ECG and pulse oximeter probe were then connected to the patient and initial blood pressure and heart rate readings were then obtained. The patients were then premedicated with injection midazolam 0.05mg/kg, 3 minutes prior to induction.

Pre-oxygenation was done during these three minutes after which, induction of anaesthesia using I.V. propofol 2-3 mg/kg and morphine 0.1 mg/kg was done. For the ETT group muscle relaxation for intubation was facilitated by the use of injection succinylcholine 1 mg/kg.

Patients were then ventilated with 100 percent oxygen for a period of 1 minute prior to intubation with the aid of Macintosh laryngoscope or insertion of laryngeal mask airway. Endotracheal tubes of size 7/7.5 for female and 8/8.5 for male patients or laryngeal mask size 3/4 for female and size 4/5 for male patients were used depending on body weight. Anaesthesia was maintained using oxygen and halothane.

Duration of intubation/insertion was defined as the time from the start of laryngoscopy/LMA insertion, until cuff inflation.

Difficulty of intubation was graded I – IV according to the Cormack and Lehane criteria and insertion conditions of the LMA were graded as excellent (no resistance to insertion), good (slight resistance to insertion), poor (moderate resistance to insertion) or impossible. If insertion was impossible the patient was intubated endotracheally.

Adequacy of ventilation was monitored clinically by assessing chest expansion, auscultation of the lung fields and the epigastric region.

Surgery or any other manipulations were not allowed to commence till the study was completed i.e. for five minutes after intubation/insertion.

2.11.3 Monitoring

Heart rate, Non invasive blood pressure which included systolic, diastolic and mean arterial pressure were monitored throughout the study and recorded at the following time points

a) Pre insertion/intubation.

b) Immediately after laryngoscopy and intubation or insertion of laryngeal mask.

c) One minute after intubation or insertion of laryngeal mask.

d) Three minutes after intubation or insertion of laryngeal mask

e) Five minutes after intubation or insertion of laryngeal mask

Oxygen saturation and electrocardiography were also monitored throughout the study period.

All data was collected by the principal investigator together with the 2 study assistants. The principal investigator closely supervised the study assistants.

2.12 Data processing and analysis

The data collection sheets were checked daily by the principal investigator for correctness and consistency. Data collected was coded and entered into the SPSS software. Clean data was analyzed using SPSS version 17. Analysis between the groups was done using the unpaired sample t test while within group analysis was done using the paired sample t test. Continuous variables were described using mean ± standard deviation. A P value of < 0.05 was considered statistically significant.

2.13. Ethical considerations

Ethical clearance was sought from the Ethical and Research Committee of Muhimbili University of Health and Allied Sciences and was granted. The background, purpose, procedures of the study, measures which were taken to ensure confidentiality of participants, the voluntary nature of the study and applicability of findings were explained. Informed consent was sought from the participants of the study whereby participants were informed on the purpose and importance of the study and were only enrolled into the study if they accepted. Those who declined to participate were given anaesthesia using the standard technique currently used.

CHAPTER 3

3.0 RESULTS

This study was done at MNH and MOI between the months of July and December 2011. All the patients that met the inclusion criteria were included in the study. In the ETT group, one patient was excluded as he needed more than 2 attempts at intubation. Each group had a total of 50 participants.

3.1 Demographic data

The ETT group had 30 males and 20 females and the LMA group had 30 males and 20 females. The ages ranged from 18 to 60 years and 22 to 60 years in the ETT and LMA groups respectively. The range for weight was 45 to 85 kg and 52 to 84 kg in the ETT and LMA groups respectively. The two groups were comparable in terms of demographic data as there were no significant differences between the 2 groups in terms of age, sex, weight and ASA classification (Table 1).

Table 1: Demographic and clinical characteristics of study participants

		LMA (n=50)	**ETT (n=50)**	**p value**
MEAN AGE (years)		37.5	38.8	0.568
MEAN WEIGHT (kg)		65.7	63.8	0.278
SEX	**male**	30	30	1.000
	female	20	20	
ASA	**I**	37	30	0.137
	II	13	20	

3.2 Haemodynamic data

3.2.1 Haemodynamic parameters among ETT and LMA study participants

Table 2: Mean heart rate at different times among ETT and LMA study participants

	ETT Mean±SD	P value for difference within ETT group	LMA Mean±SD	P value for difference within LMA group	P value for difference between ETT and LMA groups
Pre insertion	93.0±13.5	-	90.8±11.8	-	0.383
Insertion	111.9±13.6	<0.0001	106.9±11.1	<0.0001	0.047
1 minute	106.5 ±13.4	<0.0001	97.8±9.2	<0.0001	0.0001
3 minutes	99.5±13.1	<0.0001	88.5±6.8	0.592	0.0001
5 minutes	92.2±11.4	0.664	85.4±6.5	0.059	0.066

ETT – endotracheal tube

LMA – laryngeal mask airway

Values are mean and standard deviation

Pre insertion values are taken as baseline values.

The heart rates of the 2 groups were comparable at induction. At insertion, the heart rate increased significantly in both groups, but the increase was substantially higher in the ETT group as compared to the LMA group. The elevation in heart rate significantly persisted for a longer period of time in the ETT group, where it returned to the baseline value by 5 minutes as compared to the LMA group where it returned by 3 minutes. By 5 minutes there was no significant difference between the groups.

Table 3: Mean systolic blood pressure at different time points among the study participants

	ETT Mean±SD	P value for difference within ETT group	LMA Mean±SD	P value for difference within LMA group	P value for difference between ETT and LMA groups
Pre insertion	121.2±10.8	-	117.0±11.9	-	0.067
Insertion	146.4±16.4	<0.0001	127.7±12.9	<0.0001	<0.0001
1 minute	135.4±12.8	<0.0001	121.5±11.4	<0.0001	<0.0001
3 minutes	128.5±11.5	<0.0001	117.6±10.5	0.487	<0.0001
5 minutes	122.0±11.8	0.665	115.4±9.1	0.147	0.002

ETT – endotracheal tube

LMA – laryngeal mask airway

Values are mean and standard deviation.

Pre insertion values are taken as baseline values.

The systolic blood pressure in the two groups was comparable at baseline. An increase in SBP was noted just after insertion of either the LMA or ETT, but the increase elicited by the ETT was significantly higher($p<0.0001$) and persisted for a longer period of time as compared to that elicited by the insertion of an LMA. It took 5 minutes for the ETT values to return to baseline and 3 minutes for the LMA values to do so.

Table 4: Mean diastolic blood pressure at different times among ETT and LMA study participants

	ETT Mean±SD	P value for difference within ETT group	LMA Mean±SD	P value for difference within LMA group	P value for difference between ETT and LMA groups
Pre insertion	76.4±7.2	-	75.7±7.1	-	0.618
Insertion	90.1±11.7	<0.0001	83.5±8.6	<0.0001	<0.001
1 minute	85.2±10.4	<0.0001	78.0±7.4	0.012	<0.0001
3 minutes	80.7±10.0	0.007	75.5±8.0	0.793	0.005
5 minutes	76.1±9.8	0.813	74.7±7.3	0.310	0.447

ETT – endotracheal tube

LMA – laryngeal mask airway

Values are mean and standard deviation.

Pre insertion values are taken as baseline values.

The diastolic blood pressure was comparable between the 2 groups at baseline. After insertion, both groups showed an increase in DBP that was statistically significant within and between the groups. The values returned to baseline by 3 minutes in the LMA group and by 5 minutes in the ETT group. The difference between the groups was lost by 5 minutes.

Table 5: Mean arterial blood pressure at different times among ETT and LMA study participants

	ETT Mean±SD	P value for difference within ETT group	LMA Mean±SD	P value for difference within LMA group	P value for difference between ETT and LMA groups
Pre insertion	91.5±7.3	-	89.7±7.2	-	0.225
Insertion	112.2±14.5	<0.0001	98.6±14.5	<0.0001	<0.0001
1 minute	104.3±10.6	<0.0001	93.3±8.1	<0.0001	<0.0001
3 minutes	97.6±9.9	<0.0001	90.8±7.6	0.219	<0.0001
5 minutes	93.2±9.7	0.228	89.2±7.0	0.536	0.019

ETT – endotracheal tube

LMA – laryngeal mask airway

Values are mean and standard deviation.

Pre insertion values are taken as baseline values.

In terms of MAP, the two groups were not statistically different at baseline. After instrumentation, the ETT group had an increase in MAP that was significantly higher and more persistent as compared to the LMA group. These changes subsided to baseline values by 3 minutes and 5 minutes in the LMA and ETT groups respectively.

3.2.2 Insertion time

It took a significantly longer time to perform laryngoscopy and ETT insertion (20.22s) as compared to the time taken to insert an LMA (12.62s) (Table 6).

Table 6: Mean insertion time for ETT and LMA among study participants

	ETT Mean±SD	LMA Mean±SD	P value
Insertion time (Seconds)	22.76±2.95	12.63±1.71	<0.0001

3.2.3 Ease of Insertion

Of the 50 ETT patients, 30(60%) were grade I, 18(36%) were grade II and 2(4%) were grade III according to the Cormack and Lehane criteria (figure2). Of the 50 LMA patients, 42(84%) had LMA insertion without resistance, 7(14%) with slight resistance and 1(2%) patient had more resistance (figure 1).

Figure 1: Ease of insertion among the LMA participants

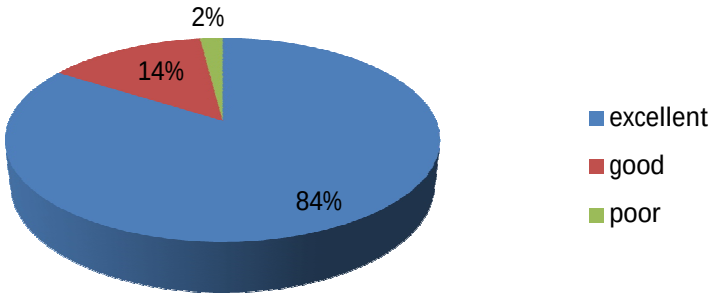
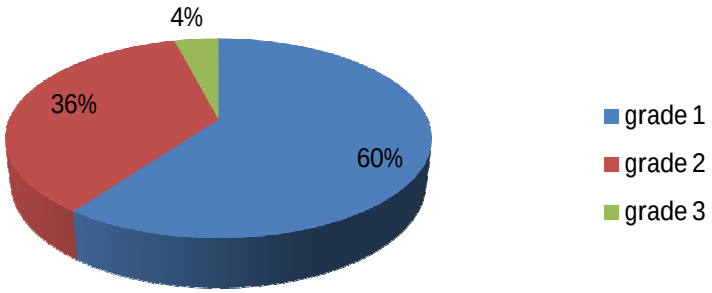


Figure 2: Ease of intubation as assessed using Cormack and Lehane criteria among the ETT participants



CHAPTER 4

4.0 DISCUSSION AND LIMITATIONS

4.1 DISCUSSION

This study conducted on a total of 100 patients, aimed at comparing the haemodynamic changes elicited by laryngoscopy with endotracheal intubation, to those elicited by laryngeal mask airway insertion. The two groups consisting of 50 participants each, were comparable in terms of age, sex, ASA class, weight and baseline haemodynamic parameters. This study demonstrated that there is a haemodynamic response consisting of an increase in heart rate, SBP, DBP and MAP that comes with laryngoscopy with ETT insertion as well as with LMA insertion. However, the response caused by laryngoscopy with ETT insertion is significantly greater than that caused by LMA insertion. It was also observed that insertion of an LMA is easier and takes a shorter time compared to laryngoscopy with ETT insertion.

After the induction of anaesthesia, and prior to insertion of any device, the SBP, DBP and MAP in both ETT and LMA groups in this study, showed a decrease from the pre induction values. The heart rates in both groups showed an increase from the pre induction values. These results were similar to those observed in a study done in Scotland, where it was shown that arterial pressure decreased significantly and heart rate increased significantly after induction of anaesthesia. The same effects were also observed in several other studies done previously. [8, 15, 20] This effect could be attributed to the hypotensive effect of the induction drugs used.

The HR, SBP, DBP as well as the MAP were significantly elevated after the insertion of the endotracheal tube in the ETT group of the study compared to the pre intubation values. The elevation persisted for a period of 5 minutes by which the parameters returned to the pre intubation values. These results are similar to those found by Millar and co workers who found that in normotensive patients, laryngoscopy and insertion of a tracheal tube is immediately followed by an average increase in mean arterial pressure of 25 mmHg.[12] The study done by Russell and colleagues also demonstrated a significant increase in arterial blood

pressure after intubation .[14] The observed changes are probably due to the sympathoadrenal response caused by stimulation of the supraglottic region and that of the trachea.

The LMA group in this study also showed a significant increase in HR, SBP, DBP as well as the MAP after insertion of the LMA. These results are similar to those of a study done to investigate the cardiovascular effects related to insertion of the Brain laryngeal mask airway compared to those after insertion of a Guedel oral airway, a significant increase in arterial pressure and in heart rate followed insertion of the laryngeal mask and the Guedel airway, with no difference between the two groups at any time.[20] As both the devices did not go through the trachea, such a similarity between the two is expected. This response could be explained by the stimulation of the supraglottic region causing activation of the haemodynamic response reflex.

The changes in haemodynamics in the LMA group were significantly lower compared to those seen with the ETT group. Similar findings were reported by the study done by Anita and colleagues who demonstrated that endotracheal intubation was associated with a significant increase in heart rate and arterial pressure compared to LMA insertion.[27] Several other studies have shown results similar to those of this study.[24, 28, 29]. The attenuated response shown by LMA could be due to the fact that the LMA avoids the sympathoadrenal response caused by insertion of the endotracheal tube through the trachea. This explanation is supported by the study done in Japan, which showed that direct stimulation by a tracheal tube induces greater cardiovascular responses than stimulation of the glottis by laryngoscopy alone.[30] In another study done in Netherlands, it was shown that the forces applied during laryngoscopy were only weakly related to the cardiovascular changes, whereas tracheal intubation had a major influence. The results of this study differed from those of Braude and colleagues and those of Griffin and colleagues who demonstrated that the difference between the LMA and ETT groups in haemodynamics was not significant.[18, 19]

SBP and DBP were almost twice as high in the ETT study group compared to the LMA study group after instrumentation. These findings are similar to those of Wilson and colleagues,

who reported that the cardiovascular responses induced by laryngoscopy and intubation were more than twice as high as those produced by the insertion of an LMA. However, the difference in HR in our study was significantly higher in the ETT group compared to the

LMA group unlike in their study where there was an increase in heart rate in both groups with no significant difference between the groups. The difference might have been picked by our study due to the larger sample size compared to that of their study. The HR increase in the ETT group lasted longer in our study similarly to the findings of their study.[8]

The haemodynamic changes in the LMA group took about 3 minutes to return to pre insertion values while it took about 5 minutes for the changes to return to pre intubation values in the ETT group. Several other studies have demonstrated that the haemodynamic response to LMA is short lived compared to that to ETT.[8, 24, 29] The greater and more persistent changes in cardiovascular parameters seen with ETT as compared to LMA insertion probably reflect higher catecholamine levels in the ETT group as seen in previous studies.[14, 15, 16]

The time taken to perform laryngoscopy and ETT insertion was also compared to the time taken to insert an LMA. It took a significantly longer time to perform laryngoscopy with ETT insertion, as compared to the time taken to insert an LMA. These results were similar to those of the study done in Nigeria and the study done in Austria. [28, 29] The longer time needed in the ETT group could translate to a longer stimulation period, leading to a greater haemodynamic response. This was shown by the study done by Stoelting who stated that time required for perform endotracheal intubation, directly correlates with an increase in MAP.[31] In another study done by Bucx and colleagues, it was suggested that duration of laryngoscopy, was the most important factor influencing cardiovascular responses during intubation.[21]

The ease of insertion of both the LMA and ETT was also assessed in this study. The majority of the LMA patients (84%) had excellent insertion conditions while 60% of the patients in the ETT had Cormack and Lehane grade I corresponding to excellent intubation conditions. These findings were similar to those found in the study done in Nigeria whereby the LMA

was inserted easily in 82.5% of the patients and 71.4% of the ETT group had Cormack and Lehane grade I.[29] In the study done in India, insertion of LMA was easier in 94% patients while endotracheal intubation was done easily in 53% of patients only.[32] The LMA being easier to insert as compared to the ETT, could mean that more stimulation is caused while inserting the ETT thus leading to the greater haemodynamic response that we see with the laryngposcopy and ETT intubation.

4.2 LIMITATIONS

- This study was conducted on healthy, normotensive patients with normal airways. It is therefore not known how the changes would have been in hypertensive patients.
- Patients, who were enrolled in this study, were all successfully intubated in the first attempt. Perhaps the haemodynamic parameters would show a different picture in patients with difficult intubation.
- In this study, intermittent recording of the haemodynamics was used, due to the available resources. This could mean that the maximal change could have been missed especially within the first minute of intubation.
- Randomization was done but double blinding was not possible due to our theatre setup. This could mean that an element of observation bias was not completely removed from the study.

CHAPTER 5

5.0 CONCLUSION AND RECOMMENDATIONS

5.1 CONCLUSION

A significant haemodynamic response consisting of an increase in HR, SBP, DBP and MAP was seen after the insertion of both the LMA and ETT in this study. It was also observed that the haemodynamic response to laryngoscopy and ETT insertion is significantly greater than that to LMA insertion. The response is also short lived in the LMA group compared to ETT group. This response might be of no clinical importance in the healthy, normotensive patients, but might be harmful in patients with hypertension, aortic or cerebral aneurysm, raised intracranial pressure or other cardiovascular diseases. In such cases, the attenuated response of the LMA might be desirable. Time taken to insert an LMA was significantly shorter and insertion was easier as compared to laryngoscopy and ETT insertion. These factors might be contributory to the higher haemodynamic changes seen with laryngoscopy and ETT insertion.

5.2 RECOMMENDATIONS

In this study it was found out that the LMA produces a less marked pressor response. This might not be of importance in the healthy normotensive patients, but it could be of importance in the patient with pre existing cardiac or cerebral pathology or hypertension. Therefore, where appropriate, the use of the LMA would be recommended in such patient to avoid the marked response produced by the ETT.

As the LMA is not routinely used in our setting, it is recommended that strategies be developed that will encourage the routine use of the LMA in our setting.

This research was conducted on ASA I and ASA II patients. Further research on the LMA, including haemodynamic changes in other patient populations needs to be done.

This study was done at MNH and MOI which are tertiary institutions. A bigger study that will cover a larger sample of the Tanzanian population undergoing surgery at different levels of health facilities also needs to be carried out so as to get a bigger picture of how the effect of the LMA would be in the Tanzanian population.

Due to its faster and easier insertion, further research could also be done, to assess the utility of the LMA in emergency situations as a life saving airway management tool.

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ANNEXES

ANNEX I: DATA COLLECTION SHEET

COMPARISON OF HAEMODYNAMIC RESPONSE TO LARYNGOSCOPIC ENDOTRACHEAL INTUBATION AND LARYNGEAL MASK AIRWAY INSERTION

Name: _____ Age :

Sex: _____ Weight :

Date : _____ Reg. No.:

Surgery proposed: _____ ASA classification: 1 11

Intubated with Macintosh Blade Size ☐ Endotracheal Tube Size ☐

Cormack and Lehane criteria grade 1 ☐

11 ☐

111 ☐

1V ☐

Laryngeal Mask Airway/Size ☐

Insertion conditions of the LMA: Excellent (no resistance to insertion) ☐

Good (slight resistance to insertion) ☐

Poor (moderate resistance to insertion) ☐

Impossible ☐

Observations

	HR	SBP	DBP	MAP
Pre induction				
Post induction				
Immediately post insertion				
1 min after				
3min after				
5 min after				

Insertion time: …… seconds

Complications: I) More than one attempt at intubation

II) Failure to intubate or ventilate

ANNEX II

INFORMED CONSENT FORM

Thank you for your time and agreeing to listen/read this. My name is Karima Khalid, a postgraduate student in the department of Anaesthesiology from Muhimbili University of Health and Allied Sciences. I would like to conduct the following study as part of the requirement for fulfillment of my post graduate studies.

Title of the study:

Comparison of haemodynamic responses to insertion of laryngeal mask airway and laryngoscopy with endotracheal intubation

Purpose of the study:

The aim of the study being conducted is to evaluate the beneficial effects of the new airway device laryngeal mask airway over traditional endotracheal intubation in reducing pulse rate and blood pressure changes seen with airway instrumentation.

What participation involves:

Through an intravenous cannula you will be given injection Propofol 2-3mg/kg, succinylcholine 1mg/kg. After 1 min either laryngoscopy and endotracheal intubation or blind insertion of appropriate size of Laryngeal mask airway will be carried out. Heart rate, systolic blood pressure, diastolic blood pressure will be recorded at regular intervals i.e., after induction, at the time of laryngoscopy and intubation or insertion of laryngeal mask and 1 min, 3 min, 5 min after intubation or laryngeal mask insertion. Both heart rate and blood pressure recordings will be made by using a non invasive blood pressure monitor. (rager, Infinity gamma XL monitor).

Risks and discomforts:

There will be no added risks directly attributable to this study

Benefits:

Your participation in this study might not benefit you directly but will help in providing information that will benefit other patients who might require general anaesthesia in the future.

Confidentiality:

The medical information produced by this study will become part of your hospital record and will be subject to confidentiality. Information of sensitive personal nature will not be part of the medical record, but will be stored in the investigator's research file. If the data are used for publication in the medical literature or for teaching purpose, no names will be used.

Right to participate:

Your participation is voluntary and you may refuse to participate or may withdraw consent and discontinue participation in the study at any time without prejudice.

Injury statement:

In the unlikely event of injury resulting directly from your participation in this study, then appropriate treatment will be provided. No further compensation will be provided by the hospital. By agreeing to participate in this study you will not be waiving any of your legal rights.

Contact person in case of any questions:

If you have any questions about this study you are free to contact the principal investigator Dr. Karima Khalid, telephone number 0787 999991 or email: karimakhalid@yahoo.com.

If you have any questions about your right as a participant, you may call Prof. M. Aboud, Chairman of the Senate Research and Publications Committee, P.O.Box 65001, Dar-es-salaam. Tel 2150302-6.

If you agree to participate in the study, please sign this consent form.

I ……, have read/ have been told about the contents of this form and understood everything explained/written. I therefore agree to participate in the study.

Participant's signature: Date

Investigator's signature Date

ANNEX III

FOMU YA RIDHAA (CONSENT FORM) – SWAHILI VERSION

Asante kwa muda wako na kukubali kusoma hii fomu. Jina langu ni Karima J. Khalid, na ni daktari kwenye masomo ya uzamili katika idara ya nusu kaputi kutoka Chuo Kikuu cha Tiba na Sayansi za Jamii Muhimbili.

Madhumuni ya utafiti

Madhumuni ya utafiti huu ni kutazama tofauti kati ya vifaa viwili vinavyotumika katika kutoa dawa za nusu kaputi (*laryngeal mask airway na endotracheal tube*). Lengo kuu la utafiti huu ni kujenga ufahamu wa uwepo wa tofauti kati ya vifaa hivi katika kuongezeka shinikizo la damu na mapigo ya moyo, na kufanya tathmini ya utofauti huo. Hii itasaidia kupelekea kupanua ujuzi juu ya vifaa hivyo na kutusaidia kutoa dawa za nusu kaputi kwa usalama zaidi.

Nini ushiriki inahusisha:

Baada ya kupewa dawa za nusu kaputi, utawekewa kifaa kimoja kati ya viwili ambavyo vinatumika katika kuendeleza kukupa dawa za nusu kaputi. Vipimo vya shinikizo la damu na mapigo ya moyo vitachukuliwa kabla ya kuwekewa kifaa, baada ya kuwekewa, dakika 1 baadae, dakika 3 baadae na dakika 5 baadae.

Hatari na madhara:

Hakuna athari yeyote inaotegemewa kutokana na utafiti huu.

Faida:

Utafiti huu utakusaidia wewe kupata dawa za nusu kaputi kwa usalama na pia kufaidika kwa wagonjwa wengine watakaokuja baada yako kupata huduma zilizo bora zaidi.

Usiri:

Taarifa zote zinayotokana na utafiti huu zitakuwa ni sehemu ya kumbukumbu za hospitali na zitatunzwa kama siri.

Haki ya kushiriki kwenye utafiti

Uko huru kuchagua kushiriki au kutoshiriki. Uko huru kujibu maswali jinsi utakavyo wewe ili mradi uwe na amani. Kama hutajisikia kushiriki uko huru kuacha ushiriki wako wakati wowote utakaotaka.

Endapo utapata madhara:

Kama utapata matatizo yeyote kutokana na ushiriki wako katika utafiti huu, utapewa matibabu sahihi kutoka hospitali kuu ya Muhimbili.

Kuwasiliana na mtu ukiwa na maswali yoyote:

Kama una maswali yoyote kuhusu utafiti huu uwe huru kuwasiliana na mkuu wa uchunguzi Dk Karima Khalid, simu namba 0787999991 au barua pepe: karimakhalid@yahoo.com.
Kama una maswali yoyote kuhusu haki yako kama mshiriki, unaweza wasiliana na Prof M. Aboud, Mwenyekiti wa Utafiti wa Seneti na Kamati ya Machapisho, SLP 65,001, Dar-es-salaam.
Tel: 2150302-6
Kama umekubali kushiriki katika utafiti, tafadhali weka saini katika fomu hii ya ridhaa.

Mimi _____, nimesoma / nimeambiwa yaliyomo katika fomu hii na kuelewa kila kitu kilichoelezwa / kilichoandikwa. Kwa hiyo nakubali kushiriki katika utafiti kwa hiari yangu mwenyewe.

Sahihi ya mshiriki : _____ Tarehe_____

Sahihi ya mtafiti: _____ Tarehe _____