

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



**EFFECT OF PROPOFOL VERSUS THIOPENTONE WITH LIGNOCAINE
SPRAY FOR LARYNGEAL MASK AIRWAY INSERTION, AT TIKUR
ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA, 2017 : A
PROSPECTIVE COHORT STUDY**

BY: ENGDWORK BELETE

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REQUIREMENTS OF MASTERS OF SCIENCES DEGREE
IN THE ADVANCED CLINICAL ANAESTHESIA

June, 2017

Addis Ababa, Ethiopia

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Full title of the research

Effect of Propofol versus Thiopentone with Lignocaine Spray on hemodynamic change and response condition during LMA insertion on patients age above 10 years who undergoing elective surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, from January 20/2017 to April 20/2017: A Prospective Cohort Study

INVESTIGATOR: Engdawork Belete (BSc)

CONTACT ADDRESS: Email-- engda20xy@yahoo.com

Telephone: +251913715278

ADVISOR: Misrak W/Yahones (BSc, MSc)

Signature _____ Date _____

June, 2017

Addis Ababa, Ethiopia

CERTIFICATION

The undersigned certify that the research entitled effect of propofol versus thiopentone with lignocaine Spray on hemodynamic change and response condition during LMA insertion on patients age above 10 years who undergoing elective surgery at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, from January 20/2017 to April 20/2017: 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

Name _____ Signature _____ Date _____

2. Internal Examiner

Name _____ Signature _____ Date _____

3. External Examiner

Name _____ Signature _____ Date _____

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ABBREVIATION AND ACRONYMS

ASA	American Society of Anesthesiology
DBP	Diastolic Blood Pressure
GA	General Anesthesia
ECG	Electro Cardio Graph
ETB	Ethiopian Birr
HR	Heart Rate
IV	Intra Venous
LMA	Laryngeal Mask Airway
MAP	Mean Arterial Blood Pressure
MINT	Minutes
P	Propofol
PI	Principal Investigator
SBP	Systolic Blood Pressure
SPSS	Statistical Package for social sciences
TASH	Tikur Anbessa Specialized Hospital
TL	Thiopentone with Lignocaine
NIBP	Non Invasive Blood Pressure

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ABSTRACT

Background: Insertion of laryngeal mask airway (LMA) requires an adequate depth of anesthesia. The choice of the intravenous induction agent was influence the insertion conditions depending on its ability of optimize the pharyngeal, laryngeal reflexes and hemodynamic stability.

Objectives: This study aims to compare the effect of Thiopentone with 10% topical Lignocaine spray(TL) and propofol(P) on hemodynamic change and response condition during LMA insertion on patients age above 10 years who was undergoing elective surgery at Tikur Anbessa Specialized Hospital from January 20/2017 to April 20/2017.

Methods: Study 84 participant followed in prospective cohort study, who fulfills inclusion criteria in to either TL or P based on induction type of study drugs. Data collector record baseline, after induction and LMA insertion (MAP and HR), insertion response and apneic time and dates analyzed using SPSS 20 with 95% CI, unpaired student's t-test to continuous outcome variables, chi-square test for categorical and finally results presented as Mean \pm SD and percentage. $P < 0.05$ was considered as statistically significant difference.

Result: The comparison of data showed that reduction mean arterial blood pressure (MAP) of P group compare with thiopentone with 10% topical lignocaine group within 10 mint Mean \pm SD at 1 mint after induction (74.8 ± 4.73 vs 81.8 ± 5.6) $p < 0.001$, at 1 mint after LMA insertion (78.4 ± 5.5 vs 81.8 ± 5.6) $p < 0.001$, at 5 mint (80.6 ± 4.6 vs 84 ± 5.4) $p < 0.002$ and at 10 mint (82.5 ± 4.3 vs 85.6 ± 4.6), $p < 0.03$. There was no statistically significant differences regarding the HR change and insertion conditions between the two groups ($P > 0.05$). Apneic time was prolonged in P group compare to TL group (138 ± 45.8 vs 85 ± 13.8) seconds, $p < 0.001$. Compared the two groups on cost inquiry TL group per case 27 ET Birr cost reduced than propofol group.

Conclusion and recommendation: Thiopentone with 10% topical Lignocaine is alternative for insertion of LMA to propofol, with better hemodynamic stability and cost effectiveness. We recommend that use of TL induction of anesthesia for LMA insertion age above 10 years.

Key Words: Topical lignocaine, Propofol, Thiopentone, Insertion Condition, Elective Surgery

CHAPTER ONE

INTRODUCTION

1.1 Background of the study

Maintenance of airway was key importance during any anesthetic procedure. The mission for finding an ideal device for the maintenance of unobstructed airway was on from the time when the beginning of general anesthesia. Looking to the existing airway devices like facemask or endotracheal tube, LMA can be called “the missing link” between the Face Mask & Endotracheal tube. (1)

The safest and most common method for maintaining the airway during general anesthesia is direct laryngoscopy and endotracheal intubation. Hemodynamic changes, such as tachycardia, hypertension, and arrhythmias can occur during intubation, which can cause myocardial ischemia. To prevent adverse cardiovascular responses, laryngeal mask airway can be used instead of laryngoscopy and tracheal intubation during airway management. (2)

Laryngeal mask airway (LMA) was developed in 1981 by Dr. Archie Brain. It was available for clinical use in the United States by 1992 and has become very popular in routine medicine practice during past 10 years. LMA was an ease of insertion without a laryngoscope or muscle relaxant. The cardiovascular response to insertion it is much lower than that of endotracheal intubation, and the incidence of postoperative sore throat is lower after LMA use as compared to endotracheal intubation. (3)

Successful insertion of LMA without any unwanted effects, such as coughing, gagging, laryngospasm, body movement and may lead to desaturation, regurgitation, and aspiration requires adequate depth of anesthesia and suppression of the upper airway reflexes.(4)

Inadequate depth of anesthesia may provoke coughing, gagging and laryngospasm which may lead to adverse hemodynamic changes and increase incidence of regurgitation and aspiration. Therefore, the optimal condition for LMA insertion mandates a generous use of an anesthetic agent for induction. (5)

A popular method of providing anesthesia for LMA insertion is with the use of IV propofol, which has the advantages of inducing anesthesia rapidly and depressing upper airway reflexes. However,

propofol is expensive and painful on injection and associated with a greater degree of ventilator depression and longer apnea than thiopental, also causes greater cardiovascular depression (adverse effects like hypotension) than thiopental during induction of anesthesia. (6)

Thiopentone has advantage of painless injection and less incidence of hypotension, but it does not provide good jaw relaxation and can cause coughing, gagging and laryngospasm when used alone for LMA insertion. It has been used with prior topical lignocaine spray to the posterior pharyngeal wall or co-induction with intravenous midazolam for LMA insertion in adults (7)

1.2 Statement of the problem

Successful airway management is the vital component of safe anesthesia. Endotracheal intubation is the gold standard for securing airway, but can lead to life-threatening stress response such as tachycardia, hypertension, and myocardial ischemia. LMA, which is a supraglottic device, can replace laryngoscopy and intubation thereby preventing these stress responses during airway management (8)

Smooth insertion of LMA requires adequate mouth opening and suppression of upper airway reflexes to prevent coughing, gagging, and laryngeal spasm. Several methods have been introduced for LMA insertion while no standard anesthesia induction method has been proposed to guarantee a proper placement of the device. (9)

Intravenous induction technique either with a single or two drugs is commonly used to insert an LMA. In the latter method, propofol is used with another anesthetic drug such as thiopentone or a volatile agent, opioids and lidocaine which blunt laryngeal reflexes and may be useful in facilitating LMA insertion. Since the duration of action of these drugs is rather long, their use in short term surgeries may be contraindicated. (10).

Propofol, when used alone often exceeds 2.5 mg/kg which causes cardiorespiratory depression. Other problems associated with it were apnea, hypotension, excessive involuntary patient limb movements and laryngospasm, pain on injection site, and. Also it's expensive and may not be available for regular use world-wide. So, propofol as a single agent is unsatisfactory. (5)

Therefore, using propofol may have an impact on patient, and the country's economy also controversy on probability of addiction and infection due to its combination.

Thiopentone increases airway irritability because of the relatively greater depressant effect of the drug on the sympathetic than on the parasympathetic reflex arch and it is clear that successful insertion with thiopentone would require either adequate reflex suppression or a deeper plane of anesthesia. (11)

1.3 Significance of the study

There have been numerous papers that looked into co-induction techniques combining a lower dose of propofol or thiopentone with other agents, including benzodiazepines, rapidly acting opiates, neuromuscular blocking agents and topical or intravenous local anesthetic agents. (12)

Thiopentone had been assessed for the insertion of an LMA but produces less satisfactory conditions than propofol because not effective at suppressing airway reflexes. Various drugs are used as adjuvants to thiopentone to decrease the incidence of adverse responses to insertion of the LMA. (13, 15)

The same research was not conducted in our country; Ethiopia to show effect of either drug for LMA. Therefore, this study was designed to compare the effect of thiopentone with 10% topical lignocaine spray and propofol on hemodynamic change, and response condition during LMA insertion on patients age above 10 years who was undergoing elective surgery at TASH

Also this study was designed to compare costs inquired of patients by using thiopentone with 10% topical lignocaine and propofol drugs to LMA insertion.

So after this study knowing the effectiveness of the either drug in terms of hemodynamic stability, cost reduction and produce optimal LMA insertion conditions helps anesthesia professionals to select good alternative drug for LMA had better outcomes of the patient with less cost to the patient and institutions.

On the other hand, this research will open the gate to enhance evidence based practice, to bring quality education and training

Also the stakeholders, anesthetist, will be mindful of the relative effectiveness and side effects of the study drugs used for LMA

The data in this study will help as base line information for researchers to do related topic because lacks of references was problem to do comparative study design in our country.

CHAPTER TWO

2.1 LITERATURE REVIEW

Airway management and patient safety have always been great importance for physicians of both modern and ancient medicine while numerous devices and methods have been developed to fulfill this goal. (9)

Laryngeal mask airway have become an integral part of anesthetic care in airway management and increasing emphasis on day care anesthesia has led to the greater use of laryngeal mask airway as an alternative to the face mask and in some cases to tracheal intubation . (16)

Safe insertion of LMA requires deep level of anesthesia without airway reflexes because inadequate anesthesia can cause coughing, gagging, laryngospasm, body movement and may lead to desaturation, regurgitation, and aspiration. (17)

According to study done by Nirmala.B.C in 2014 showed us there was no difference in the incidence of jaw relaxation, coughing, laryngospasm. Laryngospasm was absent in both the groups ($p=0$). Moderate degree of swallowing/gagging was present in 5 patients in thiopentone group and absent in propofol group ($p< 0.01$ significant) and overall ease for insertion of LMA in thiopentone and fentanyl group was 92% and propofol group was 100% ($p< 0.001$ significant).The statistical analysis showed that ease of insertion was significantly better in patients who were administered propofol compared to those given thiopentone and fentanyl. (p value <0.01 significant). (18)

Similar to above study, done by Vandana T and colleagues and found that ease of insertion was significantly greater with propofol as compared to thiopentone. They considered easy in 96% patients in propofol group and 76% in thiopentone group. Hemodynamic parameters measured during induction exposed a significantly greater decrease in heart rate and arterial pressures in propofol group as compared to the thiopentone group. (19)

A double blinded controlled trial study done by Yuan-Yi Chia and colleagues shows that less head movement (10%), and gagging (0%), in the propofol than in the thiopentone group (42% and 16.7% $P < 0.05$ respectively). There was no difference in MAP between the groups except 1 min after insertion of LMA. In both group mean MAP decreased significantly in comparison to base line mean MAP taken before induction, in 1, 3, 5 and 10 min after insertion of LMA. (20)

An additional to above comparative study, study done by Mrunalini Parasa in 2014 also show between propofol and thiopentone groups exhibited statistically significant difference in insertion condition with more attempts in thiopentone group and number of additional doses of induction agent required with more additional dose requirements in propofol group . There is more decrease in HR, SBP and DBP in propofol group, than in thiopentone group after administration of induction agent and after LMA insertion. Finally their conclusion, induction with of Propofol was associated with better conditions for LMA insertion and lesser adverse effects like gagging, coughing, head and limb movements than with thiopentone. (21)

Although study done by Patrick Scanlon, et al assessed the patient responses to LMA insertion shows us thiopentone was associated with an adverse response in 76% of patients compared with 26% in propofol. No patient in propofol group required treatment for laryngospasm. No patient was judged to be inadequately relaxed in propofol group and this was less than 11%in the thiopentone group. They were concluded that at these doses, propofol was superior to thiopentone as an induction agent for insertion of laryngeal mask airway. (22)

In 2015, comparative study done by Kantharaja H E et al in India founded thiopentone and lignocaine had a mean (SD) apneic time of 96.1 (65.4) s and those receiving propofol had a mean (SD) apneic time of 184.9 (102.6) s ($p < 0.005$). There was no significant difference in heart rate an insertion condition between the two groups, but the decrease in systolic and diastolic blood pressure was significantly greater in the propofol group (systolic $p < 0.05$, diastolic $p < 0.01$). Finally they conclude that if 40 mg of topical lignocaine is sprayed onto the posterior pharyngeal wall 3 min before induction of anesthesia with thiopentone, the conditions for insertion of an LMA are equal to those following an equipotent dose of propofol, but with greater hemodynamic stability and significantly less respiratory depression.(13)

According to study done by Mohammad S et al in 2015, insertion condition that there were statistically insignificant compared TL and propofol group.($P > 0.05$). Additionally, they found the mean duration of apnea in propofol group was 108 ± 15.1 and in topical lignocaine and thiopentone was 74.4 ± 10.1 . These values were statically compared and the result obtained was significant ($P < 0.05$). (14)

Comparable to above study done by C. R. Seavell and colleagues prospective randomized, double blind study to compare the response to insertion LMA ,in patients receiving thiopentone and lignocaine had a mean (SD) apneic time of 96.1 (65.4) s and those receiving propofol had a mean (SD) apneic time of 184.9 (102.6) s ($p < 0.005$). No patient had oxygen saturation less than 96% at any stage before they resumed spontaneous ventilation. There was no significant difference in heart rate between the two groups, but the decrease in systolic and diastolic blood pressure was significantly greater in the propofol group (systolic $p < 0.05$, diastolic $p < 0.01$).**(24)**

2.2 Framework of the Study

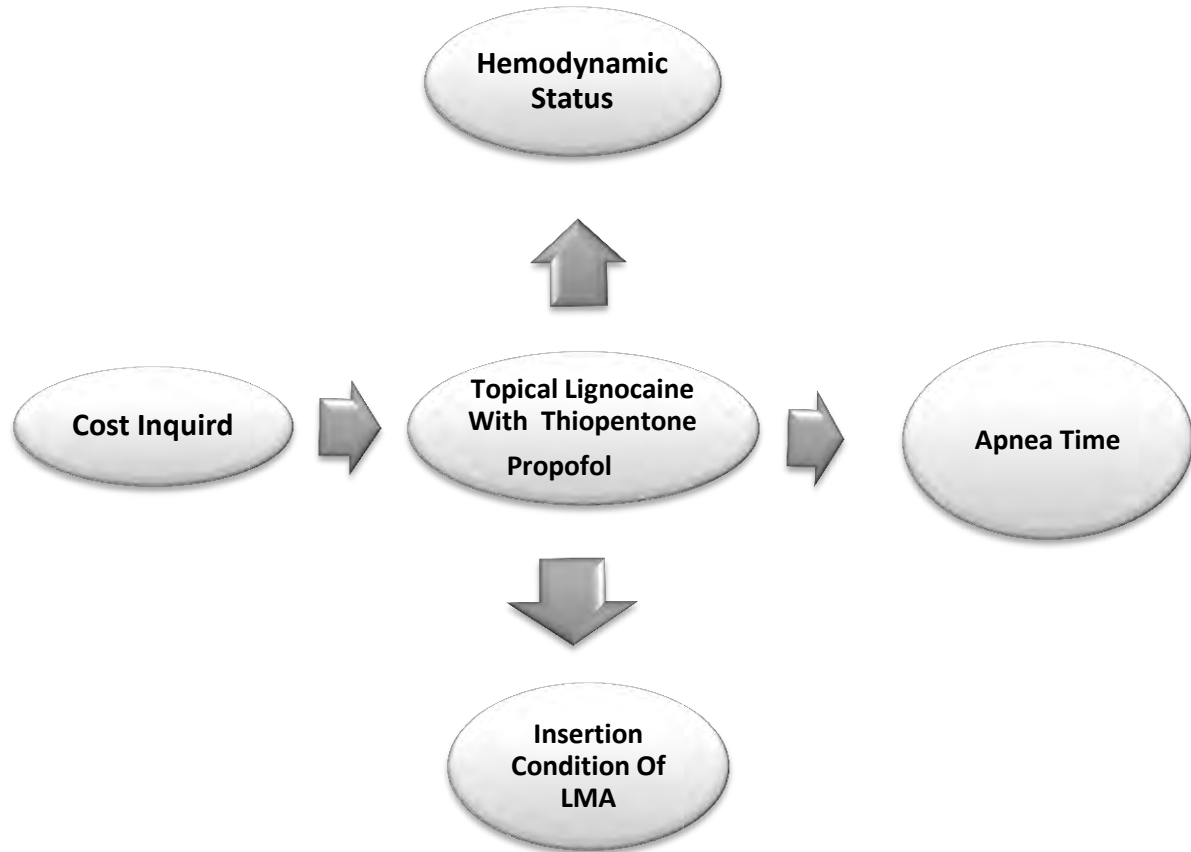


Figure 1 conceptual frame work

CHAPTER THREE

OBJECTIVES

3.1 General objective

The aim of this study was to compare the effect of thiopentone with 10% topical lignocaine spray and propofol on hemodynamic change and response condition during LMA insertion on patients age above 10 years old who undergoing elective surgery at TASH from January 20/2017 to April 20/2017.

3.2 Specific objectives

1. To compare the hemodynamic response during induction and after LMA insertion between two groups
2. To compare the patient response condition during insertion of LMA between two group
3. To compare apneic time after induction of patients and costs incurred using between two group

CHAPTER FOUR

METHODOLOGY

4.1 Study Area

This study was conducted at Tikur Anbessa Specialized Hospital in Addis Ababa, Ethiopia. This hospital is multi-specialist tertiary care teaching hospital in Ethiopia, since 1972. Now a days; it is serving as main referral hospital and teaching facility to the country. This hospital has a total of 12 functional operating theatres and more than other 11 public hospitals situated in Addis Ababa.

4.2 Study Period

The study was conducted from January 20/2017 to April 20/2017 at TASH

4.3 Study Design

Hospital based prospective observational cohort study.

4.4 Population

4.4.1 Source population

All surgical patients those undergone surgery under general anesthesia used LMA for airway security at TASH.

4.4.2 Study population

All ASA I&II and age above 10 years patients whose underwent elective surgery under general anesthesia with LMA was indicated and induced with either P or TL in the study period at TASH.

4.5 Eligibility Criteria

4.5.1 Inclusion criteria; Age greater than 10 years, ASA I and II elective patient scheduled for deferent type of surgery under general anesthesia using LMA for securing airway with either study drugs and willing to participate in the study by giving written informed consent included in the study for age 10_18 years from their family.

4.5.2 Exclusion criteria: Those patients with any risk of difficult intubation, pregnant, emergency, used induction agent other than study drugs for LMA, patient who were premeditated with opioids or non-opioid analgesics rather than induction purpose, allergy to study drugs, inhalational agents other than halotane and anemia were excluded from this study

4.6 Sample Size

This study where plan to perform estimation of the difference between two independent population means, So to sample size determination we used the formula for sample sizes calculation for two independent samples, continuous outcomes and we require equal sample size in both groups.

Aim: Estimate population mean $\mu_1 - \mu_2$ and Want: $x_1 - x_2$ within $\pm d$ units

Based on recent study results on thiopentone with 10% lignocaine and propofol, the mean score apnea time, $\mu_1 = 75.4$ in P group, $\mu_2 = 83$ in TL group and $s_1 = 7$, $s_2 = 15$ respectively. (14)

Z = 95% confidence interval = 1.96 9 ($Z_{1-\alpha/2} = 1.96$ for a $p = 0.05$)

Power 80%, $Z_{1-\beta} = 0.83$ for 20% beta error)

Where $n_1 = n_2$ the sample size in each of the groups

$$(Z_{1-\alpha/2} + Z_{1-\beta})^2 = n \frac{(\mu_1 - \mu_0)^2}{S^2_0 + S^2_1} \dots\dots\dots (25)$$

$$(1.96 + 0.83)^2 = n (83 - 75.4)^2 / (7^2 + 15^2). \text{ So } n = 7.7841 / 0.2 = 36 \text{ per group}$$

For both groups $n = 36 \times 2 = 76$ and adding 15% contingency the final total sample size became 84. So 84 (each group = 42) of patients using either TL or P induction anesthesia for LMA and age above 10 years were participate required in our study.

4.7 Sampling Procedure

Before we start sample size determination, we done situational analysis at TASH and approximately 592 elective patients' age above 10 years used LMA under either of study drug annually this means 49 patients was used LMA each month. All qualified study inclusion criteria patients were selected using systematic random sampling technique until the required number of study participants is reached during data collection period.

The total source population size was 192(N) in our study period and desired sample size was 84. The sampling interval or sampling fraction (k) = the total population size in study period dividing by the desired sample size.

Sampling interval (sampling fraction) was k get by $192 \div 84 = 2.2 \sim 2$. Therefore, $k = 2$ so every other two participates select, starting participant on sample frame is randomly choice and we used number one on list.

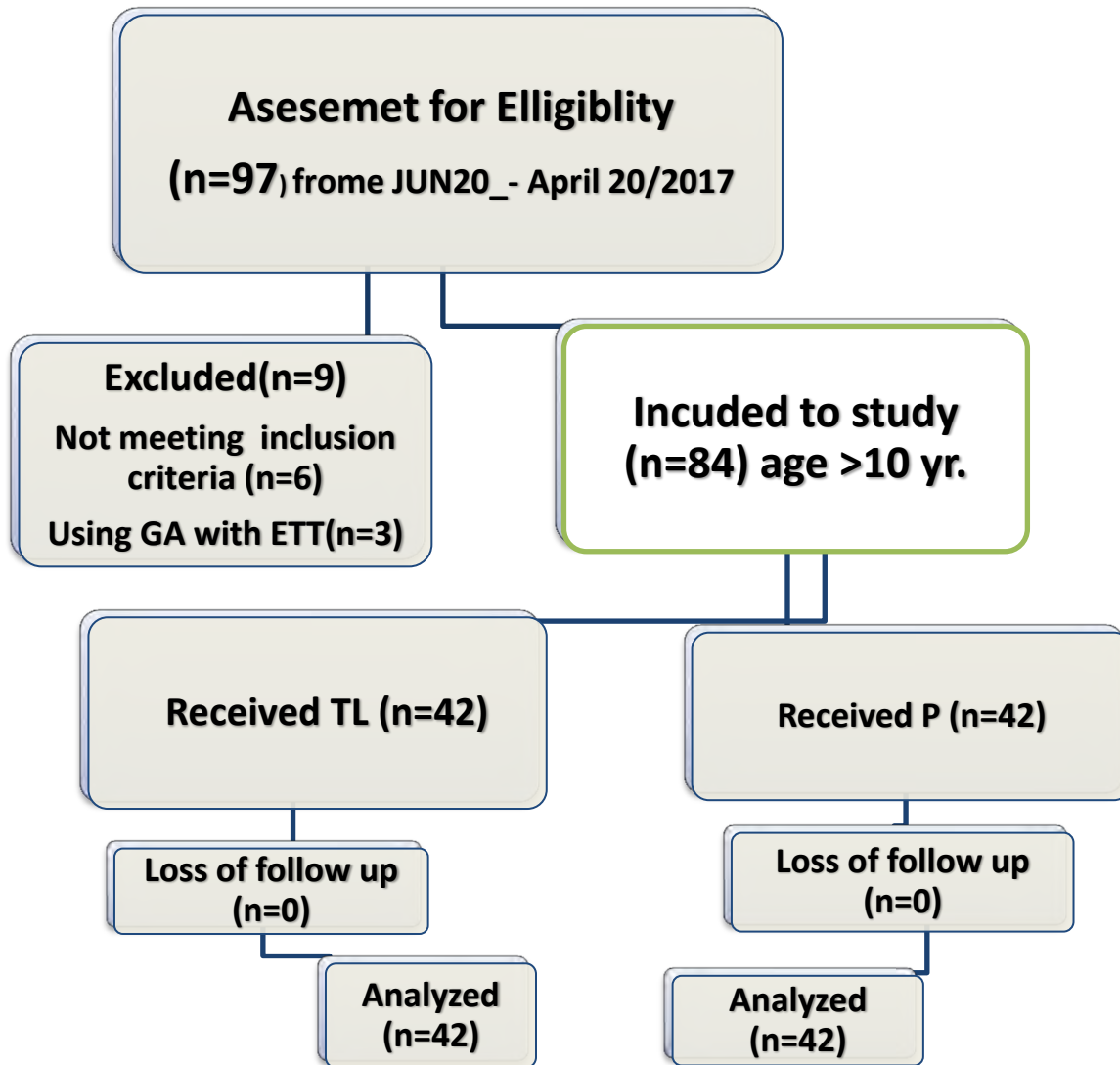


Figure: 2 Consort flow diagram of the observation

4.8 Study variables

4.8.1 Dependent variable

- Hemodynamic status of the patient (HR and MAP)
- Apnea time
- Insertion condition of LMA

4.8.2 Independent variables

Main independent (exposure) variable:

- Type of anesthesia used (10% Topical lignocaine with thiopentone versus propofol)

Possible covariates (confounding variables):

- Weight
- Sex

4.10 Data collection methods

4.10.1 Anesthetic technique

In TASH clients who are eligible for general anesthesia were asked for their consent to perform the general anesthesia and most common method for maintaining the airway during general anesthesia was direct laryngoscopy and endotracheal intubation and LMA. Anesthesia management for LMA insertion in our study hospital was usually carried out by propofol induction with opioid analgesia using standard dose per kg and inhalational agent with 100% oxygen.

However, MSc anesthesia professionals were used thiopentone with 10% lignocaine sprays for LMA insertion during our study period rather than propofol and they were performed by given 4 spray of 10% lignocaine to the posterior oropharynx (2 spray right and 2 spray on left side by mouth opening and protrude tongue out) before pre-oxygenation and induced 3 mint after spray applied with thiopentone IV.

4.10.2 Training for data collectors

Four MSc anesthetists who were assigned to collect data undertook a training program by the principal investigator on the objectives of the study, the method of sampling (selecting study group), coding , and filling out the data collection sheets to try we had standardized data collection procedures.

4.10.3 Pretest study

A pretest study was conducted at TASH in 5% of total sample size study subjects to check the effectiveness of the questionnaire and finally based on result of pretest we made corrections to the questionnaire.

4.10.4 Data collection technique and instrument

After getting ethical clearance and permission from the Addis Ababa University, Department of Anesthesia and the hospital, data was collected by trained four MSC anesthesia students. All patients' who fulfill inclusion criteria was scheduled for elective surgery under general anesthesia with LMA used either propofol or thiopentone with lignocaine spray induction were selected using systematic random sampling technique on secluded program.

During each procedure the data collectors were recorded the observed patient's baseline vital sing (MAP and HR) using pulse ox meter, ECG and NIBP and demographic data such as age, sex, ASA class and weight together with pre-anesthetic evaluations data recorded on patient card and asking patient themselves for further if we miss on cards and finally during induction time assign patients either to TL or P group.

After one mint induction, at 1, 5 and 10 min after the insertion of the LMA both MAP and HR recorded and also additional type and dose of drug used, apnea time

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, number of attempts to LMA insertion and laryngeal spasm) and 3 point scale (5).

The six variables, three point scores were summed to give an overall insertion condition score.

Total score insertion condition

- 18 Excellent
- 16_17 Satisfactory
- <16 Poor
- Unacceptable = 6

Table 1: Scoring system of patients response to LMA insertion

Variables	Scoring		
	3	2	1
Gagging	Nil	Slight	Gross
Coughing	nil	Slight	Gross
Patient movement	nil	Slight	Gross
Jaw relaxation	complete	Incomplete	No
Number of Attempts	one	Two	≥ three
Laryngeal spasm	nil	Incomplete	Complete

4.10 Data quality assurance

To assure quality of data, we performed pretest study on the data collection tool (the questionnaire) and given training for data collectors by PL on the objectives and significance of the study and the measurement tools provided for data collectors and supervisors by PL. During data collection, regular supervision and follow up were undertaken. Supervisors was checked each questionnaire daily for accuracy, clarity and consistency of data with further cross checking with the PL

4.11 Data processing and analysis

Data was checked manually for completeness, coded before entered into the Epi Inf version 7 software to decrease data entree error and then transferred to SPSS version 20 to analysis. Before starting analysis data were tested for normality of distribution using Shapiro Wilk normality test and homogeneity of variance was assessed by Levene's test for equality of variances and also checked entered data validity by using 10/84 data analyzed.

Analysis of demographic data for gender distribution and ASA class was chi-square test was applied whereas for age and weight distribution independent student's t-test was applied

Numerical data variables were presented as mean and standard deviation (SD). We analyzed the continuous variables between groups by means independent student's t-test for comparison in between two groups.

Categorical variables were presented as frequency and percentage. The Chi square test (with Fisher's exact test when appropriate) was used to compare LMA insertion conditions between P and TL. $P < 0.05$ was considered as significant

4.13 Presentation and dissemination of Results

The final research paper was given for Addis Ababa University Department of Anesthesia and Federal ministry of health. The result may be presented on main workshops, seminars and conference so that the stakeholders, anesthetist, will be aware of the relative efficacy and side effects of the study drugs for LMA used. It will be publish the study as journal article.

4.9 Operational definitions

Apnea time: - the time from start of breath holding to start of spontaneous breathing.

Jaw relaxation (mouth opening) during insertion of LMA. (5)

Complete relaxation: - mouth opened easily and fully.

Incomplete relaxation: - firm manual separation required opening the mouth fully

No: - no relaxation at all.

Adequate muscle relaxation for insertion of LMA: -loss of motor response to jaw thrust (26).

Effective LMA insertion (27): - when there were response to LMA insertion scoring greater than 16 (excellent or satisfactory), apnea time less than 1 minutes and no significant hemodynamic change.

Laryngeal spasm (28)

Complete - when there is laryngeal spasm and no air entry on ventilation.

Incomplete: - when there is laryngeal spasm but there is air entry.

Coughing (28)

Slight coughing:- coughing which can occurs immediately after LMA and subside by its self

Gross coughing: - coughing which needs deepening of anesthesia to be relieved.

Gagging (28)

Slight gagging: - Gagging which stays for short seconds can relieve own.

Gross gagging: - Gagging which needs deepening of anesthesia to be relieved.

Overall insertion conditions were assessed according to the modified Scheme of Lund and Stovener. (29)

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.

4.12 Ethical consideration

This research was conducted after obtaining ethical clearance and approval from Addis Ababa University Review Board (REC, Research Ethics Committee.). Official support letter was written to TASH and permission for data collection was obtained from the hospital authorities. The purposes and the importance of the study were explained & verbal informed consent was obtained from each participant. Confidentiality was maintained at all levels of the study by using nameless questionnaire.

CHAPTER FIVE

RESULTS

A total of ninety-three patients met the eligibility criteria. Six patients not meet inclusion criteria and three used endotracheal anesthesia were excluded. Eight four ASA I or II and age above 10 years patients undergoing general anesthesia with LMA used induction drug either TL or P were analyzed. The p-value of less than 0.05 was considered to be statistically significant difference.

5.1 Socio demographic characteristics of study Participants

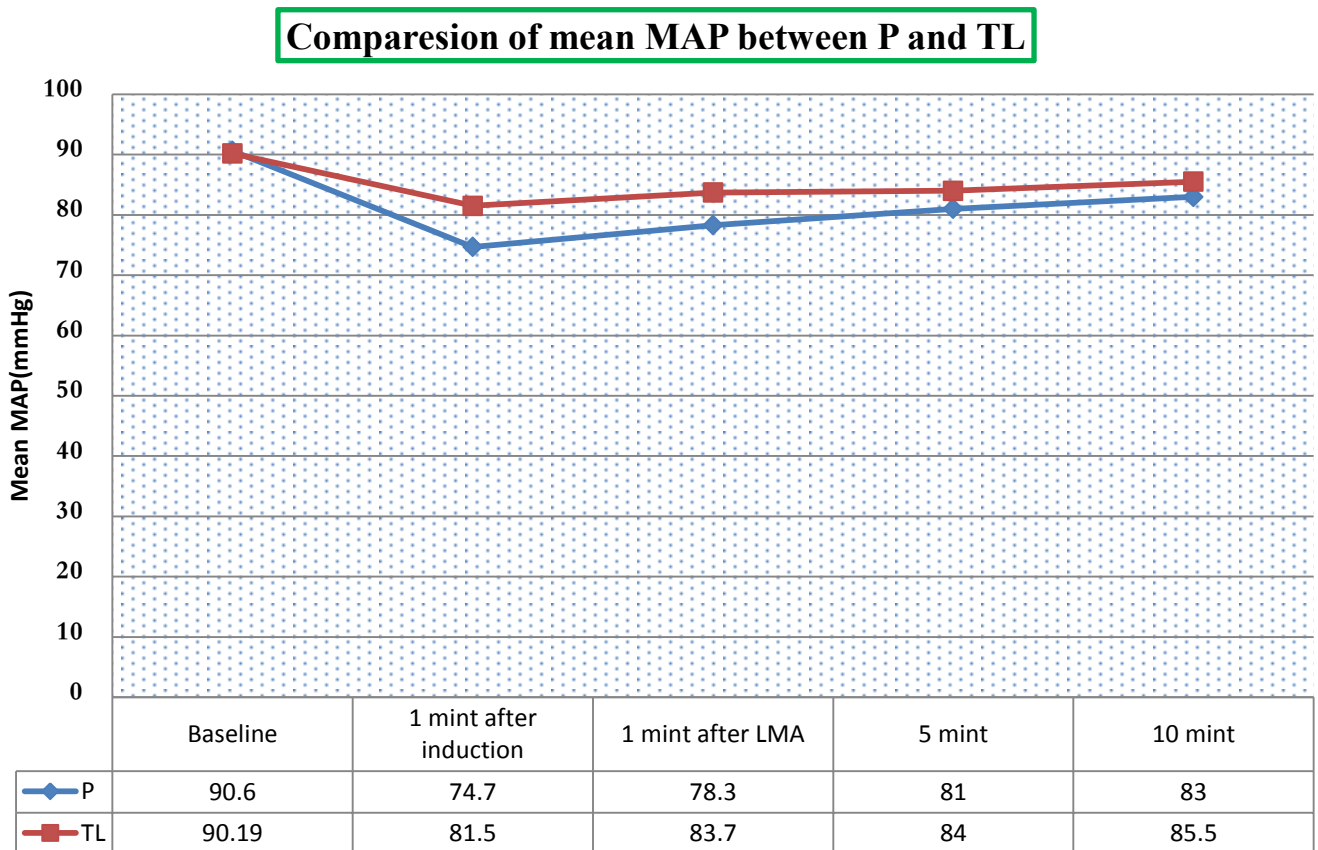
There was no significant difference between the two group on demographic data like age, ASA class, weight or sex distribution were all the same among the groups with each ($p > 0.05$)

Table 2: Socio-demographic and operative values in each group of patients age above 10 yrs. (thiopentone with 10% topical lignocaine, n=42 and propofol, n =42).

Variables	TL	P
Gender :M/F	32/10	31/11
ASA class: ASAI/ASA II	37/5	36/6
Age; years	18.3±6.6	18.1±6.5
Weight; kg	43.3±12.7	42.8±12.8

5.2 Hemodynamic parameters

The baseline mean of MAP of two groups are comparable and statistically not significant. But following induction of anesthesia and LMA insertion reduction of mean MAP in P group more decrease compare with TL group from the baseline (90.6 ± 4.1 vs 90.4 ± 6.3), $p = 0.5$, at 1 mint after induction (74.8 ± 4.73 vs 81.8 ± 5.6), $p < 0.001$, 1 mint after LMA insertion (78.4 ± 5.5 vs 81.8 ± 5.6), $p < 0.001$, at 5 mint (80.6 ± 4.6 vs 84 ± 5.4), $p < 0.002$ and at 10 mint (82.5 ± 4.3 vs 85.6 ± 4.6), $p < 0.03$

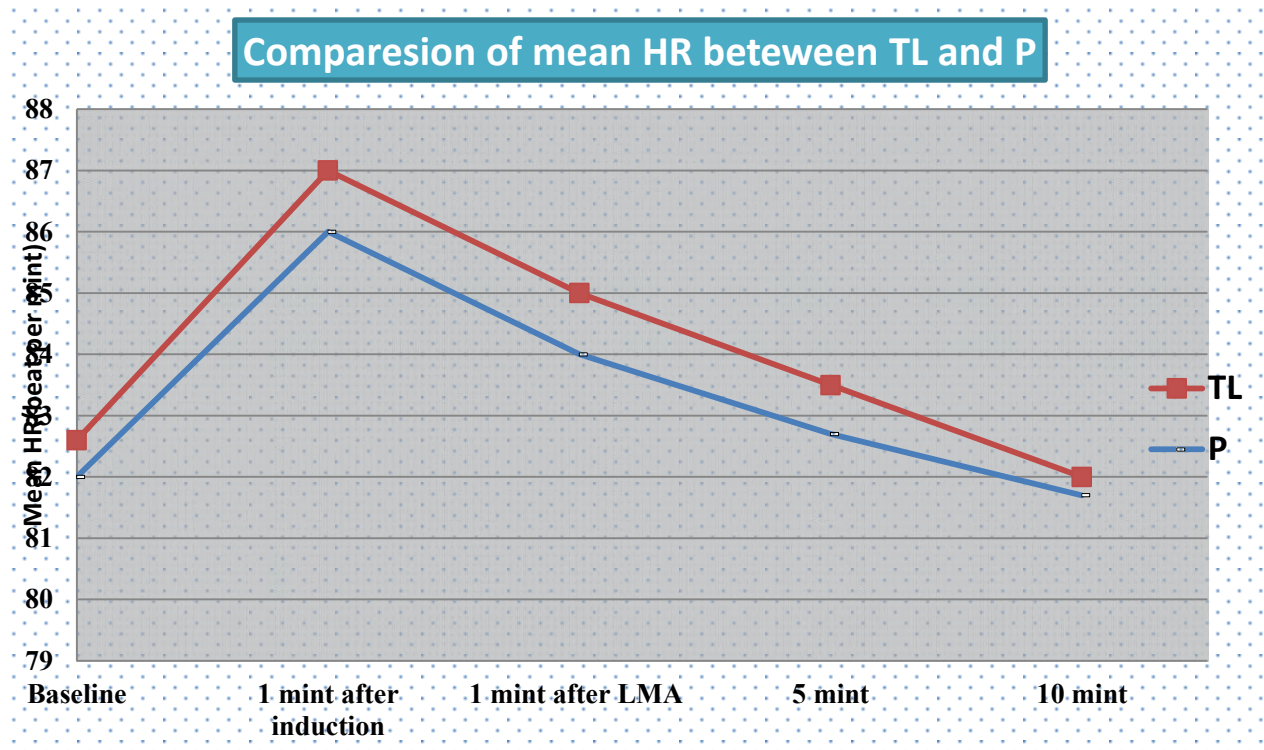


P = propofol group

TL = Thiopentone with 10% Topical lignocaine group

Figure: 3 Showed comparison of observed mean MAP changes during induction of anesthesia and different time after LMA insertion between two (thiopentone with 10% topical lignocaine, n=42 and propofol, n =42) groups

As shown in below figure HR, were taken at different period before, after administrated study drugs and insertion LMA. Comparison of the change of HR between the two groups showed there were no statistically significant differences in mean heart rate. ($P > 0.05$)



P = propofol group

TL = Thiopentone with 10% Topical lignocaine group

Figure: 4 Line graph showed comparison of observed mean heart rate changes during induction of anesthesia and different time after LMA insertion between thiopentone with 10% topical lignocaine (TL) and propofol (P)

5.3 Mean Dose of Drug Consumption and Cost

The requirement of total mean dose of propofol for induction 2.8(mg/kg) and fentanyl 1.2mcg/kg to LMA and thiopentone with 10% lignocaine spray 4.6mg/kg, fentanyl 1.1mcg/kg and 10% topical lignocaine spray 40 mg.

Total cost requires per case used both drug (table 4) for LMA with general anesthesia compare in the TL group was mean of 25 Ethiopia birr and in the P group it was 52 birr.

Table: 3 Comparison of the costs inquired by using thiopentone with 10% topical lignocaine and propofol drugs to LMA insertion.

Prices in Birr(Ethiopia Birr)		
Drug Type	Cost per case(P)	Cost per case (TL)
Mean weight(kg)	42.8	43.3
Fentanyl (100 mcg) (40 Birr)	20.50	19
Propofol (200 mg) (60 Birr)	32.10	
Thiopentone (500 mg) (15 birr)		6
Lignocaine (100 gm.) (350 birr)		0.14
Total cost (per case)	52.6	25.14
Savings		27.46 birr from propofol used

P = propofol group

TL = Thiopentone with 10% Topical lignocaine group

When we compared apnea time between TL group (85± 13.8) with P (138 ±45.8) there was highly statistical significant difference. (P <0.001)

5.4 Patient responses to laryngeal mask insertion

As shown in below table, concerning the responses of the patients to LMA insertion, there were no statically significant different between the two groups on gagging, coughing, mouth opening, laryngospasm and limb movements.

No LMA insertion requires more than two attempts and laryngospasm in both study groups.

Table: 4 Adverse responses of the patients to LMA insertion in each group of patients age above 10 years (thiopentone with 10% topical lignocaine, n=42 and propofol, n =42)

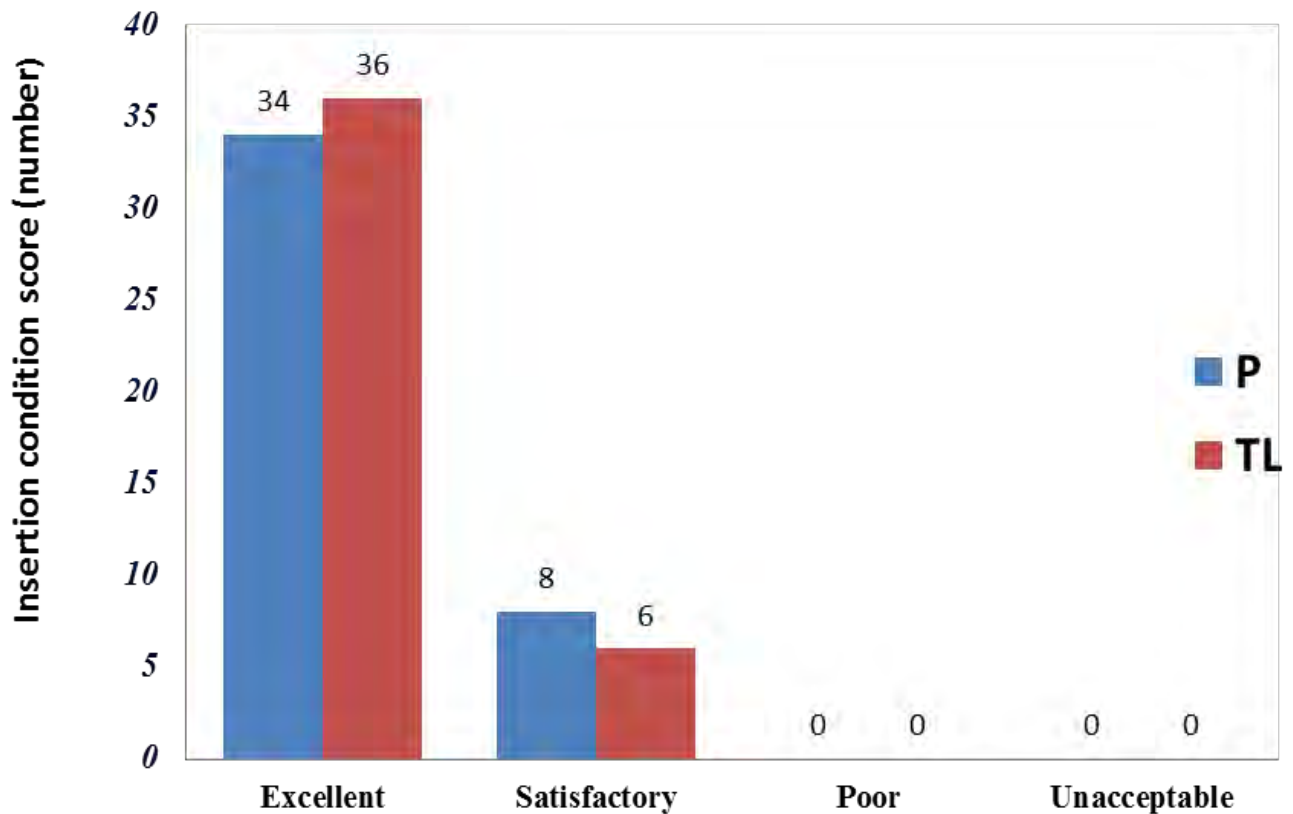
Description	Grades	TL group	P group			P_ value
		Number	Percent	Number	Percent	
Coughing	Nil	39	92.9	39	92.1	1.00
	Mild	3	7.1	3	7.9	
Mouth opening	Full	40	95.2	39	92.9	.747
	Partial	2	4.8	3	7.1	
Laryngospasm	Nil	42	100	42	100	1.00
Limb movements	Nil	38	90.5	36	85.7	0.360
	Mild	4	9.5	6	14.3	
Gagging	Nil	38	90.5	37	88.1	0.616
# of attempts	Mild	4	9.5	5	11.9	0.36
	One	37	88.1	37	88.1	
	Two	5	11.9	5	11.9	

P = propofol group

TL = Thiopentone with 10% Topical lignocaine group

5.5 Distribution of patients according to overall insertion scores

Below figure shows that insertion conditions were excellent in 34 patients (80.9%) in TL group 36 patients (85.7%) in P group which is not statistical significant difference. ($p>0.05$)



P = propofol group

TL = Thiopentone with 10% Topical lignocaine group

Figure: 4 showed a total distribution of patients according to overall insertion scores between (thiopentone with 10% topical lignocaine, n=42 and propofol, n=42)

CHAPTER SIX

6.1 Discussion

In our study showed that addition of 40m 10% topical lignocaine spray with thiopentone on the change of HR following induction of anesthesia and at 1, 5 and 10 min after LMA insertion had no statistically significant difference compare with propofol. ($P > 0.05$) The result was incomparable with prospective randomized trial study done by Sabin Gauchan and colleagues found mean HR were significantly higher in thiopentone group than in propofol group immediately after insertion of LMA, and at 1, 3 and 5 min after LMA insertion. These difference might be due to we use topical lignocaine 10% spray with thiopentone. **(28)**

But a study done by Patrick Scanlon, et al on topical lignocaine and thiopentone for the insertion of LMA comparison with propofol for LMA they found that there was no significant difference in heart rate between the two groups, but the decrease in systolic and diastolic blood pressure was significantly greater in the propofol group ($p < 0.05$). These might be due to almost similar dose we used in our study. **(30)**

Another recent study in Karnataka, 2015 compare topical lignocaine 10% spray with thiopentone and propofol support our result, they observed that there was decrease in MAP following induction of anesthesia and at 1, 5 and 10 min after LMA insertion in both the groups, but decrease was more in propofol group compared to thiopentone group which was statistically significant. Also they show this difference due to cardiovascular depressant effects of propofol may be attributed to direct myocardial depression and decreased systemic vascular resistance. ($p < 0.001$) **(13)**

Our results are consistent with above two consecutive studies regarding to change of MAP there, was decrease in blood pressure after the induction in both the groups. However decrease was more in propofol group mean MAP after 1 mint induction $p < 0.001$, at 1mint $p < 0.01$, at 5 mint, and at 10 min $p < 0.03$ after LMA insertion compared to thiopentone group. This similarity might be due to the same type and relatively similar mean dose of propofol and thiopentone used but we used 10mg sprays of 10% lignocaine more than they used.

Our study is in accordance with the above study there were no statistical significant difference in mean heart rate at various time intervals in both groups (TL and P), because propofol alters the baroreflex mechanism, resulting in a smaller increase in HR for a given decrease in arterial

pressure. Cardiovascular depressant effects of propofol may be attributed to direct myocardial depression and decreased systemic vascular resistance.

With regard to our study on apneic time in seconds, compare between P (138 ±45.8) with TL group (85± 13.8) there was highly statistical significant difference. (P <0.001) Our results are consistent with the study conducted by Patrick Scanlon, et al and colleagues found patients receiving thiopentone and lignocaine had a mean (SD) apneic time of 96.1 (65.4) s and those receiving propofol had a mean (SD) apneic time of 184.9 (102.6) s (p < 0.005). (22)

The apneic time was relatively lower in above study compared to our observation even we used all most the same type and mean dose of drug. This difference might be due to they didn't used neither volatile agents nor nitrous oxide to patients immediately after securing airway, until the patient start spontaneous breathing, however in our observational study immediate securing airway with LMA anesthesia was maintained with halothane which make patient relatively prolong apnea time in both groups.

Our result was also in line with randomized double blind study done by Mohammad Sadiq his colleagues in 2015 shows duration of apnea was more in propofol group (108sec) as compared to thiopentone with lignocaine10% group (74 sec) and difference between two groups was statistically significant and concluded propofol is a potent respiratory depressant. The apneic time were relatively lower in their study compared with our result, this difference might be due to the study participants in their study were mean age was 45 years.

Patrick Scanlon, et al, in 1993, assessed the patient responses to laryngeal mask insertion after induction of anesthesia with propofol 2.5mg/kg or thiopentone 5mg/kg. Thiopentone was associated with an adverse response in 76% of patients compared with 26% in propofol. No patient was judged to be inadequately relaxed in propofol group and this was less than 11%in the thiopentone group. It was concluded that at these doses, propofol was superior to thiopentone as an induction agent for insertion of laryngeal mask airway .Similar results showed by Brown GW, et al significantly higher incidence of coughing and gagging in thiopentone group. He suggested that propofol was more effective at providing satisfactory conditions than the thiopentone for insertion of laryngeal mask.(22,23)

Both studies suggested that thiopentone increases airway irritability because of the relatively greater depressant effect of the drug on the sympathetic than on the parasympathetic reflex arch and it is clear that successful insertion with thiopentone would require either adequate reflex suppression or a deeper plane of anesthesia.

However our results are not in accordance the above two prospective randomized trial study result. We found there was no significant difference among the two groups in insertion condition of the patient,(80.9% vs.85.7%) excellent insertion condition for TL and P groups respectively($p>0.05$). This difference might be related with on we use of 40mg of 10% lidocaine spray prior to thiopentone in our patients was associated with reduce side effects thiopentone by airway reflex suppression.

Supporting our result was done by Kantharaja H E et al in 2015,found excellent insertion score was observed in 35(87.5%) and 34(85%) patients in propofol and thiopentone with local anesthetic spray group respectively. None of the patients had poor insertion score in both the groups. This similarity might be due to the same dose and type drug which was used. (13)

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

The total cost 10% lignocaine (100 g) was 350 Ethiopia Birr .We use 40 mg of 10% lignocaine spray (4 sprays = 0.004ml) per case not mean dose . Therefore 100 g of lignocaine (10ml) used for 250 cases, that means 350 birr divide to 250 cases and we get 0.14 ET Birr per case

The requirement of total mean dose of thiopentone 4.6(mg/kg) and propofol for induction 2.8(mg/k) to LMA to LMA insertion

Propofol (200 mg) (60 Birr) and mean weight of propofol group was 42kg and propofol per kg calculation we used 32 birr per case ($\{60 \text{ Birr}/[2.8\text{mg/kg} \times 42 \text{ kg}]\}$) and assumed we use similar cost to fentanyl in both groups and the same for thiopentone (500 mg) (15 birr) based on above calculation method we get 6 birr per cases.

- Per case cost TL= Thiopentone (6 birr) + lignocaine (0.14 birr) 6.14 Birr
- Per case P= Propofol (32 birr)
- Cost difference per case between groups was almost 26 Birr

Based on situational analysis approximately 592 patients used LMA annually at TASH. Even if propofol is considered necessary for many of these cases e.g., day cases, we feel that thiopentone with 10% topical lignocaine spray combination could be a suitable alternative in those patients and we will save 15392 birr annually.

6.2 Limitation of study

The time from application of 10% lignocaine spray with thiopentone to LMA insertion was shorter than that required to achieve the peak effect of lignocaine spray (about 3min) which might have led us to underestimate the frequency of optimal LMA insertion conditions and hemodynamic stability in the lignocaine spray with thiopentone group.

We didn't include all age groups then modify should need because this data may not applicable to patient's age less than 10 years.

Limited studies in the area around our topic and there is no related topic study on in our country, so lack of lacks of references

Data collected only when MSc Anesthetists implement 10% lignocaine with thiopentone to LMA insertion in TARH, so data collection period extended for two months and waste our time for data collection on TL group participant.

6.3 Strengths of the study

1. Pretest was performed
2. Subjects were homogeneous between two groups
3. We did this research without references was done in related topic in our country, Ethiopia
4. Even though we performed observational cohort study we try to similar in both study groups on the additional drugs fentanyl and Halothane used were similar in both groups

Chapter Seven

Conclusion and Recommendation

7.1 Conclusion

Based on our study we conclude that the frequency of optimal LMA insertion conditions achieved by the combination of thiopentone and 40 mg of 10% topical lignocaine spray comparable alternative to that achieved using propofol ,with better hemodynamic stability and shorter period of apnea and much lesser cost

7.2 Recommendations

Based on the result of our study the following recommendations were forwarded

Even though there is no standard anesthesia induction method has been proposed to guarantee a proper placement of LMA, based on our observation we will suggest that to use thiopentone with 10% topical lignocaine spray as an alternative to propofol with fentanyl for LMA insertion in order to get advantage TL on hemodynamic stabilization and produce short apnea time with less cost to the patient and institutions.

I recommend for the MOH, hospital management stuffs and concerned stake holders to make 10% topical lignocaine spray available to all hospital pharmacies like other anesthesia drugs since it is cost effective and has better hemodynamic stability.

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

Information sheet

Information sheet to get permission for the research

Hello! My name is -----I am one of the members of the research team. This information sheet is prepared to explain the research project that you are asked to join by a group of research investigators. The research team includes four MSc students, one senior advisor anesthetists for data collection from Addis Ababa University.

Name of Principal investigator: - Engdawork Belete (MSc Anesthesia student)

Advisor's name: - Misrak W/Yahonnes (BSc, MSc)

Name of sponsor: - Addis Ababa University

Name of organization: Addis Ababa University, College of Health Science, Department of Anesthesia

This information sheet is prepared by the above mentioned investigator.

Risk

There is no any risk or harm that will face by participating in this research. Any personal information registered in the book will not be copied and transferred to other bodies. Every piece of information will be kept confidentially. No individual information will be transferred.

Benefits

There is no incentive or payment to be gained by taking part in this project. The information collected from this research project will be kept confidential and only accessed the researcher and research assistant only. This research project will be reviewed and approved by ethical committee of the AAU.

Dear participants

The aim of this study is to compare effect of thiopentone with 10% topical lignocaine spray and Propofol on MAP, HR, and insertion response and apnea time for LMA who will give surgery at Tikur Anbessa Specialized Hospital ,Addis Ababa, Ethiopia 2017. You are selected to participate in this study by chance. The purpose of this study is to generate information about which one of the two drugs required among like you or your child during surgery under LMA. In order to achieve the objective of the research, we are requesting your participation.

There are a few questions for you to answer politely and there is no need to put your name on the questionnaire; no individual response will be reported. Your response will be completely confidential. It is your full right to accept or refuse to give answer for questions. However; your honest answer to those questions will help us to assess and understand the effect of two drugs. So; we are requesting you to give honest response and keep participation.

I understood about the advantage of the research and the roles I will have in the research. I have ----
----- to participate in the research.

A. Agree

B. Disagree if Respondent agrees to be interviewed, the interview will be started

Questionnaire Code _____

Date of data collection _____

Name of data collector _____ signature _____

Annex II

Questionnaire

**Addis Ababa University
College of Health Science,
School of Post Graduate Studies
Department Of Anesthesia**

Questionnaire prepared to compare Thiopentone with 10% topical lignocaine spray and Propofol to LMA insertion under general anesthesia in elective patients' age above 10 years at Tikur Anbessa Referral Hospital

Instruction: For each of the following questions, please circle the number of alternative(s) that fit the response or fill the blank space

Questionnaire TL_____

Questionnaire P_____

I. Demographic status of the patient.

1. Age _____
2. Sex _____
3. Weight _____
4. ASA class _____
5. LMA Number _____

II. Drugs used type and dose

1. Fentanyl _____ mg/kg
2. Thiopentone _____ mg/kg
3. Topical lignocaine spray _____ mg
4. Propofol _____ mg/kg
5. Halotane _____ %

III. For Q. No. 2 is additional dose of the drug given?

1. Yes____, if yes ,type and dose of the drug _____
2. No _____

IV. Response to LMA insertion.

- | | | | |
|-----------------------|-------------|---------------|------------------|
| 1. Gagging | a. Nil | b. Slight | c. Gross |
| 2. Coughing | a. Silt | b. Slight | c Gross |
| 3. Number of Attempts | a. One | b. Two | c. > two |
| 4. Patient movement: | a. Nil | b. Slight | c Gross |
| 5. Laryngeal spasm: | a. Nil | b. Incomplete | c. Complete |
| 6. Jaw relaxation | a. Complete | b. Incomplete | c. No relaxation |

V. Qualities of LMA insertion

a) Apnea time _____sec

VI. Mean Arterial Blood Pressure

a) Baseline MAP _____mmHg

b) MAP 1 mint after induction _____mmHg

c) MAP 1 mint after LMA insertion _____mmHg

d) MAP 5 mint after LMA insertion _____mmHg

e) MAP 10 mint after LMA insertion _____mmHg

VII. Heart Rate

a) Baseline HR _____beat per mint

b) HR 1 mint after induction _____beat per mint

c) HR 1 mint after LMA insertion _____beat per mint

d) HR 5 mint after LMA insertion _____beat per mint

e) HR 10 mint after LMA insertion _____beat per mint