A COMPARISON OF THE HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY IN PATIENTS UNDERGOING ELECTIVE PROCEDURES AT DR GEORGE MUKHARI ACADEMIC HOSPITAL

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By

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2016
DECLARATION

I, DR MARIA KATLEGO MPHAHLELE, hereby declare that this research is my own, unaided work. It has not been submitted before for any other degree at this or any other university. The research protocol was approved by the Medunsa Research Ethics Committee, Faculty of Medicine, University of Limpopo (Medunsa Campus) with clearance certificate number MREC/M/60/2014: PG

Signed…………………………………………   Date……………………

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To the patients who consented to my study, I am deeply thankful, without them this study could not have been possible.

Thank you, LORD for always being there for me.
DEDICATION

I dedicate the work of my dissertation to my daughter, Reatlegile and to my wonderful partner in life, Mphiwa who has been a constant source of support and encouragement throughout my studies. A special feeling of gratitude to my loving parents, thank you for your love, continuous support and motivation to complete this task. Without your support, this task would have been impossible to complete.
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A COMPARISON OF THE HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY IN PATIENTS UNDERGOING ELECTIVE SURGICAL PROCEDURES AT DR GEORGE MUKHARI ACADEMIC HOSPITAL

ABSTRACT:

BACKGROUND:

The safest and most common method for securing a definitive airway during general anaesthesia is direct laryngoscopy and endotracheal intubation. The problem with endotracheal intubation is that it causes a reflex increase in sympathetic activity that may result in hypertension, tachycardia and arrhythmias. These changes are associated with a rise in catecholamine levels and although they are transitory and are of no consequence in healthy individuals, they may be hazardous to patients with cerebrovascular disease, myocardial insufficiency, and hypertension. The use of a laryngeal mask airway (LMA) has been shown to have less haemodynamic responses, as its insertion requires neither the visualization of the cord nor the penetration of the larynx.

AIM:

The aim of the study was to compare the haemodynamic responses between an endotracheal intubation and a LMA insertion in patients undergoing elective surgery at DGMAH.
OBJECTIVES:

The objectives of the study were:

1. To determine the haemodynamic responses to LMA.
2. To determine the haemodynamic responses to laryngoscopy and endotracheal intubation.
3. To compare the haemodynamic response associated with LMA insertion and laryngoscopically aided endotracheal intubation.

PATIENTS AND METHODS:

This was a prospective, randomized, single blind study conducted in theatre at DGMAH on 90 patients aged between 18 and 65 years old with ASA I or ASA II (American Society of Anaesthesiologists classification) scheduled for elective surgery. Patients were randomized into two groups, 45 patients in group I (endotracheal intubation), and 45 patients in group II (LMA). Each patient was pre-oxygenated for three minutes followed by induction of anaesthesia with midazolam 0.02mg/kg, fentanyl 2mcg/kg, propofol 2mg/kg and vecuronium 0.1mg/kg. The haemodynamic parameters such as heart rate, systolic and diastolic blood pressure were measured in the ward, before induction of anaesthesia and again at one minute, three minutes and five minutes after insertion of either a laryngeal mask airway or endotracheal intubation. The results were then compared.
RESULTS:

Patients in both groups were similar in terms of gender and age. Following an endotracheal intubation there was a significant increase in heart rate at one-minute post-intubation \( (p = 0.0013) \) and at three minutes \( (p = 0.0076) \), but there was no significant increase at five minutes post-intubation \( (p = 0.2875) \). There was no change in Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at one minute, however there was a decrease in SBP and DBP at three minutes and again at five minutes compared to baseline.

In the LMA group (group II) there were no significant changes in heart rate at one minute \( (p=0.503) \), at three minutes \( (p = 0.5174) \) or at five minutes \( (p = 0.2110) \) post-placement of LMA. There was a significant decrease in SBP and DBP at one, three and five minutes post-insertion of LMA compared to baseline values. There were also significant increases in SBP, DBP and the heart rate (HR) \( (p < 0.05) \) at one minute, three minutes and again at five minutes post-endotracheal intubation when compared to the LMA group.

CONCLUSION: Maintaining the airway with LMA is associated with less haemodynamic responses compared to direct laryngoscopy and tracheal intubation.
CHAPTER 1: INTRODUCTION

1.1 STUDY PROBLEM

Safe airway management and haemodynamic stability are integral and essential goals of any anaesthetic management plan. Laryngoscopy and endotracheal intubation is the commonest method of securing a definitive airway for the administration of anaesthesia. Endotracheal intubation is invariably associated with a reflex sympathetic response resulting in elevated heart rate and blood pressure. These changes have been observed to be associated with a rise in catecholamine levels. The responses are of little significance in healthy patients but these changes may increase morbidity in patients with myocardial ischaemia, hypertension and cerebrovascular disease. The life threatening complications that may occur are ventricular tachycardia, myocardial ischaemia and cerebrovascular accidents.

Many drugs and techniques have been utilized to attenuate the pressor responses following insertion of endotracheal tube. Pharmacological approach includes the use of opioids, lidocaine, esmolol, nitroglycerine and magnesium sulphate to attenuate the cardiovascular response to laryngoscopy and intubation. Laryngeal mask airway offers a much less invasive way of maintaining the airway as it does not pass through the glottis and it does not require the use of the laryngoscope. Therefore, it may provoke less sympathetic response and catecholamine release and as a result provides more favourable haemodynamic changes during surgery.
1.2 RATIONALE FOR THE STUDY

The use of either the endotracheal tube insertion or laryngeal Mask Airway (LMA) for securing the airway for anaesthesia has remained an empirical practice at Dr George Mukhari Academic hospital. As a result of this, there is no information relating to the use of these two procedures on haemodynamic changes during surgery and the effects these changes could have on different medical conditions of patients who have to undergo surgery. Moreover, information in the literature seems to weigh heavily in favour of adopting the use of the LMA, particularly in patients whose medical conditions may be exacerbated by tracheal intubation.

On the basis of this, a randomized prospective study comparing haemodynamic responses to the insertion of LMA with the use of endotracheal intubation, was conducted in patients booked for elective surgical procedures performed at Dr George Mukhari Academic Hospital.

1.3 STUDY QUESTION

What is the difference in haemodynamic response between patients who are intubated with endotracheal tube as compared to laryngeal mask airway insertion at DGMAH?
CHAPTER 2: LITERATURE REVIEW

Airway can be maintained by various ways in which endotracheal intubation is the gold standard. Endotracheal intubation provides an artificial conduit between the atmosphere and the patient’s trachea for the purpose of the alveolar gas exchange or protection of the lungs from extraneous substances. Endotracheal tube (Figure 1) can be used to deliver anaesthetic gases directly into the trachea and allow most control of ventilation and oxygenation, in airway obstruction and mental status alteration. Laryngoscopy and endotracheal intubation during anaesthesia are known to induce clinical changes in haemodynamic variables. This procedure leads to reflex circulatory responses characterized by an increase in heart rate and blood pressure. Sympatho-adrenergic responses that occur at intubation may lead to complications like myocardial infarction, left ventricular failure, intracranial hypertension, cerebrovascular accidents and a rise in intraocular pressure[1,2].

There are also alternatives to endotracheal intubation example being laryngeal mask airway and combitube. Laryngeal mask airway is a supraglottic airway device developed by a British Anaesthesiologist - Dr Archi Brain in 1983, it has been used to secure airway and maintain spontaneous ventilation during short surgical procedures in which general anaesthesia is required and to facilitate a passage of endotracheal tube in a patient with a difficult airway [3].

Laryngeal mask airway is shaped like a large endotracheal tube on the proximal end that connects to an elliptical mask on the distal end (Fig.2). It is designed to sit in the patient’s hypopharynx and cover the supraglottic structures, thereby allowing relative isolation of the trachea [4]. Insertion of the LMA after induction of anaesthesia has
been described to cause less haemodynamic changes than tracheal intubation. Therefore, the LMA could become useful in situations where minimal haemodynamic changes are desirable[5].

**Figure 1: Endotracheal tube**

**Figure 2: Laryngeal mask airway**

**TYPES OF LMA [4]**

1. LMA classic – is the original reusable laryngeal mask airway.
2. Flexible LMA-consists of classic LMA connected to a flexible reinforced
which prevents kinking, tube occlusion, improves surgical access and prevents cuff displacement during head and neck surgery.

3. LMA fastrach - consists of intubating laryngeal mask airway, tracheal tube and stabilizing rod. It is used to aid tracheal intubation.

4. LMA proseal – It is a double mask, forming two end-to-end junctions: one with the respiratory tract end and the other with gastrointestinal tract which protects against regurgitation and gastric insufflations.

5. Disposable LMA- made of clear medical grade polyvinyl chloride and is for single use only.

6. INDICATIONS FOR LMA
   1. Use during administration of anaesthesia
   2. To facilitate ventilation and passage of a ETT in a patient with a difficult airway
   3. To aid in ventilation during fiberoptic bronchoscopy.

CONTRAINDICATIONS FOR LMA
- Full stomach
- Poor lung compliance
- Glottis or subglottic airway obstruction
- Limited mouth opening (<1.5cm).

ADVANTAGES OF LMA COMPARED WITH ETT\[6,7\]
1. Provide rapid protection of the airway
2. Easier to insert than endotracheal tube
3. Avoidance of laryngoscopy
4. Minimal cardiovascular response
5. Less invasive

DISADVANTAGES
1. Non-definitive airway protection and patency
2. Difficult ventilation if high airway pressures
3. Risk of aspiration
4. Gastric insufflations

ANATOMY OF THE AIRWAY
The are two openings to the human airway: the oropharynx and nasopharynx both of which lead to hypopharynx. At the base of the tongue, the epiglottis separates the larynx from the hypopharynx. The larynx, consists of cartilaginous skeleton, connecting ligaments and muscles, establishes the boundary of the upper and lower airway. The glottis divides the larynx into a superior compartment (from the laryngeal outlet to the vocal cords) and an inferior compartment (from the vocal cords to the lower end of the cricoids cartilage which leads to the trachea (Figure3); (8,9).
SENSORY NERVE SUPPLY OF THE AIRWAY

The sensory supply to the upper airway is derived from the cranial nerves. The mucous membranes, the nose are innervated by the ophthalmic division (v1) of the trigeminal nerve anteriorly and by the maxillary division (v2) posteriorly (sphenopalatine nerves). The palatine nerves provide sensory fibres from the trigeminal nerve (V) to the superior and inferior surfaces of the hard and soft palate. The lingual nerve (a branch of the mandibular division (v3) of the trigeminal nerve) and the glossopharyngeal nerve provide general sensation to anterior two thirds and posterior third of the tongue, respectively[9].

The glossopharyngeal nerve also innervates the roof of the pharynx, the tonsils and the under-surface of the soft palate. The vagus nerve provides sensation to the airway below the epiglottis. The superior laryngeal branch of the vagus divides into an external nerve and internal laryngeal nerve that provide sensory supply to the larynx between the epiglottis and the vocal cords. The recurrent laryngeal nerve, branch of the vagus nerve, innervates the larynx below the vocal cords and the trachea. The muscles of the larynx are innervated by the recurrent laryngeal nerve with the exception of the cricothyroid muscle, which is innervated by the external laryngeal nerve, branch of the superior laryngeal nerve[9,10,11].
CARDIOVASCULAR RESPONSES DURING AIRWAY MANIPULATION

Manipulation of the upper airway produces physiological responses which have both sympathetic and parasympathetic element. The effect is transient, occurring 30 seconds after intubation and lasting for less than 10 minutes thereafter. The glossopharyngeal and vagal afferent nerves transmit impulses to the brainstem which in turn, causes widespread autonomic activation through the sympathetic and parasympathetic nervous systems. The response is the release of catecholamines, epinephrine from adrenal medulla and release of norepinephrine from adrenergic nerve terminal. The result of autonomic activation is an elevation in blood pressure and heart rate. The hypertensive response to endotracheal intubation also results from activation of the renin-angiotensin system. The elevation in blood pressure and heart rate during intubation process, is generally well tolerated unless the patient has an underlying cardiac disorder [13,14].
Dunges et al [15] conducted a randomized study on thirty ASA I and ASA II patients scheduled for elective orthopaedic or abdominal surgery under general anaesthesia and examined the haemodynamic instability and endocrine response during endotracheal tube placement. The report had shown that endotracheal tube placement into the non-anaesthetized trachea provokes significant haemodynamic response with increased heart rate and systolic blood pressure accompanied by a rise of plasma catecholamine levels. This response occurs even if laryngoscopy is omitted and an indirect technique, lightwand-guided endotracheal intubation is used. However, this report was flawed by not monitoring the depth of anaesthesia and a more profound induction of anaesthesia before tracheal tube insertion may also have influenced the results from this study. It was concluded that endotracheal tube placement into the non-anaesthesized trachea causes haemodynamic and endocrine stress even if direct laryngoscopy is omitted.

A pilot study conducted by Tahir et al [16] compared pressor responses following laryngeal mask airway with laryngoscopy and endotracheal tube insertion on sixty ASA I and ASA II patients scheduled for elective general surgery, suggested that the laryngeal mask airway (LMA) technique is an effective alternative and it is a less invasive airway device when compared with endotracheal intubation for spontaneous and positive pressure ventilation. This pilot study showed significant increases in heart rate, systolic and diastolic blood pressure (P <0.05) in endotracheal group when compared with LMA insertion. From these findings, it was concluded that the use of the LMA may offer advantages over tracheal intubation where evidence of changes in pressor response is of particular concern. In a similar study by Montazari et al [17] comparing haemodynamic responses induced by endotracheal intubation with those produced by insertion of LMA and face mask on 195 ASA I patients
scheduled for transurethral lithotripsy procedure, it was again demonstrated that in normotensive patients, the insertion of LMA caused smaller increases in mean arterial pressure (MAP) and heart rate (HR) than the use of face mask or endotracheal intubation. The observed increases in MAP and HR were transient and led to the conclusion that direct stimulation of the trachea by a tracheal tube has a major role in causing haemodynamic responses and LMA results in a smaller cardiovascular change than endotracheal tube.

Examination of changes in intraocular pressure, as well as haemodynamic responses, following insertion of LMA and endotracheal tube in fifty ASA I patients scheduled for elective non–ophthalmic surgical procedures, were the focus of the study by Bukhari et al [3] who reported increases in heart rate, systolic and diastolic blood pressure and intraocular pressure in both methods of airway management. However, greater increases in the parameters were observed in the endotracheal group (p<0.01). This led to the conclusion that the LMA could be useful in situations where patients have medical conditions that will require minimal haemodynamic and intraocular changes.

The relative contribution to the haemodynamic effects related to tracheal intubation by direct laryngoscopy compared with intubating laryngeal mask on seventy patients with ASA I and II for elective orthopaedic and abdominal surgery was also examined by Tabari, Alipour and Ahmadi [18]. They were able to demonstrate that both MAP (p=0.04) and diastolic blood pressure (p=0.034) at 5 minutes were significantly higher in patients that were intubated by direct laryngoscopy as compared with intubating LMA. Their conclusion was that indirect LMA should be considered for patients in whom a marked pressure response would be undesirable. Similarly, Sener et al [19] examined pressor responses as well as upper airway morbidity
amongst forty two hypertensive patients (ASA II) who were scheduled for elective ophthalmic surgery and they found that haemodynamic responses to intubation with laryngoscopy are accompanied by a smaller increase in blood pressure than with the intubating LMA.

A prospective study [20] which had compared haemodynamic and catecholamine stress responses to insertion of the Combitube, LMA and tracheal intubation on 60 ASA I and II patients scheduled for elective surgery found that haemodynamic response to insertion of the Combitube and endotracheal tube was significantly greater than the response due to laryngeal mask insertion. Akhlagh et al[21] determined haemodynamic response via direct laryngoscopy and intubating laryngeal mask airway in 80 ASA III patients undergoing coronary artery bypass graft, it was reported that a significant rise in blood pressure and heart rate was detected in both groups. However when comparing the two groups there was no significant difference. It was concluded that intubating laryngeal mask airway does not have much greater benefit over conventional direct laryngoscopy.

Milind et al [22 ] conducted a study on 100 patients ASA I and II and compared blood pressure response of LMA to endotracheal intubation. There was a fall in SBP and DBP following induction of anaesthesia with propofol, after endotracheal intubation and LMA insertion there was a steady rise of SBP.

The rise of SBP was statistically significant with \( p < 0.05 \) at 1, 2, 3, 5 and 10 minutes from time of endotracheal intubation. It was concluded that LMA is a better option to endotracheal intubation where haemodynamic responses to intubation are of concern such as in patients with coronary artery disease.
Ajuzieogu et al[23] conducted a study on seventy five patients ASA I and II, scheduled for elective surgical procedures and compared the blood pressure and heart rate responses to insertion of LMA and endotracheal intubation. In the endotracheal intubation group, significant increases in heart rate, systolic blood pressure and mean arterial pressures were detected from 1 to 10 minutes from baseline values. After LMA insertion, the increase in HR, SBP, DBP and MAP was less. It was concluded that the pressor response to LMA insertion is less and is of short duration than that of endotracheal intubation and LMA will be desirable in conditions where a pressor response will be deleterious.

In a comparative study by Smith, Smith and Becker [24], haemodynamic changes following laryngoscopy alone and after laryngoscopy was followed by tracheal intubation, was examined in eighty American Society of Anaesthesiologists(ASA) grade I and grade II patients scheduled for elective surgery and requiring general anaesthesia. In this study, it was found that laryngoscopy followed by intubation was characterized by a significant increase in heart rate and blood pressure (p=0.038). It was concluded that the intubation component is the major cause of the pressor response, associated with an increase in heart rate.

**AIM OF THIS STUDY:**
To compare the haemodynamic responses between endotracheal intubation and laryngeal mask airway insertion in elective surgical patients at DGMAH.

**OBJECTIVES:**
1. To determine the haemodynamic responses to laryngeal mask insertion.
2. To determine the haemodynamic responses to laryngoscopy and endotracheal intubation.
3. To compare the haemodynamic responses associated with LMA insertion and laryngoscopically aided endotracheal intubation amongst patients graded as American Society of Anaesthesiologists I (ASA I) and ASA II, undergoing elective surgery.

CHAPTER 3: METHODOLOGY

3.1 STUDY SETTING
The study was conducted at DGMAH - a tertiary level hospital situated at approximately 32km north of the city of Pretoria.

3.2 STUDY DESIGN
It was a single–blinded, randomized, prospective study conducted amongst patients who underwent elective surgery at DGMAH.

3.3 STUDY POPULATION
Ninety adult patients who were booked for elective surgery which required the use of ETT or LMA for anaesthesia constituted the study population.

3.4 INCLUSION CRITERIA
- All the patients in the study were aged 18-65 years
- All the patients were ASA I-II classified
- Patients who gave informed Consent

3.5 EXCLUSION CRITERIA
- Body Mass Index (BMI) ≥ 35
- Features that clinically predict a difficult laryngoscopy.
- Patients on any form of cardiovascular medication.
• Hypertensive patients were excluded
• Patients with asthma
• Patients with delayed gastric emptying
• Any patient with history of gastro-esophageal reflux.

3.6 SAMPLE SIZE
The required sample size was calculated based on a previous similar study [11] to detect a difference in haemodynamic responses taken together with an alpha-error limit of 5% (p < 0.05). A sample size of 45 for each group of the study was calculated to achieve a 90% power to detect a 10 mm Hg difference in the mean arterial pressure between the two groups.

3.7 CONDUCT OF THE STUDY
Randomization
Patients were randomised (using the closed envelope technique) into two groups: Group I (laryngoscopy and endotracheal intubation group) and Group II (laryngeal mask airway group)

PRE-OPERATIVE PREPARATION OF THE PATIENT
A Written Informed Consent was obtained from all participants before randomisation was carried out. Ninety ASA I and II patients aged 18 to 65 years scheduled for elective surgery and requiring general anaesthesia with tracheal intubation or LMA insertion were enrolled into the study. Baseline readings of blood pressure and heart rate were recorded in the ward.

MATERIALS, APPARATUS AND INSTRUMENTS USED
STANDARD MONITORING
• Electrocardiogram
• Non-invasive blood pressure monitor
• Pulse oximetry
• Capnography

**ANAESTHESIA**

On arrival in the operating room, each patient was connected to an intravenous line with an 18 G intravenous cannula and monitoring was instituted using Datex monitor. Patients were pre-medicated with intravenous midazolam (0.02mg/kg) before induction of anaesthesia. After 5 minutes rest in the operating room, systolic blood pressure, diastolic blood pressure, mean arterial pressure, heart rate and oxygen saturation were recorded. All the patients were pre-oxygenated with 100% oxygen for three minutes followed by induction of anaesthesia with fentanyl 1 – 2mcg/kg, propofol 2 – 2.5mg/kg and vecuronium 0.1mg/kg. Induction was followed by manual ventilation with isoflurane in oxygen and air to a minimum alveolar concentration (MAC) of 1.5 and after 3 minutes of ventilation laryngeal mask airway insertion or laryngoscopy and tracheal tube insertion was performed.

**3.8 OUTCOME VARIABLES**

• Blood pressure and heart rate were recorded in the ward

• These measurements were repeated immediately prior to induction of anaesthesia in the theatre and were repeated at 1 minute, 3 minutes and 5 minutes after insertion of LMA or endotracheal tube.

• Surgical stimulation was avoided during the period of the procedure.

**3.9 DATA COLLECTION**

Data from this prospective study was collected by researcher into a data form which was designed to include all relevant information for the assessment of the variables of the study. A copy of the data collection form is attached (Appendix B).
3.10 STATISTICAL ANALYSIS:

Data generated from the study were analysed by descriptive statistics and summarised for means, standard deviation and 95% Confidence intervals of the differences between the two groups. This was done by the method of repeated analysis of variance (ANOVA) which was then transformed through Student \( t \)-test to establish any statistical significant difference in hemodynamic responses from the two procedures. Specific differences between the times of measurements (from pre-operative to 5 minutes after instrumentation) were assessed by pair-wise comparison using the Fisher’s exact test.

RELIABILITY AND VALIDITY

Reliability: Reliability refers to the reproducibility and consistency of information or data and the degree to which a method gives the same results when used on more than one occasion under the same condition. To ensure reliability:

1. Selection of patients who met the criteria for the study was done only by the Researcher. The prospective design of the study as well as the randomization of patients also add to the reliability of the study.
2. Induction of anaesthesia, all recordings for blood pressure and heart rates, were carried out only by the Researcher, in order to avoid inter-observer differences.
3. Statistical derivation of sample size has been applied so as to ensure appropriate power of the study and to provide the required measure of reliability on results of the study.
4. The Statistician with whom the Researcher performed data analyses was not involved in the conduct of the study.
**Validity:** Validity refers to the concept of accuracy of a study and it is also the degree to which the measurement reflects the true value of the variables. The validity of this study was ensured by taking the following steps:

1. The performance of laryngoscopy, endotracheal intubation and laryngeal mask airway followed the international guidelines for these instrumentations. The researcher is already versed in the performance of these procedures.
2. All recordings for blood pressure and heart rate were recorded directly into a data collection form so as to avoid any possibility of transcription errors.
3. All information relevant for the evaluation of findings from the study were recorded prospectively and therefore eliminated the possibility of wrong information being encountered.

**BIAS:**

Bias refers to any effect at any stage of a research process that tends to produce results that depart systematically from the true values. Types of bias that could have occurred and against which steps were taken during the proposed study were:

1. **Selection Bias:** This was guarded against by making sure that the Researcher was the only professional who determined the inclusion of any patient into the study based on pre-study inclusion criterion of patients being ASA I or ASA II classification.

2. **Transcription Error:** Transcription errors during the transfer of intra-operative instrumental recordings onto the data collection forms were guarded against as only the Researcher was involved in this exercise.

3. **Data Presentation and Interpretation:** Appropriate research methodological approach was adopted in presenting results emanating from the study. The
interpretation of results was undertaken after both the Researcher and the Statistician had deliberated on the results.

4. **Generalization and Inferences:** Over-generalization of the findings from this study as well as making wrong inferences on results were avoided in order not to introduce unnecessary bias into the findings of the study.

**ETHICAL CONSIDERATIONS**

Permission to conduct the study was sought and obtained from the Chief Executive officer (CEO), Clinical Manager of Dr George Mukhari Academic Hospital and Head of Department of Anaesthesiology. Conduct of the study was also approved by an Institutional Review Committee - Medunsa Research Ethics Committee (MREC) of the University of Limpopo (Clearance Certificate Number: MREC/M/60/2014:PG)

Each patient was briefed about the study and only those who consent and signed the informed consent form were randomized for the study. Complete confidentiality of patient’s information was maintained during and after the conduct of the study.
CHAPTER 4: RESULTS

A total of ninety patients were enrolled into the study, forty five patients were randomly allocated to each of two groups, one group had laryngoscopy and endotracheal intubation (Group I), and the other had laryngeal mask insertion (Group II). The ages of the patients in the two groups ranged from 18 – 60 years and the mean (± standard deviation) for both groups were not statistically different (p = 0.3278).

Table 1a: Demographic features of the patients – Age

<table>
<thead>
<tr>
<th>Age(years)</th>
<th>Group I Patients</th>
<th>Group II Patients</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>18 – 60</td>
<td>19 – 60</td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>36.8</td>
<td>34.4</td>
<td></td>
</tr>
<tr>
<td>SDev.</td>
<td>11.0</td>
<td>11.9</td>
<td>0.3278</td>
</tr>
</tbody>
</table>

Key: [SDev = Standard Deviation; n = number of patients; p-value = Level of statistical significance]

Table 1b: Demographic features of the patients - Gender

<table>
<thead>
<tr>
<th>Gender</th>
<th>Group I Patients [N (%)]</th>
<th>Group II Patients [N (%)]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Females</td>
<td>Males</td>
</tr>
<tr>
<td></td>
<td>21(46.7)</td>
<td>24(53.3)</td>
</tr>
<tr>
<td>p - value</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>15(33.3)</td>
<td>30(66.7)</td>
</tr>
</tbody>
</table>

Gender distribution for each of the two groups was similar with no statistically significant difference between males and females for Group I(p = 0.6481) or Group II(p = 0.2074) (see figure 5a & 5b).
Table 2: ASA classification for the patients

<table>
<thead>
<tr>
<th>ASA Classification</th>
<th>Group I (N = 45; %)</th>
<th>Group II (N = 45; %)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>43(95.6%)</td>
<td>43(95.6%)</td>
<td>-</td>
</tr>
<tr>
<td>II</td>
<td>2(4.4%)</td>
<td>2(4.4%)</td>
<td>-</td>
</tr>
</tbody>
</table>

Key: p-value = Level of statistical significance

Table 2 shows the ASA classification of each of the patients in the two groups. ASA classification for the patients were similar for both groups of patients and the vast majority (95.6%) of the patients in each group were of ASA I classification.

Table 3: Surgical procedure performed

<table>
<thead>
<tr>
<th>Type of surgery</th>
<th>Group I</th>
<th>Group II</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>General surgery</td>
<td>6(13.3%)</td>
<td>7(15.6%)</td>
<td>0.6251</td>
</tr>
<tr>
<td>Orthopaedic surgery</td>
<td>35(77.8%)</td>
<td>34(75.6%)</td>
<td>0.8372</td>
</tr>
<tr>
<td>Ophthalmology</td>
<td>2(4.4%)</td>
<td>4(8.9%)</td>
<td>0.2945</td>
</tr>
<tr>
<td>Gynaecology</td>
<td>2(4.4%)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Key: p-value = Level of statistical significance for the difference between Groups I & II
Table 3 shows the types of surgery performed for the patients. Patients in the two groups underwent various surgeries for which endotracheal intubation with laryngoscopy (Group I) or laryngeal mask airway intubation (Group II) was utilized. The surgical procedures carried out were not statistically different in number for patients in the two groups: General surgery (Group I, 13.3% vs Group II, 15.6%; p = 0.6251); orthopaedic surgery (Group I, 77.8% vs Group II, 75.6%; p = 8372); ophthalmology (Group I, 4.4% vs Group II, 8.9%; p = 0.2945). There were two additional patients who had gynaecological surgery among Group I patients.

In-Ward Vitals were assessed for systolic, diastolic blood pressure and for heart rate as illustrated in Table 4 below, in order to evaluate the impact of the use of either laryngoscopy for endotracheal intubation or LMA on patients’ haemodynamic changes.

### Table 4: Evaluation of In-Ward blood pressure and heart rate prior to surgery

<table>
<thead>
<tr>
<th>VITALS</th>
<th>GROUP I [Endotracheal]</th>
<th>GROUP II [LMA]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure:</td>
<td>Range</td>
<td>100 – 155</td>
<td>100 – 157</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>122</td>
<td>126</td>
</tr>
<tr>
<td></td>
<td>SDev</td>
<td>11.8</td>
<td>14.1</td>
</tr>
<tr>
<td>Diastolic Blood Pressure:</td>
<td>Range</td>
<td>47 – 92</td>
<td>54 – 97</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>73</td>
<td>74</td>
</tr>
<tr>
<td></td>
<td>SDev</td>
<td>10.3</td>
<td>12.0</td>
</tr>
<tr>
<td>Heart Rate:</td>
<td>Range</td>
<td>63 – 99</td>
<td>53 – 113</td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>79</td>
<td>81</td>
</tr>
<tr>
<td></td>
<td>SDev</td>
<td>9.0</td>
<td>13.0</td>
</tr>
</tbody>
</table>

Key: SDev = Standard Deviation; LMA = Laryngeal Mask Airway
The range, mean and standard deviation of the values for systolic and diastolic blood pressure did not show any statistically significant differences when the two groups were compared: [systolic blood pressure, p = 0.1700; diastolic blood pressure; p = 0.6762]. Similarly, the in-ward evaluation of heart rate revealed no statistically significant difference (p = 0.4268) between patients in Group I as compared with patients in Group II.

The same haemodynamic evaluations were repeated in-theatre, prior to surgery and the results are shown in Table 5. The two groups had similar recordings for systolic and diastolic blood pressure measurements with no statistically significant differences:

**Table 5: Evaluation of blood pressure and heart rate in the theatre prior to intubation or placement of LMA**

<table>
<thead>
<tr>
<th>VITALS</th>
<th>GROUP I</th>
<th>GROUP II</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range Systolic BP:</td>
<td>101 – 158</td>
<td>104 – 176</td>
<td>0.2683</td>
</tr>
<tr>
<td>Mean</td>
<td>127</td>
<td>131</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>15.0</td>
<td>18.5</td>
<td></td>
</tr>
<tr>
<td>Range Diastolic BP:</td>
<td>46 – 98</td>
<td>49 – 107</td>
<td>0.2483</td>
</tr>
<tr>
<td>Mean</td>
<td>76</td>
<td>75</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>11.0</td>
<td>11.7</td>
<td></td>
</tr>
<tr>
<td>Range Heart Rate:</td>
<td>59 – 113</td>
<td>54 – 140</td>
<td>-</td>
</tr>
<tr>
<td>Mean</td>
<td>80</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>11.0</td>
<td>14.9</td>
<td></td>
</tr>
</tbody>
</table>
Systolic blood pressure (Group I vs Group II, p = 0.2686) and diastolic blood pressure (Group I vs Group II, p = 0.2483). In addition, the heart rates were similar for both groups in theatre and prior to surgery.

Following endotracheal intubation [Group I] and placement of the laryngeal mask airway [Group II], the effects of these two procedures on intra-operative changes in vital signs were determined in each group. As illustrated in Figure 6a [Group I] below, there was no immediate change in systolic blood pressure, one minute following endotracheal intubation when compared with the baseline value (p = 0.7801). However by three and five minutes after endotracheal intubation, there were noticeable decreases in systolic blood pressure which were statistically significantly different from baseline values: (3 minutes, p = 0.0088; 5 minutes, p = 0.0001). For diastolic blood pressure, there was no change at 1 minute following endotracheal intubation but a slight change noticeable after 3 minutes was not statistically significant when compared with the baseline value. By 5 minutes after intubation the reduction in diastolic blood pressure as compared with the baseline value was statistically significant at p < 0.0001. Heart rate for patients who had endotracheal intubation had an initial increase at 1 minute post-intubation (p = 0.0013) and this increase persisted for the 3 minute assessment (p = 0.0076). However, by 5 minutes after intubation the heart rate recorded was similar to what was found immediately prior to intubation (baseline) with a p-value of 0.2875.

Similar comparisons were made for changes in systolic and diastolic blood pressure and heart rate among patients who were managed by laryngeal mask airway (Figure 6b). In this group of patients [Group II], there was a steady statistically significant decrease in systolic blood pressure at 1 minute (p < 0.001), 3 minutes (p < 0.0001)
and at 5 minutes ($p < 0.0001$) in comparison with values obtained at baseline immediately prior to placement of the LMA. A similar pattern of decrease was

was recorded for diastolic blood pressure among these Group II patients over the entire 5 minutes of assessment post-placement of LMA (1 minute, $p = 0.0010$; 3 minutes, $p < 0.0001$; 5 minutes, $p < 0.0001$). There were no statistically significant changes in the heart rates over the entire 5 minutes assessment period following placement of LMA, in comparison with the heart rate at baseline before placement of LMA (1 minute, $p = 0.5303$; 3 minutes, $p = 0.5174$; 5 minutes, $p = 0.2110$).

Table 6 below shows the results of the four haemodynamic variables (systolic, diastolic, mean arterial blood pressures and heart rates), taken one minute intraoperatively for patients in the two study groups. One minute intra-operatively, there were statistically significant differences in the four parameters for patients with
endotracheal intubation when compared with those who had LMA: The four parameters were consistently significantly higher in Group I patients when compared with Group II patients: [systolic blood pressure, \( p = 0.0006 \); diastolic blood pressure, \( p = 0.0128 \); mean arterial blood pressure, \( p = 0.0008 \); heart rate, \( p = 0.0156 \)].

**Table 6: Intra-operative blood pressure and heart rate taken 1 minute after endotracheal intubation [Group I] or placement of LMA [Group II].**

<table>
<thead>
<tr>
<th>Intra-Operative Vitals</th>
<th>Group I [Endotracheal]</th>
<th>Group II [LMA]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure:</td>
<td>Range 82 – 167</td>
<td>76 – 140</td>
<td>0.0006</td>
</tr>
<tr>
<td></td>
<td>Mean 126</td>
<td>113</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 18.6</td>
<td>15.4</td>
<td></td>
</tr>
<tr>
<td>Diastolic Blood Pressure:</td>
<td>Range 40 – 103</td>
<td>50 – 105</td>
<td>0.0128</td>
</tr>
<tr>
<td></td>
<td>Mean 76</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 17.5</td>
<td>15.7</td>
<td></td>
</tr>
<tr>
<td>Mean Arterial Pressure :</td>
<td>Range 55 – 113</td>
<td>50 – 111</td>
<td>0.0008</td>
</tr>
<tr>
<td></td>
<td>Mean 92</td>
<td>79</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 15.8</td>
<td>14.5</td>
<td></td>
</tr>
<tr>
<td>HeartRate:</td>
<td>Range 51 – 129</td>
<td>53 – 128</td>
<td>0.0156</td>
</tr>
<tr>
<td></td>
<td>Mean 91</td>
<td>82</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 19</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

*Key: MABP = Mean Arterial Blood Pressure*

These measurements were repeated 3 minutes intra-operatively (Table 7) as part of the evaluation of possible changes in the haemodynamic status of the patients following the use of endotracheal intubation as against the use of LMA. Similar results were found at 3 minutes to what happened one minute intra-operatively, in the sense that patients who had endotracheal intubation had statistically significant higher
values for systolic blood pressure ($p = 0.0003$), diastolic blood pressure ($p = 0.0028$), mean arterial blood pressure ($p = 0.0001$) and heart rate ($p = 0.0033$).

Table 7: Intra-operative blood pressure and heart rate taken 3 minutes after endotracheal intubation [Group I] or placement of LMA [Group II].

<table>
<thead>
<tr>
<th>Intra-Operative Vitals</th>
<th>Group I [Endotracheal]</th>
<th>Group II [LMA]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Range</td>
<td>83 – 153</td>
<td>72 – 145</td>
<td>0.0003</td>
</tr>
<tr>
<td>Systolic Blood Pressure: Mean</td>
<td>118</td>
<td>105</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>16.5</td>
<td>15.7</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>40 – 99</td>
<td>40 – 113</td>
<td>0.0028</td>
</tr>
<tr>
<td>Diastolic Blood Pressure: Mean</td>
<td>70</td>
<td>59</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>17.0</td>
<td>16.0</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>53 – 114</td>
<td>53 – 102</td>
<td>0.0001</td>
</tr>
<tr>
<td>MABP: Mean</td>
<td>87</td>
<td>72</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>14.7</td>
<td>12.1</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>59 – 123</td>
<td>57 – 128</td>
<td>0.0033</td>
</tr>
<tr>
<td>Heart Rate: Mean</td>
<td>88</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>SDev</td>
<td>16</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Key: MABP = Mean Arterial Blood Pressure

The same exercise of evaluating possible haemodynamic changes was repeated 5 minutes intra-operatively as shown in Table 8 below. Even at 5 minutes, intra-operatively, all the recordings show that the use of endotracheal intubation in patients resulted in statistically significant higher values when compared with those who had laryngeal mask airway. The statistical differences in values for the four
parameters were: systolic blood pressure ($p = 0.0002$); diastolic blood pressure ($p = 0.0022$); mean arterial blood pressure ($p = 0.0013$) and heart rate ($p = 0.0312$).

**Table 8: Intra-operative blood pressure and heart rate taken 5 minutes after either Endotracheal intubation [Group I] or placement of LMA [Group II].**

<table>
<thead>
<tr>
<th>Intra-Operative Vitals</th>
<th>Group I [Endotracheal]</th>
<th>Group II [LMA]</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic Blood Pressure:</td>
<td>Range 87 – 140</td>
<td>83 – 132</td>
<td>0.0002</td>
</tr>
<tr>
<td></td>
<td>Mean 113</td>
<td>103</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 12.9</td>
<td>12.2</td>
<td></td>
</tr>
<tr>
<td>Diastolic Blood Pressure:</td>
<td>Range 47 – 94</td>
<td>45 – 81</td>
<td>0.0022</td>
</tr>
<tr>
<td></td>
<td>Mean 64</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 12.9</td>
<td>12.7</td>
<td></td>
</tr>
<tr>
<td>MABP:</td>
<td>Range 54 – 105</td>
<td>50 – 110</td>
<td>0.0013</td>
</tr>
<tr>
<td></td>
<td>Mean 81</td>
<td>70</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 13.7</td>
<td>13.1</td>
<td></td>
</tr>
<tr>
<td>Heart Rate:</td>
<td>Range 56- 120</td>
<td>51 – 129</td>
<td>0.0312</td>
</tr>
<tr>
<td></td>
<td>Mean 83</td>
<td>76</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SDev 15.0</td>
<td>14.8</td>
<td></td>
</tr>
</tbody>
</table>
Endotracheal intubation is a rapid, simple, safe and non-surgical technique that achieves all the goals of airway management. It maintains airway patency, protects the lungs from aspiration and permits leak-free ventilation during mechanical ventilation and remains the gold standard procedure for airway management. Endotracheal intubation and laryngoscopy is associated with a rise in blood pressure, heart rate and cardiac dysarrythmias [25].The haemodynamic responses are due to reflex sympathoadrenal discharge resulting in increased catecholamines provoked by epilaryngeal and laryngotracheal stimulation subsequent to laryngoscopy and tracheal intubation [4, 26&27].

Direct larygoscopy produces a marked transient response, with detrimental effects on the coronary and cerebral circulation in high risk patients, particularly in those with systemic hypertension, coronary artery or cerebrovascular diseases. The pressor response from laryngoscopy in such individuals may predispose to development of pulmonary oedema, myocardial insufficiency and cerebrovascular accident. To attenuate such consequences during induction of anaesthesia various methods and techniques have been employed which include increasing the depth of anaesthesia, beta adrenergic blockers, lidocaine, opioids nifedipine, clonidine and nitroglycerine. Alternative airway management strategies like LMA have been suggested to minimise cardiovascular changes. However, all such manoeuvres had limitations. The search for the ideal technique or agents for attenuation of hemodynamic changes is still ongoing [28,29]. Laryngeal mask airway is a useful airway devise for general anaesthesia, difficult or failed intubation and for emergency airway maintenance. The LMA is inserted blindly into pharynx, without the use of laryngoscope, forming a low pressure seal around the laryngeal inlet and permitting gentle positive–pressure ventilation [4].
Jarineshin et al[30] compared haemodynamic responses of laryngeal mask insertion to laryngoscopy and tracheal intubation on 150 patients with ASA I for elective general surgery. The study disclosed that HR and BP were significantly higher in ETT Group than LMA group. The authors then concluded that the use of LMA is associated with less cardiovascular responses especially changes in heart rate and lesser duration of insertion compared to endotracheal intubation. They recommended the use of LMA in patients with ischaemic heart disease.

Rooke et al [31] conducted a study on the haemodynamic effects of intubation and LMA insertion on 27 hypertensive patients (ASA II) who were scheduled for ophthalmic surgery. There was no significant difference in terms of gender and age. Blood pressure and heart rate decreased in both groups after induction of anaesthesia. However, after tracheal intubation, heart rate but not blood pressure increased above baseline levels and haemodynamic variables were unchanged after laryngeal mask insertion. They concluded from the study that anaesthetic technique used completely blocked the pressor response to laryngeal mask insertion.

The heart is the main determinant of myocardial oxygen consumption and patients with coronary artery disease have low tolerance to tachycardia. The heart rate more than 110 bpm increases the incidence of myocardial ischaemia during anaesthesia [32]. The current study evaluated the haemodynamic responses following insertion of LMA and endotracheal intubation. The patients in both groups were similar in terms of gender and age. The results of examining the mean heart rates of the patients in two groups at different time points indicate that there is no significant difference between these two groups at baseline. However, in the first, third and fifth minute after intubation, the mean heart rates in
the ETT group showed a significant increase compared to LMA group \( [p=0.0156, p=0.0033, p=0.0312] \). This finding is consistent with results of previous studies [30,31]. Das et al compared heart rate responses to laryngoscopic endotracheal intubation and to endotracheal intubation using intubating laryngeal mask airway in thirty-four patients with pure mitral stenosis for closed mitral commissurotomy. It was found that the mean heart rate in conventional laryngoscope at 2 minutes, 3 minutes, 4 minutes and 5 minutes post-intubation were significantly higher than in ILMA group \( (p<0.05) \). It was concluded that the use of LMA may be a preferable device for endotracheal intubation in patients with isolated mitral stenosis [33].

Smith et al [24] similarly investigated the haemodynamic changes after laryngoscopy alone to laryngoscopy followed by tracheal intubation on eighty ASA I and II patients scheduled for elective surgery. There were no differences with regard to gender and ages of the patients. They have observed significant increase in heart rate post tracheal intubation but decrease in blood pressure. The decrease in blood pressure post instrumentation or intubation could be due to induction technique used, lignocaine, alfentanil and propofol. This may have attenuated expected increases in blood pressure but not increases in heart rate after intubation [34]. Induction of anaesthesia with propofolcaused a decrease in blood pressure, while heart rate is not affected significantly [35]. Based on these findings the authors concluded that intubation results in increased pressor response.

Wilson et al [36] evaluated haemodynamic responses to endotracheal intubation and laryngeal mask airway insertion on forty ASA I and ASA II patients who underwent gynaecological surgery. There were no significant differences between the groups in terms of age and gender. They observed significantly marked
increase in heart rate, systolic blood pressure and diastolic blood pressure after endotracheal intubation as compared to LMA insertion. The mean maximum increase in SBP after intubation was 51.3% and 22.9% for laryngeal mask airway. They concluded that haemodynamic responses to LMA are significantly lower than ETT and LMA could be useful in situations where minimal changes in haemodynamic response are desirable such as in patients with hypertension and coronary artery disease. The study by Wood et al [37] compared the haemodynamic responses with LMA insertion and endotracheal intubation on forty ASA I patients scheduled for elective surgery. There were no significant differences between the groups in terms of age and gender. They found a significant increase in blood pressure following endotracheal intubation compared to laryngeal mask airway. There was also a significant increase in heart rate following endotracheal intubation, which did not occur following laryngeal mask airway insertion. They concluded that insertion of the LMA is accompanied by less cardiovascular responses.

In the present study, SBP and DBP in both groups at baseline were comparable and there was no statistically significant difference between the two groups (p > 0.05). Following induction with propofol and at 1 minute, 3 minutes and 5 minutes post intubation, there was a fall in SBP and DBP in both groups compared to the baseline values. The possible reason for the decrease in blood pressure noted in the present study could have been due to the fact that propofol was used for induction of anaesthesia which caused greater hypotension compared to sodium thiopental used in most other studies [17,38]. The previous studies have shown that induction of anaesthesia with propofol is known to be associated with hypotension which ranges from 30% to 17% from the basal values[22,39].
minute, 3 minutes and 5 minutes were significantly higher in intubation group I when compared with laryngeal mask airway used for group II (p < 0.05).

The findings in the present study closely correlate with those of Anita et al [40] who studied the haemodynamic response to insertion of cuffed oropharyngeal Airway (COPA), LMA and ETT on seventy-five ASA I and II patients who underwent short urological procedures. There were no differences in three groups in terms of age and gender. They found significant increase in heart rate and blood pressure (p < 0.05) following endotracheal intubation and attenuated pressor response to insertion of the laryngeal mask airway and COPA. The conclusion was that COPA and LMA are valuable alternatives to ETT because they result in with less complications and less pressor responses.

Rehman et al [41] conducted a study on haemodynamic responses of classic laryngeal mask airway in comparison with conventional tracheal intubation on one hundred ASA I and II patients scheduled for general surgery, orthopaedic and gynaecological surgical procedures. The authors concluded that there was statistically significant rise in systolic blood pressure, diastolic blood pressure, mean arterial pressure and heart rate as compared to laryngeal mask airway insertion. Stimulation of mechanoreceptors spread over the pharyngeal wall, epiglottis, arytenoids cartilages, vocal cords are the cause of increased haemodynamic response to laryngoscope and intubation.

Krishna et al [42] evaluated haemodynamic responses between laryngeal mask airway insertion and endotracheal intubation on fifty ASA I patients scheduled for general surgery. The authors reported slight increase in heart rate, systolic blood pressure and diastolic blood pressure which in LMA group was short lived as
compared to endotracheal intubation group which showed a statistically significant increase in heart rate, systolic blood pressure at 1 minute, 3 minutes and 5 minutes (p<0.001). It was concluded that pressor response and its duration to LMA insertion is much less than that of endotracheal intubation.

Lamb et al [43] studied the effects of the laryngeal mask airway and endotracheal tube on intraocular pressure and stress response. The study demonstrated an attenuated response to haemodynamic and intraocular pressure changes following insertion of LMA, which correlate with findings of the current study. Attenuation of pressor response with the use of LMA may be due to decreased catecholamine release. The reason for this could be due to the fact that the LMA insertion requires neither visualization of cords nor penetration.

Another study by Akhtar et al [44] compared the use of LMA with endotracheal tube for intraocular ophthalmic surgery on thirty ASA I, II and III patients and observed that insignificant changes in blood pressure, heart rate and intraocular pressure were produced after the insertion of LMA or endotracheal intubation. Their findings are not in agreement with the results from the present study. The difference might be due to various factors such as pressure exerted through laryngoscope, choice and dose of opioids and the depth of anaesthesia.

The study by Bennet et al[45] for cardiac anaesthesia, examined the insertion of LMA as compared to tracheal intubation, these workers concluded that LMA insertion does not result in a rise in heart rate and blood pressure and should be used in patients with coronary artery disease.
CHAPTER 6: CONCLUSION
Laryngoscopy and endotracheal intubation is associated with an increase in pressor response (that is: increase in heart rate, systolic and diastolic blood pressure) compared to laryngeal mask airway. Therefore, considering the more favourable hemodynamic changes following insertion of laryngeal mask airway in the present study, especially with regard to changes in heart rate, it establishes the usefulness of laryngeal mask airway in airway management in situations where minimal changes in haemodynamic responses are desirable, such as in patients with hypertension and ischaemic heart disease.

RECOMMENDATIONS
Laryngeal mask airway should be used in situations where minimal changes in haemodynamic response are desirable such as in patients with hypertension and coronary artery disease and the procedure should not be more than 2hrs. Laryngeal mask airway has attenuated pressor response therefore it should be available for patients who cannot tolerate increase in pressor response from laryngoscopy and endotracheal intubation.

Future randomised study is advocated to determine haemodynamic responses to LMA and endotracheal intubation in hypertensive patients which may be different to normotensive patients.
REFERENCES


45. Bennett SR, Grace D, Griffin SC. – Cardiovascular changes with the laryngeal mask airway in cardiac anaesthesia. *British Journal of Anaesth*, 2004;92(6):885-887
APPENDIX A

UNIVERSITY OF LIMPOPO (Medunsa Campus) ENGLISH CONSENT FORM

Statement concerning participation in a Clinical Trial/Research Project*.

Name of Project / study/ trial study/ trial

COMPARISON OF HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY IN PATIENTS UNDERGOING ELECTIVE PROCEDURES AT DR GEORGE MUKHARI ACADEMIC HOSPITAL

I have read the information on *heard the aims and objectives of* the proposed study and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the study are sufficiently clear to me. I have not been pressurized to participate in any way.

I understand that participation in this Clinical Trial / Study / Project* is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this Trial / Study / Project* has been approved by the Medunsa Campus Research and Ethics (MREC), University of Limpopo (Medunsa Campus) / Dr George Mukhari Hospital. I am fully aware that the results of this Trial / Study / Project* will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this Trial / Study / Project*.

..........................................................................................

Name of patient/volunteer  Signature of patient or guardian.

..........................................................................................

Place.  Date.  Witness
Statement by the Researcher

I provided verbal and/or written* information regarding this Trial / Study / Project*

I agree to answer any future questions concerning the Trial / Study / Project* as best as I am able.

I will adhere to the approved protocol.

DR ........................................  ........................................  ........................................  ........................................

Name of Researcher  Signature  Date  Place

*Delete whatever is not applicable.
Seteitemente se se ka ga go tsaya karolo mo Tekopatlisisong / Porojeke ya Patlisiso*.

Leina la Porojeke / Patlisiso / Tekelelo*

**COMPARISON OF HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY IN PATIENTS UNDERGOING ELECTIVE PROCEDURES AT DR GEORGE MUKHARI ACADEMIC HOSPITAL**

Ke buisitse tshedimosetso mo * / ke utlwile maitlhomo le maikemisetso a* patlisiso e e tshitshintsweng mme ke filwe tšhono ya go bota dipotsotse le go fiwa nako e e lekaneng ya go akanya gape ka ntlha e. Maitlhomo le maikemisetso a patlisiso e a thaloganyega sentle. Ga ke a patelediwa ke ope ka tselo epe go tsaya karolo.

Ke thaloganya gore go tsaya karolo mo Tekopatlisisong e / Patlisiso / Porojeke* ke boithaopo le gore nka ikapgela morago mo go yona ka nako ngwe le ngwe kwa ntle ga go neela mabaka. Se ga se kitla se nna le seabe sepe mo kalafong ya me ya go le gale ya bolwetsi jo ke nang le jona e bile ga se kitla se nna le tlotlhetelese epe mo tšhokomelang e ke e amogelang mo ngakeng ya me ya go le gale.

Ke a itse gore Tekopatlisiso / Patlisiso / Porojeke* e e rebotswe ke Patlisiso le Molao wa Maitsholo tsa Khampase ya Medunsa (MREC), Yunibesithi ya Limpopo (Khampase ya Medunsa) / Bookelo jwa Ngaka George Mukhari. Ke itse ka botlalo gore dipholo tsa Tekelelo / Patlisiso / Porojeke* di tla dirisetswa mabaka a saentifikasi e bile di ka nna tsa phasaladiwa. Ke dumelana le seno, fa fela go netefadiwa gore se e tla nna khupamarama.

Fano ke neela tumelelo ya go tsaya karolo mo Tekelelong / Patlisiso / Porojeke* e.

...........................................................................................................  ........................................................
Leina ka molwetse/moithaopi Tshaeno ya molwetse kgotsa motlamedi.

...........................................................................................................  ........................................................
Lefelo. Letha. Paki
Seteiteme ka Mmatlisisi

Ke tlamentse tshedimosetso ka molomo le/kgotsa e e kwadilweng malebana le Tekelelo / Patlisiso / Porojeke* e.

Ke dumela go araba dipotso dingwe le dingwe mo nakong e e tlang tse di amanang le Tekelelo / Patlisiso / Porojeke* ka moo nka kgonang ka teng.

Ke tla tshegetsa porotokolo e e rebotsweng.

DR ........................................ ........................................ ........................

Leina la Mmatlisisi Tshaeno Letha Lefelo

*Phimola sengwe le sengwe se se seng maleba.
UNIVERSITY OF LIMPOPO (Medunsa Campus) SEPEDI CONSENT FORM

Setatamente mabapi le go tšea karolo ka go Protšeke ya Dinyakišišo tša Teko ya Klinikhale *.

Leina la Protšeke / Dinyakišišo / Teko*

COMPARISON OF HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY IN PATIENTS UNDERGOING ELECTIVE PROCEDURES AT DR GEORGE MUKHARI ACADEMIC HOSPITAL.

Ke badile/ke kwele ka ga tshedimošo mabapi le *maikemišetšo le morero wa* dinyakišišo tšeo di šišintšwego gomme ke ile ka fiwa monyetla wa go botšiša dipotšišo gomme ka fiwa nako yeo e lekanego gore ke naganišše ka ga taba ye. Ke tloga ke kwešiša maikemišetšo le morero wa dinyakišišo tše gabotse. Ga se ka gapeletšwa go kgatha tema ka tsela efe goba efe.

Ke a kwešiša gore go kgatha tema Protšekeng/Dinyakišišong tše tša Teko ya Klinikhale* ke ga boithaopo gomme nka tlogela go kgatha tema nakong efe goba efe ntle le gore ke fe mabaka. Se se ka se be le khuetšo efe goba efe go kalafo yaka ya ka mehla ya maemo a ka gape e ka se huetše le ge e ka ba tihokomelo yeo ke e humanago go ngaka yaka ya ka mehla.

Ke a tseba gore Teko/Protšeke/Dinyakišišo tše* di dumeletšwe ke Medunsa Campus Research and Ethics (MREC), Yunibesithi ya Limpopo (Khamphase ya Medunsa) / Dr George Mukhari Hospital. Ke tseba gabotse gore dipelo tša Teko/Dinyakišišo/ Protšeke tše* di tla dirišetšwa merero ya saense gomme di ka phatlalatšwa. Ke dumelelana le se, ge fela bosephiri bja ka bo ka tišetšwa.

Mo ke fa tumelelo ya go kgatha tema Tekong/Dinyakišišong/ Protšekeng *.

............................................................

Leina la molwetši/ moithaopi Mosaeno wa molwetši goba mohlokomedi.

............................................................

Lefelo. Letšatšikgwedi. Tlhate

............................................................
**Setatamente ka Monyakišiši**

Ke fana ka tshedimošo ka molomo le/goba yeo e ngwadilwego * mabapi le Teko/Dinyakišišo/ Protšeke ye .*

Ke dumela go araba dipotšišo dife goba dife tša ka moso mabapi le Teko/Dinyakišišo/ / Protšeke ka bokgoni ka moo nka kgonago ka gona.

Ke tla latela melao yeo e dumeletšwego.

.............................................. .............................................. .............................................. ..............................................

Leina la Monyakišiši Mosaeno Letšatšikgwedi Lefelo

*Phumola tšeo di sego maleba.*
## DATA COLLECTION FORM

**COMPARISON OF HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY: DR GEORGE MUKHARI ACADEMIC HOSPITAL EXPERIENCE**

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<thead>
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<th>GROUP II</th>
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Group I = Laryngoscopy/Endotracheal intubation
Group II = Laryngeal Mask Airway (LMA)

### RECORDINGS

<table>
<thead>
<tr>
<th>BLOOD PRESSURE [mm Hg]</th>
<th>HEART RATES</th>
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- In-Ward
- In Theatre before anaesthesia

### HAEMODYNAMIC RESPONSES AFTER INDUCTION

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<th>INTRA-OP RECORDINGS</th>
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<td>3 minutes post-Induction</td>
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<td>5 minutes post-Induction</td>
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APPENDIX C

AMERICAN SOCIETY OF ANAESTHESIOLOGISTS (ASA) CLASSIFICATION:

ASA I – A normal healthy patient, with no disease other than surgical pathology and no systemic disturbances.

ASA II – A patient with mild systemic disease, systemic disturbances due to general disease or surgical condition.

ASA III – A patient with moderate to severe systemic disease, systemic disturbances due to general disease or surgical condition that limits activity but not incapacitating.

ASA IV – A patient with severe disease that is incapacitating and which is an imminent threat to life.
APPENDIX D

UNIVERSITY OF LIMPOPO
Medunsa Campus

MEDUNSA RESEARCH & ETHICS COMMITTEE

CLEARANCE CERTIFICATE:

MEETING: 02/2014
PROJECT NUMBER: MREC/M/60/2014: PG
PROJECT:
Title: Comparison of haemodynamic responses between the insertion of an endotracheal tube and laryngeal mask airway: Dr George Mukhari Academic Hospital
Researcher: Dr MK Mphahlele
Supervisor: Dr LT Mpholo
Co-supervisor: Dr TC Maganyane
Hospital Superintendent: Dr ME Sithole (Dr George Mukhari Academic Hospital)
Department: Anaesthesiology & Critical Care/Intensive Care
School: Medicine
Degree: MMed Anaesthesiology

DECISION OF THE COMMITTEE:
MREC approved the project.

DATE: 06 March 2014

PROF GA OGUNBANJO
CHAIRPERSON MREC

The Medunsa Research Ethics Committee (MREC) for Health Research is registered with the US Department of Health Human Services as an International Organisation (ORG0004319), as an Institutional Review Board (IRB00005122), functions under a Federal Wide Assurance (FWA00009419) Expiry date: 11 October 2016

Note:
(i) Should any departure be contemplated from the research procedure approved, the researcher(s) must re-submit the protocol to the committee.
(ii) The budget for the research will be considered separately from the protocol. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.
APPENDIX E

STUDY PROTOCOL

TITLE: COMPARISON OF HAEMODYNAMIC RESPONSES BETWEEN THE INSERTION OF ENDOTRACHEAL TUBE AND LARYNGEAL MASK AIRWAY AT DR GEORGE MUKHARI ACADEMIC HOSPITAL.

RESEARCHER: DR M.K MPHALELE
[Student Number:210147781]

Department of Anaesthesia
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Medunsa Campus

SUPERVISOR: DR L. MPHOTO

Department of Anaesthesia
University of Limpopo
Medunsa Campus

CO-SUPERVISOR: DR T.C. MAGANYANE

Department of Anaesthesia
University of Limpopo
Medunsa Campus

2013
**STUDY PROBLEM:** Airway management is a fundamental aspect of anaesthetic practice. Laryngoscopy and endotracheal intubation is the commonest method of securing a definitive airway for the administration of anaesthesia. However, it is associated with a reflex increase in sympathetic activity that may result in hypertension, tachycardia and arrhythmia. These changes have been observed to be associated with a rise in catecholamine levels.

The responses are transient and of little significance in healthy patients but these changes may be fatal in patients with hypertension, myocardial ischaemia and cerebrovascular disease. The life threatening complications that may occur are ventricular tachycardia, acute left ventricular failure, myocardial ischaemia and cerebrovascular accidents.

Pharmacological and non-pharmacological methods have been utilized to limit the pressor responses following insertion of endotracheal tube. The use of laryngeal mask airway has been shown to be an effective means of securing a clear airway in fasting patients who are to undergo elective surgery. Its insertion requires neither visualisation of cords nor the penetration of larynx, making the placement less stimulating than endotracheal tube insertion. Therefore, it may provoke less sympathetic response and catecholamine release and as a result provide more favourable haemodynamic changes during surgery.

**RATIONALE FOR THE STUDY:** The use of either the endotracheal tube insertion or laryngeal Mask Airway (LMA) for securing the airway for anaesthesia, has remained an empirical practice at Dr George Mukhari Academic hospital. As a result of this, there is no information as to the effects of these two procedures on haemodynamic changes during surgery and the effects these changes could have on different medical conditions of patients who have to undergo surgery. Moreover, information in the literature seems to weigh heavily in favour of adopting the use of the LMA, particularly in patients whose medical conditions may be exacerbated by tracheal intubation.

On the basis of this, I intend to conduct a randomized prospective study comparing haemodynamic responses to the insertion of LMA with endotracheal intubation, in elective surgical procedures performed at Dr George Mukhari Academic Hospital.
LITERATURE REVIEW: Airway management by direct laryngoscopy and endotracheal intubation during general anaesthesia are known to induce clinical changes in haemodynamic variables [1]. This procedure leads to reflex circulatory responses characterized by an increase in blood pressure and heart rate. Laryngeal mask airway (LMA), originally described by Brain [2] has recently become widely used as an acceptable alternative to endotracheal intubation. Insertion of the LMA after induction of anaesthesia has been described to cause less haemodynamic changes than tracheal intubation [3, 4]. Therefore, the LMA could become useful in situations where minimal haemodynamic changes are desirable.

The report of Dunges et al [5] had shown that endotracheal tube placement into the non-anaesthetized trachea provokes significant haemodynamic response with increased heart rate and systolic blood pressure accompanied by a rise of plasma catecholamine levels. This response occurs even if laryngoscopy is omitted and an indirect technique, lightwand-guided endotracheal intubation is used. However, this report was flawed by not monitoring the depth of anaesthesia and a more profound induction of anaesthesia before tracheal tube insertion may also have influenced the results from this study.

In the comparative study reported by Smith, Smith and Becker [6], haemodynamic changes following laryngoscopy alone and after laryngoscopy was followed by tracheal intubation, was examined. In this study, it was found that laryngoscopy followed by intubation was characterized by a relatively constant blood pressure but a significant increase in heart rate. It was concluded that the intubation component is the major cause of the pressor response, associated with an increase in heart rate.

A pilot study conducted by Tahir et al [4] with the laryngeal mask, suggested that the laryngeal mask airway (LMA) technique is an effective alternative and it is a less invasive airway device when compared with endotracheal intubation, for spontaneous and positive pressure ventilation. This pilot study evaluated the pressor response of tracheal intubation with that of laryngeal mask insertion in normotensive patients and showed significant
increases in heart rate, systolic and diastolic blood pressure in endotracheal group when compared with LMA insertion. From these findings, it was concluded that the use of the LMA may offer advantages over tracheal intubation where evidence of changes in pressor response is of particular concern. In a similar study [7] comparing haemodynamic responses induced by endotracheal intubation with those produced by insertion of LMA, it was again demonstrated that in normotensive patients, the insertion of LMA caused smaller increases in mean arterial pressure (MAP) and heart rate (HR) than the use of face mask or endotracheal intubation. The observed increases in MAP and HR were transient and led to the conclusion that direct stimulation of the trachea by a tracheal tube has a major role in causing haemodynamic responses.

Examination of changes in intraocular pressure, as well as haemodynamic responses, following insertion of LMA and endotracheal tube in normotensive patients, were the focus of the study by Syed [3] who reported increases in heart rate, systolic and diastolic blood pressure and intraocular pressure in both methods of airway management. However, greater increases in the parameters were observed in the endotracheal group. This led to the conclusion that the LMA could be useful in situations where patients have medical conditions that will require minimal haemodynamic and intraocular changes.

The relative contribution to the haemodynamic effects related to tracheal intubation by direct laryngoscopy compared with intubating laryngeal mask, was also examined by Tabari, Alipour and Ahmadi [8]. They were able to demonstrate that both MAP and diastolic blood pressure at 5 minutes were significantly higher in patients that were intubated by direct laryngoscopy as compared with intubating LMA. Their conclusion was that indirect LMA should be considered for patients in whom a marked pressure response would be undesirable. Similarly, Sener et al [9] examined these effects as well as upper airway morbidity amongst hypertensive patients and they found that haemodynamic responses to intubation with laryngoscopy are accompanied by a smaller increase in blood pressure than with the intubating LMA.
A prospective study [10] which had compared haemodynamic and catecholamine stress responses to insertion of the Combitube, LMA and tracheal intubation found that haemodynamic response to insertion of the Combitube and endotracheal tube was significantly greater than the response due to laryngeal mask insertion.

**STUDY QUESTION**: What is the difference in haemodynamic response between patients who are intubated with endotracheal tube as compare to laryngeal mask airway insertion at DGMAH?

**AIM**: To compare haemodynamic responses between endotracheal intubation and laryngeal mask airway insertion in elective surgical patients at DGMAH.

**OBJECTIVES**: Three objectives are to be evaluated in this study:

1. To determine the haemodynamic responses to laryngeal mask insertion.
2. To determine the haemodynamic responses to laryngoscopy and endotracheal intubation.
3. To compare the haemodynamic responses associated with LMA insertion and laryngoscopically aided endotracheal intubation amongst patients graded as American Society of Anaesthesiologists I (ASA I) and ASA II, undergoing elective surgery.

**STUDY SETTING**: The study will be conducted at the department of Anaesthesiology of DGMAH. A tertiary level hospital situated at approximately 32 km, north of the city of Pretoria.

**PATIENTS & METHODS**:  
**STUDY DESIGN**: The study will be conducted as an experimental, prospective, randomized, single-blinded study, involving patients who are to undergo elective surgery at DGMAH.

**STUDY POPULATION (PATIENTS)**: All the patients that will participate in the study would have been booked for elective surgery, requiring general anaesthesia at DGMAH and the following will constitute the inclusion and exclusion criteria:
INCLUSION:

- To be included in the study the patient must be between 18 and 65 years old.
- Each patient will be clinically graded to be either ASA I or ASA II.
- Each patient who agrees to give a signed consent for the study.

EXCLUSION CRITERIA:

- Body Mass Index (BMI) ≥ 35
- Features that clinically predict a difficult laryngoscopy.
- Patient on any form of cardiovascular medication.
- Hypertensive patient
- Patient with delayed gastric emptying
- Any patient with history of gastro-esophageal reflux
- Patient with Asthma.

SAMPLE SIZE: The required sample size has been calculated, based on a previous similar study [11], to detect a difference in haemodynamic responses - accepting an alpha-error of 5% (p < 0.05). A sample size of 45 for each group of the study, has been calculated to achieve a 90% power to detect a 10 mm Hg difference in the mean arterial pressure between the two groups.

PROCEDURES: Each patient will be randomized (using the closed envelope technique) into two groups: Group I (those who will have laryngoscopy and endotracheal intubation and Group II (those who will have the laryngeal mask airway). Each patient will be pre-oxygenated for three minute followed by induction of anaesthesia with combined midazolam 0.02 mg/kg, fentanyl 2.0 μg/kg, propofol 2 mg/kg and vecuronium 0.1 mg/kg. This induction will be followed by manual ventilation with isoflurane in oxygen and air to a mean alveolar concentration (MAC) of 1.5. Laryngoscopy will be performed once adequate muscle relaxation has been attained.
Blood pressure and heart rates will be recorded in the ward and in the operating theatre these measurement will be repeated prior to induction of anaesthesia. The measurements will be carried out at 1, 3 and 5 minutes after laryngoscopy and endotracheal intubation (Group 1 patients) or after placement of the laryngeal mask airway.

**OUTCOME MEASURES:**

1. Blood pressure and heart rates would have been recorded in the ward.
2. These measurements will be repeated immediately prior to induction of anaesthesia in theatre and thereafter will be repeated at 1, 3 and 5 minutes.

**DATA COLLECTION:** Data from this prospective study will be collected directly into a data collection form which will be designed to include all relevant information for the assessment of the variables of the study. A copy of the data collection form is attached with this protocol.

**STATISTICAL ANALYSIS:** Data generated from the study will be analysed by descriptive statistics. Data will be summarized by means, standard deviation and 95% Confidence intervals of the differences between the two groups. This will be done by the method of repeated analysis of variance (ANOVA) which will then be transformed through Student t-test to establish any statistical significant difference in hemodynamic responses from the two procedures. Specific differences between the times of measurements (from pre-operative to 5 minutes after instrumentation) will be assessed by pair-wise comparison using the Fisher’s exact test.

**RELIABILITY & VALIDITY:** Reliability refers to the reproducibility and consistency of information or data and the degree to which a method gives the same results when used on more than one occasion under the same condition. The study will ensure reliability through the following steps:

1. Selection of patients who meet the criteria for the study will be done only by the Researcher. The prospective design of the study also adds to the reliability of the study.
2. Induction of anaesthesia, all recordings for blood pressure and heart rates, will be carried out only by the Researcher, in order to avoid inter-observer differences.

3. Statistical derivation of sample size has been applied, so as to ensure appropriate power of the study and to provide the required measure of reliability on results of the study.

4. The Statistician with whom the Researcher will perform data analyses will not be involved in the conduct of the study.

**VALIDITY:** Validity refers to the concept of accuracy of a study and it is also the degree to which the measurement reflects the true value of the variables. The validity of this study will be ensured by the following:

4. The performance of laryngoscopy, endotracheal intubation and laryngeal mask airway will follow the international process for these instrumentations. The researcher is already versed in the performance of these procedures.

5. All recordings for blood pressure and heart rate will be recorded directly into a data collection form so as to avoid any possibility of transcription errors.

6. All information relevant for the evaluation of findings from the study are to be recorded prospectively and will therefore avoid incomplete information being encountered.

**BIAS:** Refers to any effect at any stage of a research process that tends to produce results that depart systematically from the true values. Types of bias that may occur for which steps are to be taken during the proposed study are:

5. **Selection Bias:** This will be guarded against by making sure that the Researcher is the only professional that will determine the inclusion of any patient into the study, as defined for ASA I and ASA II.
6. **Transcription Error:** Transcription errors during the transfer of intra-operative instrumental recordings onto the data collection forms, will be guarded against as only the Researcher will be involved in this exercise.

7. **Data Presentation and Interpretation:** Appropriate research methodological approach will be adopted in presenting results emanating from the study. The interpretation of results will only be applied after the Statistician would have analysed the results.

8. **Generalization and Inferences:** Over-generalization of the findings from this study as well as making wrong inferences on results will be avoided, in order not to introduce unnecessary bias into the findings of the study.

**ETHICS:** Before the commencement of this study, the protocol will be submitted to the Ethics committees of Medunsa (SREC & MREC) for approval to conduct the study. Similarly, permission will also be sought and obtained from the DGMAH management before the study starts. Each patient will be briefed about the study and only those who consent and sign the informed consent form will be randomized for the study. Complete confidentiality of patients’ information will be maintained during and after the conduct of the study.

**BUDGET:** All the materials and facilities necessary for this study are routinely provided by the hospital for the care of the patients. However, the following extra costs are to be incurred in conducting the study:

- Stationery R200
- Secretarial costs (protocol and Dissertation) R400
- Statistician input R2000
- Binding of dissertation for examination R150
- Hard copy binding of dissertation R1000

**TOTAL:** R3,750

- The total cost will be borne by the Researcher.
**STUDY TIME-LINE:** The study time-line is as follows:

1. Protocol Development  
   September 2013
2. Submission of protocol to SREC  
   October 2013
3. Corrections based on suggestions by SREC  
   October 2013
4. Approval by MREC  
   November 2013
5. Conduct of the study  
   December/February 2014
6. Writing of dissertation  
   February/March 2014
7. Submission of dissertation for examination  
   March 2014

**REFERENCES**


