ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
SCHOOL OF MEDICINE
DEPARTMENT OF ANESTHESIA

A COHORT STDUY ON EFFECT OF THIOPENTONE WITH LIDOCAINE VERSUS PROPOFOL FOR LARYNGEALMASKAIRWAY INSERTION AMONG ADULT PATIENTS UNDERGOING ELECTIVE SURGERY AT MINILIK II REFERAL HOSPITAL ADDIS ABABA,ETHIOPIA:

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A RESEARCH THESIS TO BE SUBMITTED TO DEPARTMENT OF ANESTHESIA COLLEGE OF HEALTH SCIENCES, ADDIS ABABA UNIVERSITY IN PARTIAL FULFILLMENT FOR THE REQUIREMENT OF THE DEGREE, MASTER OF SCIENCES IN CLINICAL ANESTHESIA

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ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES SCHOOL OF MEDICINE DEPARTMENT OF ANESTHESIA.

RESEARCH THESIS

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Name of Advisor(s)	Betelihem Girma,Lidya Haddis
Full title of the research	Effect of thiopentone with Lidocaine versus propofol for laryngeal mask airway insertion among adult patients undergoing elective surgery. Observational prospective cohort study
Duration of project	From December1, 2018 to April, 30 2019
Study Area	Minilik II referral hospital
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Certification

The undersigned certify that the research entitled effect of thiopentone with Lidocaine versus propofol on conditions and hemodynamic change during LMA insertion on adult patients who undergo elective surgery at Minilik II referral Hospital, Addis Ababa, Ethiopia, from December1,2018 to April 30/2019: A prospective cohort study is my original work and any literature and/or data cited in this article were listed in the reference section and any assist done during this period has been given an acknowledgement.

Approval of the Board of Examiners

1. Advisor

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2. Internal Examiner

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3. External Examiner

Name _____ Signature _____ Date _____

Abstract

Background: Laryngeal mask airway is a simple supra-laryngeal device which is used to establish and maintain air way. Maintaining airway is maintaining patient's oxygenation and ventilation which is vital in anesthesia practice and for patient's life. Propofol is the most common induction agent for LMA insertion but has side effects on cardiovascular and respiratory systems. And it is not available in all countries.

Objective: To compare effects of Thiopentone with Lidocaine versus propofol for LMA insertion for elective surgical patients at Minilik II hospital, Addis Ababa, Ethiopia from December1, 2018 to April,30, 2019.

Methods: An institutional based observational prospective cohort study was conducted on eighty eight eligible adult patients at Minilik II referral hospital from December, 2018 to April30, 2019. The study participants were allocated in to Thiopentone-Lidocaine and propofol group. T-L group (n =44) and P group (n =44). Data was entered in to Epi info version 7 software by investigator and transported to SPSS version 23 program for analysis. Normality of the data was checked by Shapiro wilk test and histogram. Independent t- test was used to determine the mean differences between two groups. For non-parametric tests Chi square test was used. And when appropriate fisher exact test was used. Those variables with p-value < 0.05 were considered as statistically significant.

Results: The overall insertion score was comparable in both the groups. Excellent insertion score was 33(75%) and 36(81.8%) in T-L and P group respectively. Satisfactory was 9(20.5%) in T-L group and 8(18.8%) in P group. (p=0.34). A significant fall in mean arterial pressure was noted in Propofol group at 1,2and 3 minutes following LMA insertion. At 1 min after LMA insertion it was (84.61±9.8) vs (72.25 ±11.16), p<0.000,At 2 min (81.14± 10.43) vs (75.32± 12.15) p<0.01,At 3 min (83.66± 9.24) vs (77.2± 10.98) p<0.004.A significant apnea time was also observed in group P. (p<0.02), There was no significant difference in HR and SpO2 . 30.54 ET Birr cost was reduced in T-L group than propofol group per case.

Conclusion and recommendation: Thiopentone with 2% IV Lidocaine is alternative for insertion of LMA to propofol, with better hemodynamic stability and cost effectiveness. We recommend that use of T-L induction of anesthesia for LMA for adult patients.

Key Words: Thiopentone, IV Lidocaine, Propofol, LMA

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List of acronyms

LMA	Laryngeal mask air way
T-L	Thiopentone with Lidocaine
ASAPS	American society of a physical anesthesiologist physical status
Mcg	Microgram
Kg	Kilogram
V/s	Vital signs
BP	Blood pressure
SBP	Systolic blood pressure
DBP	Diastolic blood
MAP	Mean arterial blood pressure
HR	Heart rate
ETT	Endotracheal tube
AAU	Addis Ababa university
GA	General Anesthesia
OR	Operating room
IV	Intravenous
BMI	Body mass index
NIBP	Noninvasive blood pressure

Chapter one: Introduction

1.1 Background

The fundamental responsibility of an anesthesia professional is proper maintenance of a patent airway during surgical procedures. Because air way management and patient safety have always been of great importance. (1, 2)(One of the most important measures employed for patients under general anesthesia in the operating room, was to maintain patent airway and provide sufficient ventilation.(3)

The management of the airways is an essential component of anesthesia training and the inability to establish a secure airway is the most prevalent concern about anesthesia, in relation to mortality and morbidity. Laryngeal mask airway (LMA) plays an important role in modern anesthesia. It is usually used to maintain the airway during spontaneous breathing of patients undergoing elective short-term surgeries, having a difficult airway and under emergency situation. (3)

Many airway devices like facemasks, airways and endotracheal intubation are used for the management of airway. Endotracheal intubation is regarded as a gold standard technique for maintaining airway but this technique needs an expert for intubation and is associated with increased pressure response and postoperative complications like sore throat. LMA insertion is associated with less airway stimulation, tachycardia, hypertension, post-operative pharyngeal discomfort and dysphonia as compare to endotracheal intubation, as it does not stimulate the trachea which is considered to be one of the most sensitive parts of the body(4).Due to this Airway management has been revolutionized with new airway devices like laryngeal mask airway. (5)Which is discovered by a British anesthesiologist Dr Archie Brain in 1981and become a popular airway device and also it was incorporated in ASA difficult airway algorithm in 1996.(2)

LMA is one of the new supra glottic airway devices used commonly to maintain airway. (5-8) It is an alternative to endotracheal intubation and facemask for spontaneous as well as controlled positive pressure ventilation. Compared to facemask, it provides better seal in edentulous patients or if the patient has beard. Besides it keeps anesthesia professionals hands free, so

fatigue is less and remote observation is possible. It has become popular in airway management during elective anesthesia and difficult airway.(5)

The placement of an LMA is less stimulating and leads to less presser response than direct laryngoscopy by avoiding direct laryngoscopy, instrumentation of larynx. And vocal cord visualization. (9)Insertion LMA requires sufficient depth of anesthesia for jaw muscles to relax and suppression of airway reflexes for the device to be tolerated within the hypo pharynx without undue coughing, gagging, and patient movement.(9, 10) Such conditions are provided by a generous dose of an intravenous (IV) anesthetic induction agent.(11, 12) Propofol is the induction agent used commonly for LMA insertion but produce prolonged apnea, hypotension, and bradycardia, pain at injection site, expensive and not available in all countries.(6, 13-15)

It produces a decrease in systemic arterial pressure greater than with a comparable dose of thiopentone. The decrease in blood pressure is due to both a decreased systemic vascular resistance and a reduced myocardial contractility (MC).Despite a decrease in arterial pressure, the heart rate (HR) remains unchanged due to depression of the baroreceptor response**.(16)**Thiopentone sodium is also one of the most commonly used intravenous induction agents throughout the world. It causes a decrease in MC as well as peripheral vasodilation. Heart rate may fall but there is often a reflex tachycardia probably due to a central vagolytic effect. Cardiac output is often maintained due to increase in HR and increased MC from compensatory baro-receptor reflexes. However, HR and arterial pressure after intubation following induction with thiopentone proved to be no different from those achieved with ketamine. It has been shown that a mixture of thiopentone and propofol produces less hypotension as compared to propofol alone**.(16)**

A less expensive and equally effective induction technique would be a useful alternative. Lidocaine or midazolam used as adjuvants to Thiopentone may decrease the incidence of adverse responses to insertion of the LMA.(17) So far studies have been conducted on optional method and pharmacological agent for insertion of LMA but Propofol is popular.(9)

Considering what have been mentioned about the uses and mechanism of the effect of Propofol and thiopental and most importantly, the presence of contradicting studies about the effect of Propofol and thiopental –Lidocaine combination on blood pressure and facilitation of laryngeal mask insertion, in this study, by comparing the use of Propofol and thiopental-Lidocaine the effects created on hemodynamics and ease of LMA insertion, was investigated.

1.2 Statement of the Problem

The laryngeal mask airway is commonly used in anesthetic practice. (5) In order to introduce LMA during anesthesia, one requires an induction agent e.g.; Propofol or Thiopentone which are the most commonly used induction agents. (18)

There are complications due to LMA insertion that includes laryngospasm, bronchospasm, and local irritation, aspiration of gastric contents, hemodynamic changes, and sore throat. But the rate is likely to be higher in emergency setting. (4, 19, 20) And Therefore, the insertion of LMA requires the abolition of upper airway reflexes to prevent gagging, coughing, and laryngospasm.(5) Propofol depresses airway reflexes more than Thiopentone and therefore allows easy insertion of LMA with reduced side effects eg; coughing, gagging ,or laryngospasm. Although Propofol is the induction agent most commonly used to facilitate the placement of LMA, this drug is expensive, painful on injection and may not be available for regular use worldwide. A less expensive and equally effective induction technique would be a useful alternative.(7) Thiopentone has been assessed for the insertion of an LMA but produces less satisfactory conditions than Propofol .This may be because Propofol is more effective at suppressing airway reflexes than Thiopentone.(5)

Intravenous Lidocaine is known to suppress cough reflexes and reduce cardiovascular responses associated with tracheal intubation. Its use prior to induction has been reported to improve LMA insertion conditions. (14) Lignocaine administered prior to the use of Thiopentone may therefore be expected to produce conditions equal to those of Propofol for the insertion of an LMA.(14, 21) As described above the induction agents for LMA insertion have been studied by various investigators with conflicting ideas and conclusions. There are studies which show that the conditions for LMA insertion are equal or comparable with thiopentone with Lidocaine and propofol groups.(7, 22, 23).on the other hand majority shows that propofol is better than thiopentone alone.(5, 6, 24) etc.) one study shows that higher dose thiopentone can produce equal condition for LMA insertion with propofol.(25) with this in mind, the study is designed to assess whether Thiopentone-lignocaine would allow the insertion of an LMA as easy as propofol.

1.3 Justification of the study

Successful airway management is the vital component of safe anesthesia. Failure to achieve this can lead to ventilation failure, hypoxia, neurological insufficiency, or death of the patient.

Laryngeal mask airway (LMA) is a mainstay for difficult airway management in addition to providing patent airway. In Ethiopia, its clinical use has been advocated in seminars, workshops, and trainings by governmental and nongovernmental health organization. As the result, LMA is becoming a choice of airway device for the country's anesthetists to secure airway particularly for elective surgical patients and in case of difficult airways.

Though its applicability is increasing, its insertion is done mostly using propofol which have better condition regarding to air way reflexes. But this drug is costy, unavailable in all places and has side effects on respiratory and cardiovascular systems. Studies show that combination of Thiopentone with Lidocaine can be used in place of propofol. Still anesthetist depend only propofol and goes to ETT if not available.

This study will compare these drugs and provide basic information regarding airway reflexes, hemodynamic stability and ease of insertion between them and help to manage patients under LMA using these drugs in place of propofol.

Previously, there is no published research on comparison of Thiopentone –Lidocaine for LMA insertion condition in the study area. The purpose of this study is to provide base line information in the study area for anesthesia management and to initiate other researchers for further investigation. With this in mind, the study is designed to assess whether Thiopentone-lignocaine will be comparable to the insertion of an LMA as propofol indifferent aspects.

Chapter two: Literature review

A2014 study conducted in India on 60 ASA1and 11 patients with age group of20-60 years of both sex to assess agents for LMA insertion, comparative study between sodium Thiopentone and propofol showed that residual air way reflexes can be easily suppressed with 2.5mg/kg of propofol compared to Thiopentone alone in managing the airway.(2)

An analytical,non interventional, cross sectional comparative study in 2010 done on 100 patients at Pakistan that compare sodium Thiopentone and propofol for LMA insertion in day case surgery conclude that propofol is superior to Thiopentone as an induction agent for LMA insertion.(24)

A 2010 prospective randomized double blind study on 60 ASA1and11patients undergoing elective minor surgical procedures under GA taken for study. This was done in Guntur medical college, to compare ease of insertion and hemodynamic response to LMA with propofol and Thiopentone. This study show that premedication with Fentanyl (1.5mcg/kg, Midazolam 0.02mg/kg,Lidocaine1.5 mg/kg) IV, before induction of anesthesia with propofol or Thiopentone the conditions for insertions of LMA are equal. Except Thiopentone provides better hemodynamic stability and significantly less respiratory depression with more cost effecviness (22)

A study conducted in 1996 at Royal Berkshire Hospital on 150 ASA 1and 2 patients undergoing elective surgeries to assess ease of insertion of LMA. They divided the patients in to three groups who received propofol, Thiopentone with Lidocaine, Thiopentone with midazolam respectively. They concluded that midazolam and Thiopentone combination is less expensive than propofol alone and provides equally good conditions for the insertion of LMA.(7)They also show that use of Lidocaine(1.5mg/kg prior to Thiopentone in their patients were associated with a lower incidence of side effects than those of scanalonet.al(2) And also another a1998 study conducted at Illinois Masonic medical center on 100ASAI and II elective surgical patients to compare thiopentone ,propofol and sevoflurane for LMA insertion were grouped into four groups in which group one received Thiopentone 4mg/kg,group 2 Thiopentone 4mg/kg plus Lidocaine I mg /kg,group3propofol 2mg/kg plus Lidocaine1mg/kg and group4 sevoflurane6%in N2O/O2.Conclude that all three drugs are equally acceptable for LMA insertion if IAAS are

needed sevoflurane provides added benefit of maintaining spontaneous breathing throughout the induction period. They also conclude as their finding did not support reports of propofol are superior to Thiopentone.Concurent administration of fentanyl and midazolam may have contributed to these narrowing effects of induction drugs were their assumption. Addition of Lidocaine 1mg/kg to thiopentone doesn't influence LMA insertion.(23)

An Indian study conducted at Madhya Pradesh, in 2018 on elective 60 patients with age group of16-45 years for comparison of topical and IV lignocaine for the insertion of LMA with propofol shows that topical lignocaine 10% aerosol prior to propofol induction provides excellent condition for LMA insertion without the use of neuromuscular drugs.(8)

A study was conducted in 2012 Western Australia on 90 ASA 1and 2 patients posted for elective surgery to assess the efficacy of topical versus intravenous Lidocaine prior to intravenous thiopentone in providing good conditions for LMA insertion. They showed that application of topical Lidocaine on posterior pharyngeal wall before thiopentone induction provides good conditions for LMA insertion. But there was no significant difference between hemodynamic response and apnea between the three groups.(15) (10)

Another study conducted in 2012 on 96 patients or induction of classic LMA insertion by comparing two doses of fentanyl(1and 2 mg/kg)conclude that both doses of fentanyl provide comparable condition for LMA .fentanyl in lower dose provides a more stable hemodynamic profile.(11)

In 2013 a study conducted in Iran on 120 children undergoing outpatient surgery by comparing effect of two doses of propofol(2.5,3.5 mg/kg)with premedication (midazolam0.03mg/kg,fentanyl1mcg/kg,Lidocaine 1mg/kg) shows that both doses of propofol are equally effective for LMA insertion following IV midazolam, fentanyl and Lidocaine.(26)

In 2010a study conducted on 90patients to compare two regimes of thiopentone and propofol for I –gel SGAD insertion showed that increasing dose of thiopental to 7mg/kg instead of6mg/kg as a sole induction agent produce comparable I-gel SGAD insertion condition with that of 2.5 mg/kg of propofol. **(25)**

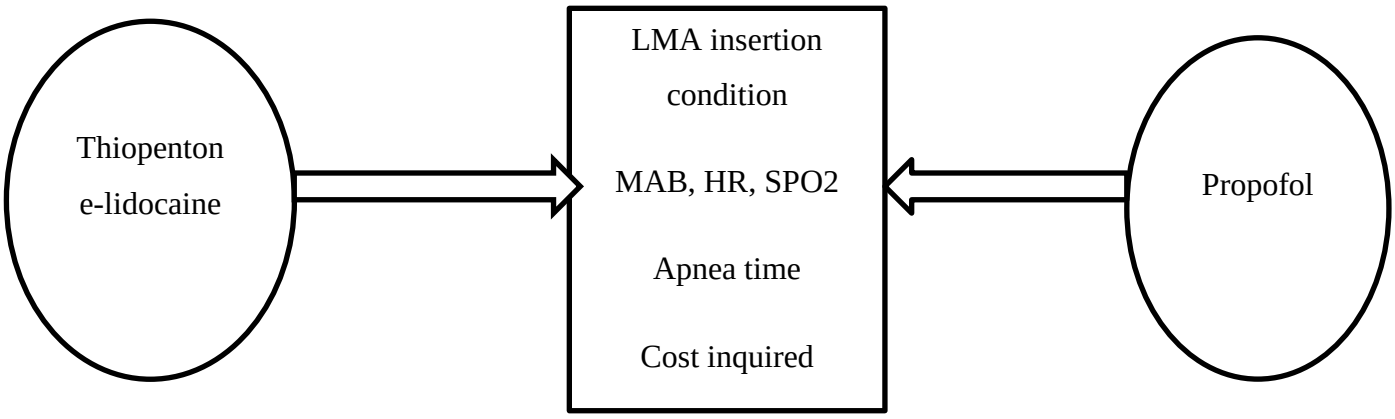

Figure1: Conceptual framework of the study

Chapter three: Objectives

3.1 General objective

- ✓ To compare effects of Thiopentone with Lidocaine versus propofol for LMA insertion for elective surgical patients at Minilik II hospital, Addis Ababa, Ethiopia from December 2018 to April 2019

3.2 Specific objectives

- ✓ To compare conditions for LMA insertion
- ✓ To assess hemodynamic response
- ✓ To compare which is cost effective

3.3: Research Hypothesis

HO: There was no statistically significant difference in conditions for LMA insertion, heart rate and oxygen saturation between the groups.

H1: There was statistically significant difference in mean arterial blood pressure at 1, 2 and 3 mint after LMA insertion and apnea time between the groups.

-+

Chapter four: Methodology

4.1 Study area

The study was conducted at Minilik II referral hospital which is located in Addis Ababa capital city of Ethiopia. The hospital gives different services including medical, surgical, pediatrics wards, ICU, operation room and recovery room.Totaly it has 7 ORs that divides into general surgery 4 rooms. Obstetrics 2 rooms and ophthalmology 1room.

4.2 Study design and period

An institutional based Prospective observational cohort study design was conducted from December1, 2018 to April 30, 2019

4.3 Population

4.3.1Source population

All adult patients who undergone elective surgery under general anesthesia with LMA at Minilik II referral hospital

4.3.2 Study population

All adult patients who underwent elective surgeries under general anesthesia with LMA in the study period and those who fulfilled inclusion criteria were included in the study.

4.4 Eligibility criteria.

4.4.1 Inclusion criteria

-Elective surgeries under GA with LMA

-ASA status I and II

-Patients age between 18 and 60

-Patients BMI between 18.5 and 29.5.

4.4.2 Exclusion criteria

-Risk of aspiration

-Those with respiratory diseases

-Mouth opening <2.5 cm

-Hx of allergy to one of the study drugs

-Hx of URTI in the 2 week preceding surgery

4.5 Sample Size and Sampling Techniques.

4.5.1Sample size

Sample size for the study was calculated using double population proportion formula for comparison of two proportions with equal sample size based on the following assumptions: significance level 5% (α= 0.05), power of study (1 – β) of 80%. According to a 2016 study on 138 patients in Iran the prevalence of limb and head movement was 52% in Thiopentone – Lidocaine group and 23% in propofol group.(13)

So by taking 52% as p1 and 23% as p2 the calculated sample size will be

$$n \text{ (in each group)} = \underline{(Z_{\alpha/2} + Z_{\beta})^2 \times ((p_1q_1) + (p_2q_2))}/(p_1 - p_2)^2$$

Where; p1=0.52 q1=0.48

P2=0.23 q2=0.77

Zα =Standard normal variate for 95% level of significance= 1.96

Zβ=Standard normal variate for power of 80% or type 2 error = 0.84

$n= (1.96 + 0.84)^2 \times ((0.52 \times 0.48) + (0.23 \times 0.77))/ (0.52 - 0.23)^2$

n= 40, Taking 10% for non-response rate or sudden withdrawal the total sample size become 88.

4.5.2 Sampling technique

Systematic random sampling technique was used till to get the required sample size during the study period. The daily operation schedule list was used as sampling frame. The situational analysis show that 8 patients who fulfill our inclusion criteria were operated in the hospital log book per week; according to this data we had 160 patients in our study period from which we collect data from only 88 patients.

Therefore, K=N/n= 160/88 = 2 (skip interval) and the first participant (random start) was selected using lottery method. Then, every two patients were included in this study from the daily operation schedule.

4.6 Variables

4.6.1 Independent Variables

-Age

-Sex

-weight

-ASA

-Propofol

-Thiopentone with Lidocaine

4.6.2 Dependent variable

Conditions of LMA insertion

Hemodynamic (HR, MAP and SPO2) change

4.7 Operational definitions

ASA PS I - A normal healthy patient

ASA PS II - A patient with mild systemic disease

ASA PS III – A patient with a severe systemic disease that limits activity

ASA PS IV - A patient with an incapacitating disease that is a constant threat to life

Induction agent-A drug that produce unconsciousness of a patient

Baseline record-Recording of V/S before induction

Hypertensive response- 20% increment in BP from base line

Hypotensive response-20% decrement in BP from base line.

Tachycardia response-20% increment in HR from base line

Bradycardia response-20% decrement in HR from base line

Desaturation - A decrease in oxygen concentration in the blood. In the study, a pulse oximetry reading below 95% is considered as desaturation.

Apnea-Cessation of spontaneous breathing

Conditions for LMA insertion-patient response or reactions that occur during LMA insertion.

1, Gagging – A noisy voice heard when sensation or feeling of vomiting occur without expulsion of stomach content

2, Laryngospasm- A closure of the larynx that blocks the passage of air into the lungs and managed with positive pressure of ventilation or propofol or suxamethonium injection.

3, Coughing - to expel air from the lungs suddenly with a harsh noise, often involuntarily.

4, Mouth opening-relaxation of jaw muscles.

5, head and limb movement-undesirable movements that usually occur in head and extremities**.**

6, Number of attempt-number of trials to insert LMA. And scored as

Grade3, one attempt

Grade2, two attempts

Grade3, three attempts

Mouth opening scorings

Full (Grade3), mouth opened easily and fully

Partial (Grade2), mouth couldn't be fully opened but LMA can be inserted

No (Grade 1), firm manual separation required to open the mouth fully

The following scoring systems are for coughing, gagging, laryngospasm, head and limb movement

No (grade3) - No Adverse response

Mild (grade2)-Sustained greater than 20 second or required additional boluses of drugs

Sever (1)-if suxamethonium is required

Overall insertion conditions were assessed according to the modified Scheme of Lund and Stovener. (27)

Excellent: No gagging or coughing, no patient movement or laryngospasm.

Good: Mild to moderate gagging, coughing, or patient movement with no laryngospasm.

Poor: Moderate to severe gagging, coughing or patient movement with no laryngospasm.

Unacceptable: Severe gagging, coughing, or patient movement or laryngospasm

4.8 Methods of data collection

4.8.1 Data collection tool

Data was collected with a direct observation, and using a structured data collecting checklists prepared for this purpose.

4.8.2Data collection procedure

Data was collected using pretested adapted structured questionnaires by two degree holder anesthetist and supervised by one MSc holder anesthetist. One day training was given for data collectors on objectives and relevance of the study.

After providing training for data collectors (2 BSc anesthetists) and having verbal informed consent of patients, data were collected using a structured questionnaire. The data collectors only observe the following routine perioperative anesthetic management of Minilik II hospital anesthetists. The hospital anesthetists perform the following routine perioperative anesthetic managements. Preoperatively; the anesthetists visit patients the night before surgery to do a preanesthetic evaluation and investigations. Patients also ordered to be NPO starting from midnight during this visit. On arrival to OR they commonly attached standard monitoring such as ECG, pulse oximetry, NIBP and secure IV line if not secured. Then they preoxygenate the patient 3-5 minutes with 100% O2 and give fentanyl 2 mcg/kg before inducing the patient. Then they induce patient using thiopentone-lidocaine or propofol.

After assessing loss of verbal contact, eye lash reflex and loss of motor response to jaw thrust the hospital anesthetist insert LMA calculated based on weight and manufacturer order by standard technique. Proper placement was checked. In their observation the data collectors record the following things.. Conditions for LMA insertion will be recorded using jaw relaxation, number of attempt, gagging, coughing, limb and head movement, and laryngospasm.

If the conditions were not adequate the hospital anesthetists give additional dose of the induction drug given before. And LMA inserted but if failed for third time airway were secured by ETT.If apnea occurred ventilation was assisted until spontaneous breathings recovers.Hemodyanamic parameters namely HR,MABP were recorded at pre induction,30sec

after induction,and1,2,3 min from LMA insertion and represented as T0,T1,T2,T3and T4 respectively and recorded by data collectors. Then every 5min is recorded until operation was finished. Patient response to LMA insertion was scored based on the scoring system which has six variables **(**i.e. gagging, coughing, jaw relaxation (mouth opening), patient movement, and number of attempts to LMA insertion and laryngeal spasm**)** on a 3 point scale.

The six variables, three point scores were summed to give an overall insertion condition score. **Total score insertion condition (22)**

 18 Excellent

 16 _17 Satisfactory

 <16 Poor

 Unacceptable = 6

The scoring system of conditions for LMA insertion were graded as follow

Mouth opening - 3= Full, 2= Partial, 1= Nil,

Coughing - 3= No, 2= Mild, 1= Severe

Gagging - 3= No, 2= Mild, 1= Severe

Laryngospasm - 3= No, 2= Mild, 1= Severe

Head and Limb movements - 3= No, 2= Mild, 1= Severe

No of attempt-3=1attempt,2=2 attempt,1=3 attempt

4.9 Data quality assurance

To assure the reliability and validity of the data, questionnaires were pretested on 5% of the sample size before actual data collection. Training and orientation about the objectives and relevance of the study and each items included in the study tools and the whole process of data collection were provided for data collectors and supervisors. Informed consent was obtained from the patients. During data collection, regular supervision and follow up were undertaken. A principal investigator has checked each questionnaire daily for completeness and consistency of data. Data clean up and crosschecking of missing data was done before analysis on SPSS.

4.10 Data Processing and Analysis

Data was checked manually for completeness and then coded and entered into Epinfo version 7. Data was cleaned and analyzed with SPSS version 23 computer program. Normality of the distribution of data was tested by the Shapiro-wilk test and histogram. And homogeneity of variance was tested by Levene's test. MAB and HR between study groups was done using student t- test. Conditions for LMA insertions apnea were assessed by Chi-square tests and when appropriate fisher exact test was used. P value <0.05 is considered statistically significant for all analysis. Descriptive statistics was used to summarize data, tables and figures for display results statistically significant.

4.11Ethical Consideration

Ethical clearance was obtained from the department ethical clearance committee before the start of the study. Official support letter was written to Minilik II referral Hospital and permission for data collection was sought from the responsible authorities. The purposes and the importance of the study were explained and verbal as well as written informed consent was obtained from each participant. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. The participant's involvement in the study was on a voluntary basis; participants who are not willing to participate in the study and those who wish to quit their participation at any stage were informed and allowed to do so without any restrictions.

4.12 Dissemination plan

This paper will be disseminated to Addis Ababa University College of health science, Ethiopian Association of Anesthetists and Federal Ministry of Health. After presentation on workshops and seminars, Great effort will be made to publish the finding on international journal.

Chapter five: Results

5.1 Socio demographic characteristics of study participants

A total of eighty eight participants were enrolled in this study. Out of 88 respondents 44 were group "T-L" who has given 5 mg/kg thiopentone and 1.5mg/kg of 2% Lidocaine, and 44 were group " P" who has given 3mg/kg. All were included in the study as they were complete and showed consistency of response. There was normal distribution for age, weight, MAB, HR. (Shapiro wilk test >0.05)

Socio demographic data were observed among the study groups. A chi square test for ASA, sex and independent sample t test for age and weight shows no significant differences between the two groups. (p>0.05) as shown in table 1 below.

Table1: Socio-demographic characteristics in each group of patients at Minilik II referral hospital, 2018/19

Demographic data	**T-L group**	**P group**	**P value**
Age(years)	28.84±9.44	27.43±10.14	0.50
Sex M F	31 (64.8) 13 (35.2)	26 (59.1) 18 (40.9)	0.265
Weight(Kg)	54.18±8.73	53.16±9.77	0.61
ASA I II	38 (64.8) 6(35.2)	40 (90.9) 4(9.1)	0.50

Values are presented as: Mean ± SD, and frequency (%) p<0.05 is statistically significant

5.2 conditions for LMA insertion

As shown in table2 concerning the responses of the patients to LMA insertion, there were no statistically significant different between the two groups on number of attempt, gagging, coughing, mouth opening, laryngospasm and movements between the groups.These parametrs are assessed using chi square and fisher exact test.

No patients need more than two attempts. In T-L group one attempt were succeeded in 40(90.9%) patients and 4(9.1%) patients need two attempt. In P group 39(88.6%) and 5(11.4%) of patients had succeeded in first and second attempt. The values obtained was statistically insignificant (p>0.05).

mouth opening was graded as Full in 40(90.9 %) in group T-L and 39 (88.6) in group P patients while 4(9.1%) patients in group T-L and 5(11.4%) patients in group P showed partial grade of mouth opening. None of the patient showed Nill grade of mouth opening. The incidence was comparable in both the groups (p>0.05).

For limb and head movement, 39(88.6%) patients in group T-L and 38(86.4%) patients in group P showed no response. Mild movements were present in 5(11.4%) and 6(13.6%) patients of group T-L and group P respectively. None of the patients had severe movements in both the groups. The incidence was statistically insignificant (p>0.05).

In group T-L gagging was 38(86.4%) and 6(13.6%) for no and mild gagging respectively. In group P No response was observed in 39(88.6%) patients and mild grade of gagging in 5(11.4%) patient. The response was found to be statistically insignificant (p>0.05)

Regarding coughing in both groups coughing was absent in 40 patients (90.9%) and 4 patients (9.1%) had mild coughing. And it was statistically non-significant (p>0.05).

Laryngospasm was absent in 42 patients (95.5%) and 2 patients (4.5%) had mild laryngospasm in group T-L. While Laryngospasm was absent in 41 patients (93.2%) and 3 patients 6.8%) had mild laryngospasm. When these values compared statistically the results obtained was insignificant (P>0.05).

Apnea time is prolonged in propofol group in which 5(11.4%) patients had apnea time of more than five minutes. But none of patients in Thiopentone –Lidocaine group had apnea time of more than five minutes. This is statistically significant when we compared them ($p<0.05$).Oxygen saturation were above 95% in both groups.

Table2: conditions during LMA insertion between groups at Minilik II referral hospital, 2018/19

descriptions	grades	T-L g(F)	(%)	P g(F)	(%)	P value
No of attempt	1	40	90.9	39	88.6	0.725
	2	4	9.1	5	11.4	
Mouth opening	Full	40	90.9	41	93.2	0.694
	partial	4	9.1	3	6.8	
movement	No	39	88.6	38	86.4	0.747
	mild	5	11.4	6	13.6	
gagging	No	38	86.4	39	88.6	
	mild	6	13.6	5	11.4	0.747
coughing	No	40	90.9	40	90.9	1
	mild	4	9.1	4	9.1	
laryngospasm	No	42	95.5	41	93.2	0.645
	mild	2	4.5	3	6.8	
Apnea time	<5 min	44	100	39	88.6	0.021
	>5min	0	0	5	11.4	
Spo2	>95%	44	100	44	100	
	<95%	0	0	0	0	
No of patients needing additional dose	No	39	88.6	41	93.2	0.46
	yes	5	11.4	3	0.73	

5.2.1The overall insertion score for conditions of LMA insertion

Chi square test for overall insertion score of conditions for LMA insertion shows no statistical significant difference between groups.(p>0.05) In which satisfactory were observed in 33 patients (75%) in T-L group and 36 patients (81.8%) in P group. and satisfactory in 9(20.5% and 8(18.8%)) .2 patients had poor insertion score in Thiopentone Lidocaine group.

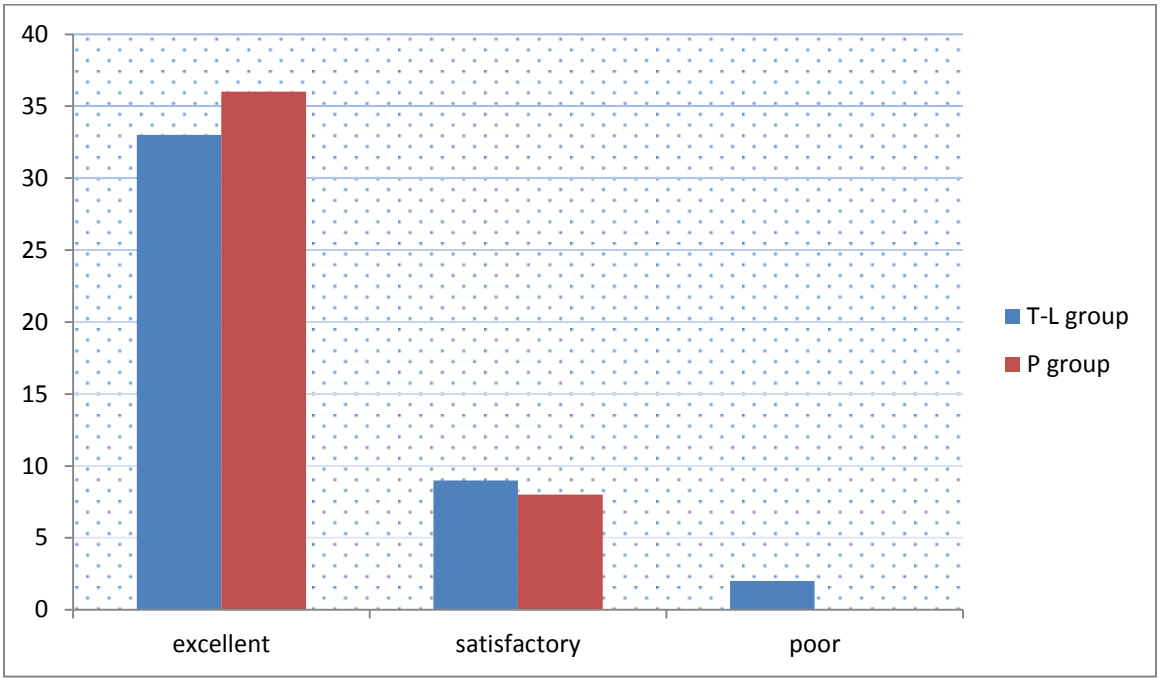

Figure2: showed a total distribution of patients according to overall insertion score for conditions of LMA insertion between (thiopentone with Lidocaine, n=44and propofol, n =44) at Minilik II referral hospital Addis Ababa, Ethiopia from December 2018-April 2019

5.3 Comparisons of Hemodynamic parameters between groups

5.3.1Changes in Mean MAP

Independent samples test were used for both comparisons of MAB and HR between groups. The baseline and 30 sec after induction MAP of two groups were comparable and statistically not significant. But following LMA insertion reduction of mean MAP were more in propofol group compared with TL group from the baseline (86.34±10.69vs88.25±11.59), p = 0.2, 1mint after LMA insertion (84.61±9.48v72.25±11.16s), p<0.000), The magnitude of the differences in the means(mean difference = -12.36, 95% CI: -16.75, -7.98) was large (eta squared = 0.27 or Cohan's d = 1.1) at 2 mint (81.14±10.43vs75.32± 12.15), p<0.01(mean difference -5.82,95%CI-10.62,-1.02 was moderate (eta squared=0.06 or Cohan's d 0.5) and at3 mint (83.66±9.24vs77.2 ±10.98), p<0.004. The magnitude of the difference in the means(mean difference -6.68,95% CI-10.92,-2.392) was large (eta squared=0.1or Cohan's d=0.7) .The mean arterial blood pressure has decreased in both groups 30 sec after induction but the decrement were more in propofol group but it is statistically not significant. (81.23±10.92vs78.66±12.40), p =0.3.

Table3: MAB between T-L and P group in study participants, who underwent elective surgery under GA with LMA at Minilik II referral hospital from December 2018-April,2019

MABchanges in mmHg	T-L group(mean±SD)	P group(mean±SD)	P value
T0(baseline)	86.34±10.69	88.25±11.59	0.42
T1(30secafterinduction)	81.23±10.92	78.66±12.40	0.30
T2(1minafterinsertion)	84.61±9.48	72.25±11.16	0.000
T3(2minafterinsertion)	81.14± 10.43	75.32± 12.15	0.01
T4(3minafterinsertion)	83.66±9.24	77.2 ±10.98	0.004

(MAB=mean arterial blood pressure-L=Thiopentone-Lidocaine=propofol.mmHg= millimeter mercury, SD=standard deviation

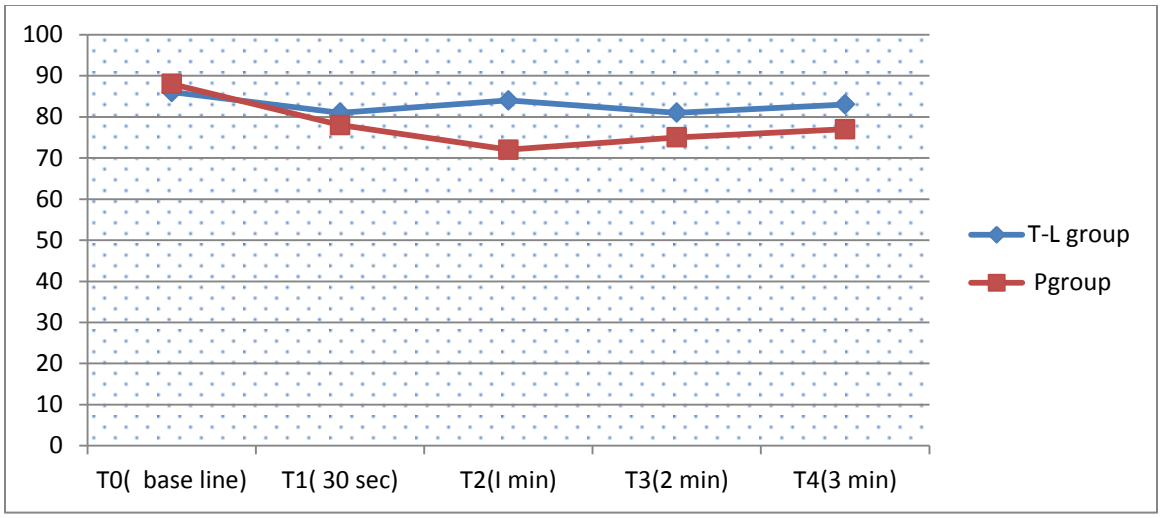

Figure3: Comparison of MAB between Thiopentone-lidocaine and Propofol group at different time intervals at Minilik II referral hospital, Addis Ababa, Ethiopia from December 2018- April 2019. T0 (base line), T1 (30 sec after induction), T2 (1min after insertion), T3 (2 min after insertion), T4 (3 min after insertion),

5.3.2 Changes in Mean heart rate in beats per minute

The mean baseline heart rate in group P was 87.27± 13.57 and in group T-L was 88.02±12.58 which was comparable (P>0.78). t test shows that no statistically significant difference in mean heart rate between the groups throughout the study.

Table4: Mean heart rate between T-L and P group in study participants who underwent elective surgery under GA with LMA at Minilik II referral hospital from December 2018-April, 2019

HR changes in BPM	T-L group(mean±SD)	P group(mean± SD)	P value
T0(baseline)	88.02±12.58	87.27± 13.57	0.78
T1(30secafterinduction)	91.36± 9.41	88.39± 8.38	0.12
T2(1minafterinsertion)	83.84 ±10.37	81.09± 9.87	0.2
T3(2minafterinsertion)	80.89 ±9.4	84.57±9.19	0.07
T4(3minafterinsertion)	85.48±11.24	84.75±10.15	0.75

HR=heart rate, SD=standard deviation BPM=beats per minute

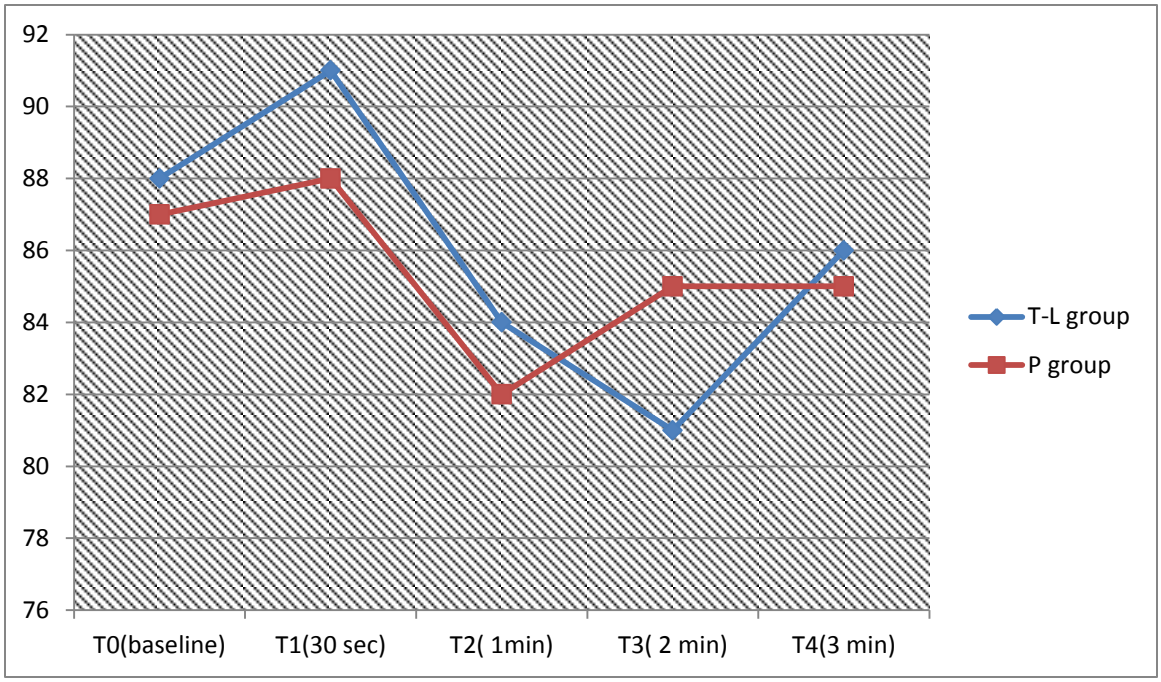

Figure4: Comparisons of HR between Thiopentone-lidocaine and Propofol group at different time intervals at Minilik II hospital, Addis Ababa, Ethiopia from December 2018- April 2019.

5.4 Mean Dose of Drug Consumption and Cost

The requirement of total mean dose of a drug was calculated using mean weight and mean dose for each group. Based on this mean induction dose for drugs were propofol 3(mg/kg) for group P and For T-L group it was 5 mg/kg, 1.5 mg/kg, for thiopentone, 2% Lidocaine respectively. Total cost requires per case used for both drugs for LMA insertion were 57.61 Ethiopia birr for T-L group and 89.38 birr for P group. So cost difference is 31.77 Ethiopian birr per case.

Table5: comparison of costs between T-L(2%) group and propofol group for study participants at Minilik II referral hospital 2018/19

Drug type and ampule cost	Price per case(T-L)	Price per case(P)
Mean weight per case(kg)	54.18	53.16
Thiopentone1gm(31.25 birr)	8.47	
2% Lidocaine 20 ml(400mg) (28.75 birr)	5.8	
Propofol 200mg(58.75birr)		46.85
Fentanyl 100 mcg(40 birr)	43.34	42.53
Total cost per case	57.61	89.38
savings	31.77 birr from propofol used	

T-L= Thiopentone Lidocaine group P=propofol group

There is 31.77 Ethiopian birr difference between T-L and P group.

Chapter six: Discussion

The laryngeal mask airway (LMA) has been an increasingly popular alternative to the face mask or endotracheal tube for securing the airway in patients undergoing elective surgery under general anesthesia. As it allows the maintenance of a clear airway while enabling the anesthesia professionals to keep both hands free and its placement is less stimulating by avoiding direct laryngoscopy.(28, 29)

Sufficient depth of anesthesia is required for insertion to relax jaw muscles and suppress airway reflexes. This is provided by generous dose of IV induction agent in which propofol is the common one .But it causes pain at injection site, prolonged apnea, cardiovascular depression, expensive and it is also not available in all countries.(13-15)Thus, a variety of anesthetics agent combinations with propofol and anesthetics agents have undergone many prospective study and clinical trials in relation to conditions and hemodynamic response to LMA insertion.(30)

The insertion condition was scored for six variables as number of attempts, mouth opening, gagging, coughing and laryngospasm in a three point scoring system. Then over all summation of insertion score was done. The changes in heart rate, mean arterial pressure, were recorded at baseline, 30 sec after induction, and 1, 2, 3, min after the insertion of LMA and also apnea time and Spo2 were recorded.

In our study there was no significant difference among the two groups in insertion condition of the patient in which 33(75%) of patients had excellent overall insertion score in TL group and 9(20.5%) had satisfactory over all insertion score. Poor insertion score was observed in 2(4.5%) but no in propofol group. In propofol group36 (81.8%) had excellent over all insertion score and satisfactory was observed in 8(18.2%) patients. ($p>0.34$)

A prospective randomized double blind study done by Dr. P.Nageswara .R.etal(2015) to Compare Ease of Insertion and hemodynamic response to LMA with Propofol and Thiopentone shows similar finding to our result. In their result excellent insertion score was observed in 24(80%) and26 (86.66%) in thiopentone-lidocaine and propofol group respectively. And satisfactory insertion score was 6(20%) in Thiopentone –Lidocaine group and 4(13.3%) in propofol group.($p>0.05$) (22)

In contrast to the above in 1996, Pramod Bapat, Compare Thiopentone-lidocaine vs propofol got a significant result. ($p<0.0001$).Excellent and satisfactory insertion score was 34(68%) vs 46(92%) in thiopentone –Lidocaine and propofol group respectively. Poor insertion score was 16(32%) in T-L group and 4(8%) in p group. This variation may be due to sex distribution variation in their research.(7)

Apnea time is prolonged in propofol group when we compared to thiopentone -Lidocaine group with p value 0f <0.02 which is statistically significant. Oxygen saturation in both groups was above 95%.

With regard heart rate changes during LMA insertion the group between thiopentone –Lidocaine and propofol group were comparable in base line values. (85.75+14.13 and85.68+14.03) respectively. ($p>0.99$) Our study found that there was no statistical significant difference in mean heart rate at various time intervals in both groups (TL and P). This is in contrast with a prospective randomized double blind study done in 2014 by Mrunalini compares thiopentone sodium and propofol who shows a decrease in heart rate in propofol group which was statistically significant. This difference may be due to oral alprazolam premedication a night before surgery fentanyl dose difference.(31)

Rao.P etal in 2015 Compare of Ease of Insertion and Hemodynamic Response to LMA with Propofol and Thiopentone using fentanyl and Lidocaine 1.5mk/kg got is non-significant finding and this is in line with our finding. (22)

In1996 T.M.Cook compare topical and IV Lidocaine with thiopentone for the insertion of LMA shows non-significant result for changes in heart rate between groups(15).Ahmed S et al. also Compare topical and intravenous lignocaine for insertion of laryngeal mask airway with propofol and found non-significant result.(8) These results are in line with ours.

A prospective randomized double blind study by Senguputa.et al in 2014 gets a significant result in changes of mean arterial blood pressure at T2,T3,T4.base line and after induction mean arterial blood pressure were comparable between groups.(2) A similar finding was shown in the same year who was conducted by Mrunalinia in comparing ideal induction agent for LMA insertion between thiopentone sodium and propofol.(31)

And also Rao.P.N etal in 2015 compares thiopentone with Lidocaine and propofol for LMA insertion shows significant change in mean arterial blood pressure between groups.(4) The above three studies are in consistent to our study regarding mean arterial blood pressure which shows significant decreasement in propofol group starting from T2. In our study the difference in T1 may be due to time interval variation.

Comparison of the two groups based on costs incurred by using these two study drug

• Per case cost TL= Thiopentone (8.47 birr) +Lidocaine (5.8 birr) 14.27 Birr

• Per case P= Propofol (46.85 birr)

• Cost difference per case between groups was almost 32.58 Birr. Depending on our situational analysis 416 patients are operated using LMA at Minilik II referral hospital per year.so using Thiopentone with Lidocaine will save13553.28 Ethiopian birr per year.

6.1 Limitations of the study

- ✓ Lack of prior study on this and related title in our country was one of our limitations to lay a foundation for understanding the problem.
- ✓ All age groups are not included

6.2 Strength of the study

- ✓ The two groups were comparable in socio demographic distribution.
- ✓ We got adequate sample size within the planed period of time.
- ✓ Pretest was performed

Chapter seven: Conclusion and Recommendation

7.1 Conclusion

In conclusion, we have shown that Thiopentone with 2% Lidocaine (IV) (1.5mg/kg) and propofol have comparable conditions for LMA insertion. Except thiopentone –Lidocaine provides better hemodynamic stability and significantly less apnea time with more cost effectiveness.

7.2 Recommendation

The anesthetists can use Thiopentone with Lidocaine (2%) for LMA insertion in place of propofol in adult patients.

This study was observational cohort study, so the researchers and the anesthetists in future to do this topic randomize control trial study design in order to minimize bias and confounding factors to decrease their impacts on outcome measurements

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Annexes

Annex I: English Version Oral Consent

Hello my name is_____. I am master's student in anesthesia from Addis Ababa University. We are doing study on the airway device called laryngeal mask airway (LMA). I am going to give you information and invite you to be part of this research. You do not have to decide today whether you will be involved in the research. Before you decide, you can talk to anyone you feel comfortable with about the research. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain.

LMA is an ordinary device that is used to open airway. It is inserted into a patient's airway after he/she took anesthesia. It provides as a channel through which the patient breaths oxygen and inhalational anesthetics. Its insertion needs drugs that makes patient unconscious that include propofol and thiopentone-lidocaine.

The reason we are doing this study is to compare these drugs in different aspects to decide which provides better outcome. And helps anesthetists to provide better patient management. All information your chart and data monitoring screen provide will be kept confidential. I will not include such as your name or exact address. Only honest data would contribute to improvement of health planning. Your role in the success of the research is important and I appreciate your contribution to the research. It is based on your interest and can withdraw at any time.

Are you voluntary to participate in the study?

A. Yes ☐

B. . No ☐

Thank you very much for your help

If Respondents are voluntary to participate, the data collection will be started. For any question or concerns you can contact the principal investigator using the following address.

Phone number: 0915856923, Email address: tiruzer.hibistu@yahoo.com.

Annex II: Amharic Version Oral Consent

ጤናይስጥልኝ ----------እባላለሁበአዲስአበባዩኒቨርስቲየሁለተኛዲግሪየአንስቴዢያተማሪነኝ Laryngeal Mask air way (LMA) በሚባልየአየርትቦመክፈቻላይጥናትእያደረኩኝነው፡፡አሁንበምነግርዎትመሰረትበጥናቱአንዲካተቱእጋብዛለሁ፡፡ፈቃደኝነትዎንዛሬማሳወቅአይጠበቅብዎትም፤ከመወሰንዎበፊትየፈለጉትንሰውስለጥናቱመጠየቅይችላሉ፡፡አሁንስለጥናቱገለጻበማደርግበትጊዜያልገባዎትነገርካለአስቁመውንመጠየቅይችላሉ፡፡ Laryngeal Mask air way (LMA) የአየርቱቦውንለመክፈትየሚያስፈልግየተለመደመሳሪያነው፡፡በታካሚዎችአየርትቦውስጥበማስገባትአከስጅንናሚሳቡየማደንዘዣ አይነቶችወደሰውነትውስጥእንዲገቡያደርጋል፡፡ይህንንምለማድረግየሚሰጡየማደንዘዣመድኃኒቶችአሉ፡፡ከእነዚህመካከልም Propofol & Thiopentone-Lidocaine ይገኙበታል፡፡የዚህጥናትአላማእነኚህንመድኃኒቶችከተለያየየጎንዮሽጉዳትአንጻር አወዳድሮየተሸለውንበመምረጥተገቢውንህክምናለታካሚዎችለመስጠትነው፡፡ስለዚህየእርስዎበጥናትውስጥመካተትለዚህጥናት መሳካትከፍተኛአስተዋጽኦአለው፡፡ከእርስዎየምናገኘውማንኛውምመረጃለምርምርአገልግሎትእንደሚውልእየገለጽኩናበማንኛ ውምሁኔታየእርስዎየግልመረጃለሌላአገልግሎትእንደማይውልለማሳሰብእወዳለሁ፡፡

ፈቃደኛነዎት

አዎ

አይደለሁም

ስለእርዳታዎበቅድሚያየላቅምስጋናአቀርባለው

የአጥኝው ስምናአድራሻ ጥሩዘር ህብስቱ

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አመሰግናለሁ!

Annex IV- Questionnaires

Questionnaire prepared to compare the effect of Thiopentone –Lidocaine vs propofol on the insertion conditions of LMA and hemodynamics stability for elective surgical patients at Minilik II referral hospital 2018/2019. This questionnaire is to be used as a guide to collect information for the data collectors.

Date----------

Part I: Socio-demographic characteristics and induction variables

1. Age_____years
2. Sex A.M B. F
3. weight_____
4. ASA Physical status A.ASA I B.ASA II
5. Induction propofol dose_____mg/kg /additional propofol _____mg/kg
6. Induction thiopentone dose: _____mg/kg /,additional thiopentone dose_____mg/kg
7. Lidocaine dose_____mg/kg
8. Fentanyl dose_____mg/kg

Part II: Conditions during insertion of LMA

2.1 Number of attempts A.1 B.2 C.3

2.2 Mouth opening condition A. Full B. Partial C. Nill

2.3 Limb and head movement A. No B. mild C. sever

2.4 Gagging A.No B. mild C. sever

2.5 Coughing A. No B. Mild C. Sever

2.6 Laryngospasm A.No B. mild C, sever

Part III: Hemodynamic changes at different stages of anesthesia

I) **mean arterial blood pressure** changes at:

3.1) T0 (base line) ___

3.2) T1 (30 sec after induction) ___

3.3) T2 (1 min after insertion) ___

3.4) T3 (2 min after insertion) ___

3.5) T4(3 min after insertion)___

II) **Heart rate changes** at:

3.6) T0 (base line) ___

3.7) T1 (30 sec after induction) ___

3.8) T2 (1 min after insertion) ___

3.9) T3 (2 min after insertion) ___

3.10) T4(3 min after insertion)___

3.11 Duration of apnea : <5min ☐ >5 min ☐

3.12 SPO2<95% A.Yes B.No

Name of data collector----------signature----------

Name of supervisor----------signature----------