ASSESSMENT OF LARYNGEAL MASK AIRWAY INSERTION CONDITIONS, WITH CO-ADMINISTRATION OF THIOPENTONE, FENTANYL AND HALOTHANE

BY: ABULU TESFA

ADVISOR: MERON ABRAR (BSC, MSC)

A RESEARCH PAPER TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY, ANESTHESIA DEPARTMENT FOR THE PARTIAL FULFILLMENT OF MSC DEGREE IN ANESTHESIA.
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ABSTRACT

Background: The laryngeal mask airway (LMA) provides a useful alternative for airway management during spontaneous or controlled ventilation. Because of benefits like, less hemodynamic changes, minimal increase in intraocular pressure after insertion; and a lower incidence of sore throat in adults, the use of LMA as an alternative to tracheal intubation is gaining popularity. So choosing an induction agent that better suppresses the airway reflexes, at usual induction dose, while, inserting LMA remains important.

Objectives: To assess conditions of LMA insertion by the co-administration of Thiopentone, Fentanyl and Halothane in elective patients, scheduled for surgery at Tikur Anbessa Referral Hospital from March16- May 30, 2015.

Methodology: - The study was conducted in TikurAnbessa Referral Hospital March16 - May 30, 2015. The study population was all elective patients, who was scheduled for elective surgery and for whom intubation with laryngeal mask airway was indicated. Institution based cross-sectional study was conducted. The total sample size is 42. Data was collected by observing the patients intubated with LMA under Thiopentone, Fentanyl and Halothane. Data was analyzed by using SPSS version 16. Association factors were checked by using cross-tabulation and chi-square.

Results: - Total number of patients involved in this research was 42. Only patients with ASA classification of class I & II and Mallampati class I &II are involved. The mean age of the patients involved in the research was 18.13 ± 12.26. The mean weight was 41.92 ± 17.78. Concerning the responses of the patients to LMA insertion, 95.2% of the patients have adequate jaw relaxation. 41(97.6%) did not develop laryngeal spasm. In 92.7% of cases LMA was inserted during the first trial. Gagging did not occur in 90.5% of the cases. Coughing did not occur in 95.2% of the cases. No movement is recorded in most of the cases (95.2%). There was no statistically significant change in the MAP and HR of the patients immediately, 5 minute and 10 minute after LMA insertion. Most of the patients (45.2%) start spontaneous breathing within the first 10sec after the combination of the drugs was administered.

Conclusion: - Thiopentone 5.12mg/kg, fentanyl 1.2mcg/kg and halothane 3% mask ventilated with 100% oxygen for 2.7 min is effective for the insertion of LMA in elective patients.
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ACRONYMS

LMA: - Laryngeal mask airway
ETT: - Endotracheal tubes
TARH: - TikurAnbessaReferralHospital
ENT: - Ear, nose, throat
HR: - Heart rate
SAP: - Systolic blood pressure
DAP: - Diastolic blood pressure
MAP: - Mean arterial blood pressure
IV: - Intra venous
CHAPTER ONE
INTRODUCTION

1.1 Background of the study

Inserting endotracheal tube into the trachea has become a routine part of delivering a general anesthesia and to secure airway. However, Laryngoscopy and tracheal intubation are noxious stimuli, which cause a reflex increase in both sympathetic and sympathoadrenal activity that may result in tachycardia, hypertension and dysrhythmias which are not desirable (1).

The laryngeal mask airway (LMA), developed by Dr Archie I. J. Brain in 1983 provides a useful alternative for airway management during spontaneous or controlled ventilation (1). It is relatively non-invasive as compared to endotracheal intubation and causes minimal disturbances in cardiovascular and respiratory system (2). Inflated cuff of LMA provides a low pressure seal over glottic opening and allow positive pressure ventilation (PPV) with inspiratory pressure of 15-20cm of water.

Figure 1: Laryngeal mask airway (LMA)
In comparison to endotracheal intubation, insertion of LMA insertion is associated with less hemodynamic changes, minimal increase in intraocular pressure after insertion; and a lower incidence of sore throat. The low frequency of coughing during emergence may be beneficial to patients following open eye or ENT surgery where excessive straining is potentially harmful. Because of these benefits use of LMA as an alternative to tracheal intubation is gaining popularity (3).

Smooth insertion of LMA requires attenuation of airway reflexes to avoid sequelae such as gagging, coughing, or laryngospasm. These sequelae can be suppressed by use of succinylcholine, but it has the disadvantage of unpleasant muscle pains. Increasing the dose of narcotics at induction is another method but its use is associated with respiratory depression and delayed recovery. Using thiopentone along with lidocaine spray is another very important option but it decreases airway reflex postoperatively. Airway reflex is used for prevention against aspiration and obtunding it during insertion of LMA is not preferred. So choosing an induction agent that better suits LMA insertion at usual induction dose remains an alternative (4).
At the present time, Propofol is accepted as the most frequently administered medication for LMA insertion. Scanlon et al. reported better results of LMA insertion while using propofol (2.5 mg/kg) compared with thiopental (5 mg/kg) (4). However propofol when used for insertion of LMA is associated with significant hemodynamic changes and longer apnea time.

Thiopentone can also be used as induction agent for insertion of LMA. However it is associated with adverse effects like gagging, coughing, patient movement and laryngeal spasm. Nowadays the use of thiopentone for LMA insertion was reduced due to these adverse effects. However it maintains the hemodynamic status of the patients and the apnea time is lower when compared with the propofol. It is also cost effective as propofol is expensive induction agent. To reduce these adverse effects explained above and to gain its advantages, many researchers do a research on a co-administration of thiopentone with other agents but there were no combinations of agents as effective as propofol induction for insertion of LMA. However agents like Halothane and Fentanyl when used were the management for the adverse effects explained above. The combination of these agents with Thiopentone for LMA insertion however is not studied. So the researcher aims to answer the question „is it effective to use the co-administration of Thiopentone, Fentanyl and Halothane for insertion of LMA”?
1.2 Statements of the problem

The choice of securing the airway during General Anesthesia often lies between endotracheal intubation and insertion of the Laryngeal mask airway. Nowadays the use of LMA in elective patient is increasing for this purpose. This is because reasonable success rate is achieved more rapidly with an LMA than with the tracheal intubation, A greater degree of skill is required for tracheal intubation, An LMA is inserted blindly, whereas a tracheal tube is normally inserted under vision, LMA insertion causes less hemodynamic stimulation than laryngoscopy and tracheal intubation do, The LMA has advantages over tracheal intubation at the time of “extubation, coughing is less frequent at LMA than at tracheal tube removal, and adverse hemodynamic effects occur less frequently, The glottic aperture is narrowed after tracheal intubation but not with use of an LMA(18).

Appropriate anesthetic depth along with sufficient muscle relaxation is required to prevent complications such as coughing, struggling, laryngospasm, and patient movement [3]. No induction agent or combination of agents which fulfill all this criteria is still reached at.

At the present time, Propofol is accepted as the most frequently administered medication for LMA insertion. However, it has some unwanted complications such as hypotension, bradycardia, prolonged apnea, pain on injection site, cardiovascular depression and probability of the infection due to its combination. When administered alone for LMA insertion, propofol could be associated with undesirable complications including coughing, gag reflex and laryngeal spasm (11). Bahket al. recommended not using single propofol in LMA insertion [5] which will further exacerbate these complications and they conclude that No propofol dose was completely satisfactory; and most of their cases developed apnea or airway obstruction.

The use of Thiopentone alone has also complications like hypotension, bradycardia, coughing, gag reflex and laryngeal spasm. Halothane alone when used for insertion of laryngeal mask airway has effectiveness of 84% (15). Low dose Fentanyl(1mcg/kg) is also effective for insertion of LMA (25). The co-administration of these agents along with Thiopentone for insertion of LMA is not studied. This combination is cost effective
than when using the frequently used Propofol. In our country some centers use these combinations to gain the advantage of its cost effectiveness although its effectiveness for LMA insertion is not studied. Therefore, this study is aimed to answer effectiveness of LMA insertion when using the co-administration of Thiopentone, Fentanyl and Halothane.

1.3 Significance of the study
A good patient conditions for insertion of LMA has a contribution in order to decrease intraoperative and postoperative morbidity and mortality. Hence the study aims to benefit the following;

➢ This study aims to give answers for the insertion of LMA using the combination of thiopental, fentanyl and halothane which some hospitals in our country were using but its adequacy is not studied.
➢ Further, this study will help to identify and reduce the incidence of hemodynamic changes commonly encountered during insertion of LMA.
➢ For future researchers the study will provide baseline information on the effectiveness of LMA insertion for more detail research going to be done on this area.
CHAPTER TWO
LITERATURE REVIEW

2.1 LMA or ETT?

Several studies were done comparing ETT and LMA for elective patients. Both have their own advantages and disadvantages. Ajuzieogu., A Amucheazi., H Ezike (8) explained on their research on comparison of LMA and ETT in terms of hemodynamic change that, After LMA insertion, the increase in HR, SAP, DAP, and MAP was less. The increases in HR, SAP, DAP and MAP were significantly greater in the ET group compared with the LMA group.

Dadmehr H. on his study in 2010 at Tabriz University of Medical Sciences, Iran, on Comparison of the Effects of Endotracheal Tube and Laryngeal Mask Airway on Immediate Postoperative Complications in Elective Operations, concluded that, There was no significant difference between the two but Cases of nausea, vomiting and sore throat in LMA group were less than ETT group. However, this difference wasn't statistically significant. But cough incidence in ETT group was significantly further than the LMA group (7).

Many studies show that Hemodynamic status of patients done under LMA is by far stable than those patients done under ETT. Comparative study done in Dar-es-salaam, Tanzania, in 2012 by KarimaJowhar Khalid, on comparison of hemodynamic response to LMA insertion and laryngoscopy with ETT in adults undergoing elective shows that, There was an increase in HR, SBP and DBP seen after laryngoscopy and ETT insertion as well as after laryngeal mask insertion. The change in haemodynamic parameters after laryngoscopy and ETT insertion were significantly greater than those elicited by LMA insertion (p<0.0001). The increase took about 5 minutes to return to pre insertion values in the ETT group, while it took about 3 minutes for the same values to return to pre insertion values in the LMA group. It took a significantly shorter time to insert an LMA (12.63 sec) as compared to time taken to insert an ETT (22.76 sec). Insertion of an LMA was rated easy in 84% of the patients while it was rated easy in 60% of the ETT patients (9).
Use of LMA for ophthalmic operations causes less rise in pulse rate (111.24 +/- 9.20 vs 121.16 +/- 19.90), Mean arterial pressure (86.10 +/- 10.60 vs 108.10 +/- 12.60) and intraocular pressure (15.20 +/- 2.10 vs 26.80 +/- 5.25) according to the research done by Qazi Ehsan Ali in 2013, in India. So they conclude that LMA can be used with great safety for patients undergoing ophthalmic surgeries especially if they have any associated risk factors including CVS anomalies, glaucoma or any other arteriovenous malformation including cerebral aneurysm where controlling rise in pulse rate, mean arterial pressure and intraocular pressure is of utmost importance

2.2 Types of induction agents

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. But many study shows that, when adjuvants like inhalational anesthetics, lidocaine spray, IV lidocaine and midazolam are added to thiopentone, it will give equivalent response with insertion of LMA with propofol.

Regarding the scoring of effectivess of LMA insertion many studies are done. according to Study done by Akanksha Dutt, Anjum Khan Joad and Mamta Sharma in India on Induction for classic laryngeal mask airway insertion with low-dose fentanyl, they use three point scale using six variables, to measure effectiveness of LMA insertion (LMA insertion condition). Total score is out of 18. Score of 18 is considered as excellent, score of 16-17 is considered as satisfactory and scores of less than 16 as is considered as poor. Finally they also conclude that, both doses of fentanyl (1 and 2 mcg/kg) provide comparable insertion conditions for LMA. Fentanyl in the lower dose (1mcg/kg) provides a more stable hemodynamic profile.

Concerning the effectiveness of thiopentone for LMA insertion, Scanlon compared equipotent doses of propofol and thiopentone and reported that thiopentone is associated with adverse response in 76% of cases as against 26% for propofol group. Even when used with narcotics (fentanyl), thiopentone was associated with a higher incidence of gagging. Driver on the other hand did not find any significant difference between
alfentanil-propofol and alfentanil-thiopentone induction when midazolam was added to both drug regimes. Requirement for bolus doses for undesirable responses was higher in the thiopentone group. Thiopentone with muscle relaxants, has been found very economical and effective (26,27). To increase this effective with thiopentone without the use of muscle relaxant, some hospitals add inhalational anesthesia. The researcher in this study will assess the effectiveness of this combination.

According to the study done by Luz María Gómez on Security and effectiveness of the laryngeal mask airway in the tonsillectomy and adenoidectomy, The insertion of the flexible laryngeal mask airway to an adequate level of anesthetic depth causes fewer hemodynamic effects than the insertion of the endotracheal tube with a significant statistical difference (p<0.001). The effects of cough, laryngospasm, and bronchospasm or saturation are less frequent in comparison with the endotracheal tube. Of the total number of patients, including those in the clinical trials (31-32-34), laryngospasm occurred in three patients of the 148 comprising the group with laryngeal masks airways versus none of the patients of the 154 in the endotracheal tube group. The difference, nonetheless, was not of statistical significance (p=0.109). they finally conclude that LMA is as effective as endotracheal tube. (24)

Study done by Kumar and his colleagues, in 2012 in India shows that, There was no significant difference between thiopentone and propofol with regard to adverse responses, severity, overall reaction, pulse rate and diastolic blood pressure (p>0.05). The fall in systolic blood pressure was significantly greater with propofol than thiopentone (p<0.01). Finally, they conclude that, when preceded by lidocaine spray, Thiopentone provided equal condition as of propofol for insertion of LMA with more hemodynamic stability (12).

Study done in 2013 on Propofol and Thiopentone as induction agent for insertion of Laryngeal Mask Airway by Gauchan S, shows thirty patients were studied in each group. There were no differences between the groups with respect to sex, weight and age. There was less head movement (10%), and gagging (0%), in the Propofol than in the Thiopentone group (43.4, and 16.7% P <0.05 respectively). Responses to LMA insertion
were graded as mild in 29 patients (96.7%) and only 1 patient (3.3%) had moderate response in propofol group. There was no severe response in this group. In theopentone group, 22 patients (73.3%) had mild response, 6 patients (20%) had moderate response while 2 patients (6.7%) had severe response requiring rescue drug Succinylcholine 25mg for adequate ventilation and oxygenation. This will complications will be decreased by increasing the concentration of inhalational agents. (13).

According to study done by Dr. Nirmala B. Con Ease of Insertion of Laryngeal Mask Airway with Propofol and Thiopentone Sodium, Adverse responses to airway manipulation such as coughing, gagging/ swallowing, laryngospasm and limb movements were graded as absent, mild, moderate and severe. Mild coughing was observed in 4 patient in Thiopentone group, and 2 patients in Propofol group (p=0.31). Mild degree of swallowing/gagging was present in 14 of patients in Propofol group compared to 15 patients in Thiopentone group statistically not significant. Moderate degree of swallowing/gagging was present in 5 patients in Thiopentone group and absent in Propofol group (p< 0.01 significant). Laryngospasm was absent in both the groups (p=0). There were mild patient movements in 1 patient in Propofol group whereas 8 patients had mild movements in Thiopentone group (p<0.01 significant). Jaw relaxation were excellent in both the groups (p=1). There was easy insertion of LMA in 42 patients in Propofol group compared to 39 in Thiopentone group. It was considered difficult in 4 patients in Thiopentone group. However, insertion was possible in all patients. The statistical analysis by Chi square test 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). The overall ease for insertion of LMA in Thiopentone and Fentanyl group was 92% and propofol group was 100% (p< 0.001 significant). However in this study the researcher did not use inhalational agent in both groups. But the researcher will add halothane to the thiopentone so that it will increase the decreased effectiveness of LMA insertion seen in this literature. (14).

Study done by T M Cook, C R Seavell, C M Cox shows that topical 40 mg lidocaine followed by 5 mg-kg -1 thiopentone produced conditions for LMA insertion that were as
good as those with 2.5 mg.kg q propofol. The lidocaine thiopentone group had less haemodynamic depression and a shorter period of apnoea. They also compared the topical lidocaine- thiopentone group with iv lidocaine (at doses of 0.5 or 1.5 mg.kg -I) before thiopentone. The conditions for insertion were poor in both iv groups (poor or unacceptable in 42%) but excellent or good in 87% of the topical group. As in Bapat's study all their patients also received fentanyl 1 mcg.kg - propofol.

They suggest that an acceptable alternative to Batap's technique of fentanyl midazolam-thiopentone is fentanyl-topical lidocaine-thiopentone. This has the advantages of good haemodynamic stability and brief apnoea. As a smaller dose of lidocaine is used the possibility of lidocaine toxicity is low. But topical lidocain obtunds the airway reflex. But airway reflex is needed to avoid the risk of aspiration. When inhalational agent (halothane) instead of topical lidocain as proposed in this study is used, airway reflex may be slightly intact and this avoids the risk of aspiration.

There are also studies done inhalational agents. Study done by Dr. Kajal N. Dedhia1 Dr. Amala Kudal kar, on halothane and sevoflurane for insertion of LMA shows that, with both drugs, conditions for LMA insertion and patient response were found satisfactory. LMA was successfully inserted at the first attempt in 29 patients induced with halothane and 27 patients induced with sevoflurane with adequate jaw relaxation in both the groups. (15)

There are many researches answering when a patient is adequately relaxed for the insertion of LMA. Study done by Sudeep Krishnappa on Optimal anesthetic depth for LMA insertion, answers this question by concluding as Loss of motor response to jaw thrust provides satisfactory LMA insertion conditions (16). Study done by Russell Townsend, at Cairns Base Hospital, Cairns, Australia also tests the hypothesis that the response to jaw thrust is an effective predictor of insertion conditions for the laryngeal mask airway. The LMA was inserted using the standard technique. Insertion conditions were considered optimal if there was no motor or upper airway reflex response to insertion. There was no response to jaw thrust in 86% (137/160) of patients and insertion was optimal in 76% (121/160) of patients. A response to jaw thrust predicted suboptimal
insertion conditions in 74% (17/23) and a lack of response predicted optimal insertion conditions in 84% (115/137). They finally conclude that jaw thrust is a reliable predictor of insertion conditions for the LMA after induction of anesthesia with propofol(17).
CHAPTER THREE
OBJECTIVES

3.1 General objective
To assess the conditions of LMA insertion after the co-administration of Thiopentone, Fentanyl and Halothane in elective patients, scheduled for surgery at Tikur Anbessa Referral Hospital from March 16- May 30, 2015.

3.2 Specific objectives
1. To assess hemodynamic changes seen during LMA insertion using co-administration Thiopentone, Halothane and Fentanyl in elective, patients, scheduled for surgery at Tikur Anbessa Referral Hospital from March 16- May 30, 2015.

2. To identify complications of LMA insertion using co-administration of Thiopentone, Halothane and Fentanyl in elective, patients, scheduled for surgery at Tikur Anbessa Referral Hospital from March 16- April 30, 2015.

3. To assess number apnea time of patients during insertion of LMA when using the co-administration of Thiopentone, Halothane and Fentanyl in elective, patients, scheduled for surgery at Tikur Anbessa Referral Hospital from March 16- May 30, 2015.
CHAPTER FOUR
METHODOLOGY

4.1 Study area

The study was conducted in Tikur Anbessa Referral Hospital. The hospital has 36 fulltime anesthetists and 4 anesthesiologists. It has also 6 operation rooms which are all functional. The operation room in which LMA is done most of the time is the two orthopedic beds. The hospital is choosed because it is the only hospital in Addis Ababa that uses the co-administration of the agents under study during the study time. The combinations of the drug the anesthetists and anesthesiologists uses currently for insertion of LMA in the hospital was Thiopentone, Fentanyl and Halothane or propofol and fentanyl when it is available.

4.2 Study period

The study was conducted from March 16 - May 30, 2015.

4.3 Study design

Institution based cross-sectional study was used. The drugs were given by the decision of the hospital staffs as usual. Dose was as per the standard dose for the specific patients. The researcher was not interfered in either selection of the drug or selection of appropriate dose of the drug. The researcher collected the data on the patients for whom LMA will only be inserted with Thiopentone, Fentanyl and Halothane.

4.4 Population

4.4.1 Source population

All elective patients, who were scheduled for surgery at Tikur Anbessa Referral Hospital

4.4.2 Study population

All elective patients, who were scheduled for surgery and for whom intubation with laryngeal mask airway was indicated and who were induced with the co-administrations of Thiopentone, Fentanyl and Halothane in Tikur Anbessa Referral Hospital.

4.4.3 Inclusion criteria

- ASA class I & II
- Mallampati class I & II
4.4.4 Exclusion criteria

- ASA class III & above
- Mallampati class III & above
- Any risk of difficult intubation
- Obese patients
- Pregnant mothers
- Emergency patients
- Premedication with benzodiazepines
- Alcoholic patients

4.5 Sample size

The proportion of mild response developed (effective LMA insertion) under Thiopentone and fentanyl induction according to research done by Gauchan S was 73%. According situational analysis done, the number of patients intubated with LMA in the last three months in the hospital was 48. Depending on this information, by using single proportion formula, the sample size will be:

\[ n = \frac{(z_{\alpha/2})^2 \times pq}{d^2} = \frac{(1.96)^2 \times 0.73 \times 0.26}{(0.05)^2} = 291 \]

By using correction formula:

\[ n_{\text{final}} = \frac{n}{1 + \frac{n}{N}} = \frac{291}{1 + \frac{291}{48}} = 42 \]

After adding 15% contingency the final sample size was 48

4.6 Sampling technique

Convenience sampling technique was used. During each procedure the data collector will observe the procedure of LMA insertion and condition of the patient. Only patients
expressed under inclusion criteria will be included on the questionnaire. The data will be filled by direct observation of the procedure and readings on the monitoring machines were directly transferred to the prepared questionnaire depending on the time, and the need.

4.7 Study variables

4.7.1 Dependent variable

- Hemodynamic status of the patient
- Apnea time
- Coughing
- Gagging
- Laryngospasm
- Initial jaw relaxation
- Patient movement
- Numbers of attempt to LMA insertion

4.7.2 Independent variables

LMA insertion with the co-administrations of Thiopentone, Halothane and Fentanyl.

4.8 Data collection

After getting ethical clearance and permission from the department and the hospital, data was collected by, trained 6 MSC anesthesia students. Training on important variables of the study, questionnaire, the consent and how to collect the data was given for data collectors. A student who inserts the LMA was not involved in filling the questionnaire. Data was filled on the questionnaire by observing the patient and recording important variables. The monitoring machines were used to record variables like the mean arterial blood pressure, heart rate and oxygen saturation of the patient. The data collectors were converted this information from the monitoring machine to the questionnaire. The variables like gagging, coughing, jaw relaxation, patient movement and laryngeal spasm were observed and recorded on the questionnaire. The anesthesia machine was also used
during the procedure for recording the percentage of Halothane administered and to administer it.

4.9 Data quality assurance

Training was given for data collectors. The questionnaires were checked for its accuracy, clarity and consistency. Any ambiguous or incompleteness was seen, it was corrected. The researcher was supervised the data collectors and checked for the completeness of the data daily. The numbers of patients involved in this research were 48. 4 questionnaires were discarded due to incompleteness and 2 questionnaires were discarded due to inadequate information. Generally 42 questionnaires were analyzed.

4.10 Data entry, analysis and interpretation

All data was collected and properly filled on the prepared format and it was coded. The data was summarized and analyzed by using SPSS version 16. The patients response to LMA insertion were scored depending on the scoring system which has six variables (i.e gagging, coughing, jaw relaxation, patient movement, attempts to LMA insertion and laryngeal spasm) and 3 point scale (25). The mean of the responses were added together to be scored out of 18 depending on the criteria explained on the table below. Associations were checked by using cross tabulation and chi-square. The variable having P-value < 0.05 will be taken as significant. The analyzed, compiled and organized data was compared, discussed and finally conclusion and recommendation was forwarded.

Table 1: Scoring system of patients response to LMA insertion

<table>
<thead>
<tr>
<th>Variables</th>
<th>Scoring</th>
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<tr>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Gagging</td>
<td>nil</td>
</tr>
<tr>
<td>Coughing</td>
<td>nil</td>
</tr>
<tr>
<td>Patient movement</td>
<td>nil</td>
</tr>
<tr>
<td>Jaw relaxation</td>
<td>complete</td>
</tr>
<tr>
<td>Attempts</td>
<td>one</td>
</tr>
<tr>
<td>Laryngeal spasm</td>
<td>nil</td>
</tr>
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Total score of 18 considered as excellent, 16-17 satisfactory and below 16 as poor.
4.11 Ethical Consideration

Before starting data collection for the research, formal letter detailing the topic of the study from the ethical committee of anesthesia department was given for the hospital’s anesthesia department. Informed verbal consent was obtained from the hospital’s anesthesia department. The purposes and the importance of the study were explained and verbal as well as written informed consent was obtained from each patient. Personal identifier information such as name was not recorded in the questionnaire.

4.12 Presentation and dissemination of study finding

The result of the study was presented using tables and figures and data was disseminated to AAU, department of anesthesia and Ethiopian anesthesia association.
4.13 Operational definitions

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


3. Jaw relaxation during insertion of LMA(21)
   a. Complete relaxation: - mouth opened easily and fully.
   b. Incomplete relaxation: - firm manual separation required to open the mouth fully
   c. No: - no relaxation at all.

4. Effective LMA insertion (13), 25: - is when there is response to LMA insertion scoring greater than 16 (excellent or satisfactory), apnea time less than 1 minutes and no significant hemodynamic change.

5. Laryngeal spasm(22)
   a. Complete - when there is laryngeal spasm and no air entry on ventilation.
   b. Incomplete: - when there is laryngeal spasm but there is air entry.

6. Coughing(22)
   a. Slight coughing:- coughing which can occurs immediately after LMA and subside by its self
   b. Gross coughing: - coughing which needs deepening of anesthesia to be relieved.

7. Gagging(22)
   a. Slight gagging: - Gagging which stays for short seconds can relieve on it’s own.
   b. Gross gagging: - Gagging which needs deepening of anesthesia to be relieved.

8. Patient movement(22)
   a. Slight movement: - movement from small muscles which can allow insertion of LMA without additional dose of the drugs.
   b. Gross movement: - movement which cannot be relieved without additional dose of the drugs.
CHAPTER FIVE

RESULTS

Total number of patients involved in this research was 48 and 4 questionnaire were discarded due to incompleteness and 2 questionnaire were discarded due to inadequate information. Generally the results of 42 patients were analyzed and discussed. Only patients with ASA classification of class I & II and Mallampati class I &II are involved. Most of them are males. The mean age of the patients involved in the research was 18.13 ± 12.26. The mean weight was 41.92 ± 17.78.

Table 2: Demographic data of the patients

<table>
<thead>
<tr>
<th></th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number (n)</td>
<td>42</td>
</tr>
<tr>
<td>Age (yr)</td>
<td>18.13 ± 12.26</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>41.92 ± 17.78</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>28</td>
</tr>
<tr>
<td>Female</td>
<td>14</td>
</tr>
<tr>
<td>ASA</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>37</td>
</tr>
<tr>
<td>II</td>
<td>5</td>
</tr>
<tr>
<td>Mallampati</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>6</td>
</tr>
<tr>
<td>II</td>
<td>36</td>
</tr>
</tbody>
</table>

Values are in mean ± SD and number.

Mean dose of theopentone used was 5.12mg/kg, fentanyl 1.2mcg/kg and halothane 3.07%. All patients were ventilated for average of 2.74 minutes with SD of 0.7 with 100% oxygen and Halothane before LMA insertion. Additional dose of Theopentone is used in two cases. No risk drug (suxamethonium) is used to relax the patient.
Table 3: The mean doses of the drugs used.

<table>
<thead>
<tr>
<th>Types of drugs</th>
<th>Mean dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thiopentone(mg/kg)</td>
<td>5.12</td>
</tr>
<tr>
<td>Fentanyl(mcg/kg)</td>
<td>1.24</td>
</tr>
<tr>
<td>Halothane (MAC)</td>
<td>3.07%</td>
</tr>
</tbody>
</table>

Concerning the responses of the patients to LMA insertion, 95.2% of the patients have adequate jaw relaxation. Only 2 of them have incomplete jaw relaxation and no patient has completely rigid jaw. 41(97.6%) did not develop laryngeal spasm. only one patient develop incomplete laryngeal spasm and none of them develops complete laryngeal spasm. In 92.7% of cases LMA was inserted during the first trial and in 3 of the cases it was inserted during the second trial. No more than second trial is done. Slight gagging occurs in 9.5% of the cases and no severe gagging. Gagging did not occur in 90.5% of the cases. Coughing did not occur in 95.2% of the cases. Slight coughing occurs in 4.8% of the cases and no severe coughing is recorded. No movement is recorded in most of the cases (95.2%). slight movement is seen in 4.8% of the cases and there was no gross movement.
Table 4: distributions of responses of patients to insertion of LMA

<table>
<thead>
<tr>
<th>Response</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gagging</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no gagging</td>
<td>38</td>
<td>90.5</td>
</tr>
<tr>
<td>Slight gagging</td>
<td>4</td>
<td>9.5</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>100</td>
</tr>
<tr>
<td><strong>Coughing</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no coughing</td>
<td>40</td>
<td>95.2</td>
</tr>
<tr>
<td>Slight coughing</td>
<td>2</td>
<td>4.8</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>100</td>
</tr>
<tr>
<td><strong>Movement</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>no movement</td>
<td>40</td>
<td>95.2</td>
</tr>
<tr>
<td>Slight movement</td>
<td>2</td>
<td>4.8</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>100</td>
</tr>
<tr>
<td><strong>Jaw relaxation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>complete</td>
<td>40</td>
<td>95.2</td>
</tr>
<tr>
<td>Incomplete</td>
<td>2</td>
<td>4.8</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>100</td>
</tr>
<tr>
<td><strong>Laryngeal spasm</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No laryngeal spasm</td>
<td>41</td>
<td>97.6</td>
</tr>
<tr>
<td>Incomplete laryngeal spasm</td>
<td>1</td>
<td>2.4</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>100</td>
</tr>
<tr>
<td><strong>Attempts to LMA insertion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>One</td>
<td>39</td>
<td>92.9</td>
</tr>
<tr>
<td>Two</td>
<td>3</td>
<td>7.1</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td></td>
</tr>
</tbody>
</table>

The scoring system which has six variable and 3 point scale was used to score the responses out of 18. Total score of 18 considered as excellent, 16-17 satisfactory and below 16 as poor. The mean of the responses was added together to be scored out of 18. The total scoring of the responses was 17.67 and it is satisfactory.
Table 5: scoring of responses of patients to LMA insertion

<table>
<thead>
<tr>
<th>Response</th>
<th>Mean</th>
<th>Std. Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gagging</td>
<td>2.93</td>
<td>.261</td>
</tr>
<tr>
<td>Coughing</td>
<td>2.95</td>
<td>.216</td>
</tr>
<tr>
<td>Attempts</td>
<td>2.93</td>
<td>.261</td>
</tr>
<tr>
<td>Patient movement</td>
<td>2.93</td>
<td>.261</td>
</tr>
<tr>
<td>Jaw relaxation</td>
<td>2.98</td>
<td>.154</td>
</tr>
<tr>
<td>Laryngeal spasm</td>
<td>2.95</td>
<td>.216</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17.67</strong></td>
<td></td>
</tr>
</tbody>
</table>

Regarding hemodynamic status of the patient, the mean of MAP before LMA insertion was 77.29 with SD of 11.528. Immediately after insertion of LMA the mean of MAP reduced to 75.83 ± 10.576. The MAP immediately after LMA, 5 minute and 10 minute after insertion of LMA is almost similar. There was no statistically significant change in the MAP of the patients immediately, 5 minute and 10 minute after LMA insertion from the MAP before LMA insertion with P-value of 0.06, 0.21 and 0.055 respectively.

Figure 3: changes in MAP of patients during LMA insertion
The mean heart rate of the patients before LMA insertion was 95.21 ± 19.65. Immediately after LMA insertion the mean HR increases to 96.9 ± 18.9. 5min after LMA insertion, the mean HR returns back to 94.7 ± 17.752 which is almost similar with the mean HR before insertion of LMA. 10 min after insertion of LMA the mean HR was 95.45. There was no significant change in the heart rate of the patients after LMA insertion with P-value of 0.195, 0.082 and 0.082 (immediately, 5min and 10min after LMA insertion respectively) from the HR before LMA insertion.

**Figure 4**: changes in heart rate of patients during LMA insertion

![Mean HR Graph](image)

Most of the patients (45.2%) start spontaneous breathing within the first 10sec after the combination of the drugs was administered. Apnea generally did not occur in 14 patients (33%). The maximum apnea time recorded is 60sec. There was no association between apnea time and age of the patients with p-value of 0.189 among the studied age groups.

**Figure 5**: line chart showing apnea time of patients after insertion.

![Apnea Time Graph](image)
The size of the LMA is selected depending on the weight of the patients based on the manufacturer’s choices. Depending on this LMA number 2 is used mostly (3/5) for the patients with weight group between 10-19.99. LMA number 2.5 is used mostly (6/9) for the weight between 20-29.99. LMA number 3 was used for (9/11) the weight between 30-49.99. No LMA number five was used generally.

Table 6: the distributions of patient’s weight for the size of LMA

<table>
<thead>
<tr>
<th>Weight in kg</th>
<th>LMA size</th>
<th></th>
<th></th>
<th></th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2</td>
<td>2.5</td>
<td>3</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>10-19.99</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>20-29.99</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>30-49.99</td>
<td>0</td>
<td>2</td>
<td>9</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>50-69.99</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>13</td>
<td>15</td>
</tr>
<tr>
<td>≥70</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>9</td>
<td>11</td>
<td>16</td>
<td>42</td>
</tr>
</tbody>
</table>
CHAPTER SIX
DISCUSSION

1. Patients’ response to LMA insertion

This study shows that, the response of patients to the insertion of LMA is low when using the combinations of Thiopentone 5.12mg, fentanyl 1.24 and halothane 3% provided that the patient is mask ventilated for 2.74min with halothane and 100% oxygen. In most of the patients there was almost no gagging during LMA insertion and there was very low frequency of slight gagging and there was no severe gagging. According to study done by Gauchan.S and his colleagues, the gagging response to LMA insertion when using Theopentone and fentanyl was 16.7%. This figure is high when compared to this study. This is because, the analgesics used in their study was Pethidine which is inferior to Fentanyl (used in this study) in suppressing airway reflexes. In their study, they also mask ventilate patients with halothane for 2 minutes. This duration of mask ventilation was lower when compared to this study (which was for 2.74 minutes). Due to the use of Fentanyl and longer duration of mask ventilation (which will deepen the anesthesia), the response in this study was lower than study done by Gauchan.S and his colleagues. Study done by Dr Nirmala also shows, high figure of gagging in patients who are induced with Theopentone and Fentanyl. However, in his study Dr Nirmala did not use any inhalational agents which are very important agent in relaxing the patient and in deepening the anesthesia to reduce the patient responses to LMA insertion. The result of this study shows, there was low coughing response to LMA insertion and there was no severe coughing. This is almost similar result when compared with the study done by Dr. Nirmala (4/46 cases) and Gauchan S. (2/50). However the figure is slightly low when compared with the study done by G.W. Brown. This is because Brown used 4mg/kg of theopentone which is lower than the dose used in this study (which was 5.12mg/kg). He also did not use inhalational agent.

Most of the patients in this study show no movement after the administration of the combinations of the drugs. There was also no gross movement to LMA insertion. This response is slightly low when compared with the study done by Dr Nirmala in which
there were 8 cases with slight movement out of 50 cases. Thiopentone when used alone cannot completely relax the patients. When inhalational agent is added to it, the combination can relax more than the Thiopentone alone does. Dr Nirmala did not include inhalational agent in his study. Both studies are similar in that there was no gross patient movement.

Jaw relaxation as indicated by lack of response to jaw thrust was almost complete (40/42) in this study. This is because halothane which has muscle relaxing property and together with sevoflurane, inhalational agent of choice for inhalational induction was given for the patients.

Thiopentone when used alone can cause laryngeal spasm. Because it cannot suppress the airway reflex. Fentanyl can suppress the airway reflex. Because of the use of these agents together, most of the patients in this study did not develop laryngeal spasm. There was also no complete laryngeal spasm. This is almost similar with the study done by Gauchan S and Dr. Nirmala.

In most of the cases LMA was inserted during the first attempt. In three of the cases LMA was inserted during the second attempt. In one case already inserted LMA was removed due to the leakage.

In this research additional dose of Thiopentone was used in two patients. According to study done by G. W. Brown (in 1991, on comparison of 2.5mg/kg propofol with 4mg/kg of Thiopentone for insertion of LMA) additional dose of Thiopentone is used in 18 cases out of 40 patients. This is probably; he studied on the 4mg/kg of thiopentone which is low dose. He also did not use inhalational agent as additive to induction agents. Still there may be probability of using additional dose of drugs in addition to the normal dose during LMA insertion because LMA insertion needs deep level of anesthesia. This is true for both thiopentone and Propofol. (5, 28)

The scoring of the responses of patient to insertion of LMA in this research was 17.67 which show the combinations of Thiopentone 5.12mg/kg, Fentanyl 1.2mcg/kg and Halothane 3.07% when the patient is ventilated for 2.7min is effective in obtunding the airway reflex. The scoring system used was taken from the study done by Akanksha Dutt(25) and his colleagues on their research on the use of low dose Fentanyl for LMA insertion.
2. Hemodynamic status of the patients

There was no significant change on hemodynamic status of the patient before insertion of LMA, immediately after insertion of LMA, 5min after insertion of LMA and 10 min after insertion of LMA. According to study done by Yasser Mohamed Amr and his colleagues, on the comparison of 6mg/kg Thiopentone, 7mg kg Thiopentone and 2.5mg/kg of Propofol for supraglottic i-gel insertion, the significant change in hemodynamic status was recorded when 7mg/kg thiopentone and 2.5mg/kg of propofol was used but not when 6mg/kg of Thiopentone was used. In my study the average dose of thiopentone was 5.12mg/kg. It is a lower dose than the dose in which significant decrease in MAP occurred in the study above.

However, study done by Gauchan S and his collagues shows that MAP was significantly decreased at 3, 5 and 10 min after insertion of LMA although there is no significance difference in my study. This difference occurs because, they used diazepam 10mg and 5mg for premedication and diazepam has cardiac depressant and vasodilatation effect which decreases the MAP and increases the HR. Again on study done by Sengupta (29) there is no significant change in MAP in the Thiopentone group but it has in the Propofol group.

The mean HR of the patients in my study did show slight decrement but no significant change immediately after insertion of LMA insertion, 5min and 10min after insertion of LMA from the HR before insertion of LMA . Also study done by Sengupta (29) on Agents for facilitation of laryngeal mask airway insertion shows that there was no significant change in HR of patients in the Thiopentone group in 1,2,3 minutes after LMA insertion. This is almost similar result. Study done by S.Vijaya, Basav Raj Munge, KK. Lakshmi Prasad, and M. Prasad Naidu(30), on Comparison of Propofol and Thiopentone Sodium as Intravenous Induction Agents shows that, there is slight variation in pulse rate pre operatively and post operatively but there is no significant pulse variation.

Generally in this study the use of Thiopentone 5mg/kg, fentanyl 1mcg/kg and halothane 3% ventilated for 2.7minute maintained the hemodynamic status of the patients.
3. Apnea time of the patients.

Most of the patients start spontaneous breathing within the first 10 sec after the combination of the drugs was administered. The maximum apnea time recorded is 60 sec. There was no association between apnea time and age of the patients with p-value of 0.189 among the studied age groups. Apnea did occur in 66% of patients. This is very lower when compared with study done by Sarabjit Kaur and his colleagues on Comparison of Induction Characteristics of Propofol-Lipuro and Etomidate-Lipuro in Cardiac Patients in Non-cardiac Surgery (31) in which apnea occurs in 90% of the cases with propofol and in 66.7% of the patients with etomidate. Another study done in Brazil by Aggarwal S, et al.(32) also shows apnea occurs in 78% of cases done under propofol and 66% of cases done under Etomidate induction. This shows the presence of apnea with propofol is higher than that of Thiopentone in this study and it is almost equivalent with Etomidate.

In summary using Thiopentone 5mg/kg, fentanyl 1mcg/kg and halothane 3% ventilated for 2.7 minute for LMA insertion will result in satisfactory patient response, did not bring significant change to LMA insertion and has apnea time less than 1 minute.

Limitations of the study
While doing the research the following limitations were encountered.

- The use of small sample size because of the lack of adequate time to involve more cases and lack of other hospital who administers the drugs under study for LMA insertion.
- Lack of references which were done in our country.
- Lack of references which were done on the topic with selected research design.
- Lack of time and budget to do comparative study.
Based on the finding of the study the following conclusions were forwarded.

- The adverse responses of patients to LMA insertion like gagging, coughing, patient movement and laryngeal spasm are minimal, the attempt to LMA insertion was reduced and the jaw relaxation was satisfactory.

- The hemodynamic status of patients immediately after LMA insertion, 5 min and 10 min after LMA insertion was also maintained with no significant change when compared with the hemodynamic status before the LMA insertion.

- The apnea time of the patients is also low that it is less than 1 minute.

- The scoring of responses of LMA insertion was satisfactory

Based on the finding of the research the following recommendations were forwarded.

- As this study was crossectional study, I will recommend the researchers and the anesthetists to do a randomized research with large sample size and experimental research on the effectiveness of the co-administration of these agents for LMA insertion.

- For those hospitals and anesthetists that were already using thiopentone for LMA insertion, it is better to make the anesthesia deep by mask ventilating the patient with halothane 3% after giving Fentanyl 1mcg/kg and Thiopentone 5mg/kg.
• I recommend the Ethiopian anesthesia association and ministry of health to prepare standard guideline for LMA insertion and involve the co-administrations of these agents in the guideline.

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I. QUESTIONNAIRE
ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
DEPARTMENT OF ANESTHESIA
Data collection format prepared on LMA insertion under Thiopentone, Fentanyl and Halothane in elective patients at TikurAnbessa referral hospital.

1. Demographic status of the patient.
   a. Age ______
   b. Sex ______
   c. Weight _____
   d. ASA class _____
   e. Mallampati class___
   f. LMA Number____

2. Drugs used
   a. Thiopentone__ Dose____ mg/kg.
   b. Fentanyl___ Dose_____ mg/kg.
   c. Halothane___ Dose_____%

3. For Q. No. 2 above, is additional dose of the drug given?
   a. Yes____
   b. No___

4. For Q. No. 2 above is suxamethonium used?
   a. Yes____
   b. No___

5. For Q. No. 3 above, For how many minutes you mask ventilate with halothane?____

6. Patient response to LMA insertion
   a. Gagging: a. nil b. slight c. gross
   b. Coughing a. nil b. slight c. gross
   c. Attempts a. one b. two c. > two
d. Patient movement:  a. nil       b. slight       c. gross

e. Laryngeal spasm:  a. nil       b. incomplete   c. complete

f. Jaw relaxation    a. complete    b. incomplete   c. no relaxation

7. Qualities of LMA insertion
   a. Time taken to insert LMA
      i. <3min
      ii. >3min
   b. Apnea time ______ sec/min

8. Mean arterial blood pressure of the patient
   a. Before LMA insertion ________________
   b. Immediately after LMA insertion ______
   c. 5min after LMA insertion ______________
   d. 10min after LMA insertion ______________

9. Heart rate of the patient
   a. Before LMA insertion ________________
   b. Immediately after LMA insertion ______
   c. 5min after LMA insertion ______________
   d. 10min after LMA insertion ______________
II. CONSENT PAPER

Name of the student: ____________________________  
Date. ____________________________  Signature ____________________________

III. ASSURANCE OF PRINCIPAL INVESTIGATOR AND APPROVAL OF THE PRIMARY ADVISOR

ASSURANCE OF PRINCIPAL INVESTIGATOR

The undersigned agrees to accept responsibility for the scientific ethical and technical conduct of the research project and for provision of required progress reports as per terms and conditions of the Research Publications Office in effect at the time of Grant is forwarded as the result of this application.

Name of the student: ____________________________
Date. ____________________________  Signature ____________________________

Approval of the primary Advisor
IV. FRAMEWORK OF THE STUDY

- Gagging
- Coughing
- Head movement
- Laryngospasm
- Jaw relaxation

- Responses of the patient to LMA insertion

- Number of attempts of LMA

- Effective insertion of LMA
  - Apnea time after LMA insertion

- Hemodynamic status of the patient
  - MAP
  - Heart rate