ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
DEPARTMENT OF ANESTHESIA

COMPARISON OF LIDOCAINE AND TRAMADOL PRE MEDICATION IN ATTENUATING PROPOFOL INJECTION PAIN IN TIKUR ANBESSA SPECIALIZED HOSPITAL ADDIS ABABA ETHIOPIA.

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A THESIS TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES, SCHOOL OF MEDICINE, DEPARTMENT OF ANESTHESIA FOR THE PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR MASTER OF ANESTHESIA

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Abstract

Background: Propofol is a widely used drug for induction of anesthesia and often causes local pain when administered into a peripheral vein it causes severe, sharp, stinging or burning pain on injection that can be distressing to the patient. Pain on injection induced by Propofol has been found to be reduced by a preceding injection of lidocaine, premedication with an opiate, use of large vein speed of injection of Propofol, speed of carrier intravenous fluid.

Objective: To assess the effectiveness of intravenous lidocaine and Tramadol in reducing the incidence and severity of pain on Propofol injection for adult elective surgical patient in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia.

Methods: Comparative cross sectional study design was employed.

A sample of 156 patients divided in to two groups of 78 each were included in the study patients 18-60 years old who underwent elective operation with general anesthesia induced with Propofol who were premedicated with either lidocaine or Tramadol was included in the study. Patient interview, chart review and pretested structured questionnaires were employed for data collection. Collected data was analyzed using SPSS version 20 window analyses was done by Mann –Whitney U Test and chi square test. P value <0.05 was consider as statistically significant.

Result: The incidence of Propofol injection pain after pretreatments with lidocaine (n=78) was 23.1% and the incidence of Propofol injection pain after pretreatments with tramadol (n=78) was 34.6% with p- value of 0.112. The severity of pain that the median and intrequartile range of NRS score were 0(0-2.25) in lidocaine group and 0(0-3) in tramadol group which was comparable between lidocaine group and tramadol group with no statistically significant difference between two group with (P 0.669)

Conclusion and Recommendation: Lidocaine and tramadol reduced both incidence and severity Propofol injection pain. Anesthetist can use both lidocaine and tramadol as pretreatment for the attenuation of propofol injection pain and further study should be conduct.

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List of Tables and Figures

List of Abbreviations and Acronyms

ASA American Society of Anesthesiologists

BMI Body Mass Index

Bsc Bachelor of Science

DRERC Departmental Research and Ethics Review Committee

FMOH Federal minister of health

GA General Anesthesia

IV intravenous

Msc Master of Science

NRS Numeric rating score

OR Operation Room

RCT Randomized Clinical Trial

SPSS Statistical Package for Social Sciences

TASH Tikur Anbessa Specialized Hospital

TIVA Total Intravenous Technique

Chapter one: Introduction

1.1 Background

Propofol (2, 6-di-isopropyl phenol) introduced clinically in 1977, is an alkyl phenol compound (1). Today's most popular intravenous (IV) anesthetic drug especially for brief cases, day surgery or when laryngeal mask airway is to be used. Propofol can be used in Total Intravenous Technique (TIVA) induction and sedation in critical care units in adults, mechanically ventilated patients, anticonvulsant, an antiemetic (2, 3) and has fast onset, smooth anesthetic induction with rapid recovery (4, 5) and also has possibility of continuous injection (6) with minimal organ toxicity (7).

Even if Propofol is an intravenous ultra-short acting general anesthetic (8) and widely used for induction and maintenance of anesthesia and possesses many characteristics of an ideal anesthetic, it is known to cause severe, sharp, stinging or burning pain on injection that can be distressing to the patient (9). Factors which appear to affect the incidence of pain of Propofol injection are: the site of injection; size of vein; speed of injection; Propofol concentration in aqueous phase; buffering effect of blood (10).

Pain resulting from Propofol injection is distressing to patients and is one of the major draw backs of the drug. The mechanism by which Propofol causes pain on injection is not fully understood (11). The pathophysiology of this pain is attributed till this moment to one and a combination of more than one of 3 proposed mechanisms.

The first mechanism relates the pain to the triggering of the local Kallikerin Kinin cascade which induces venous dilation and hyper permeability, thereby probably promoting contact between free Propofol and free nerve endings within the vascular wall, resulting in pain (3, 11).

The second suggested mechanism was the stimulation of the nociceptive receptors at the free nerve endings located between the intima and the media layers of the venous wall in which a direct and immediate response is transmitted through the A-delta fibers (7,12). The third proposed mechanism relates the pain to the pH and concentration of Propofol (3)

With the decrease in morbid adverse events after surgery, patient satisfaction with perioperative care is assuming more importance. The quality of an anesthetic agent is judged by any recall of

discomfort or pain at the time of induction (13). The best intervention to prevent pain on injection with Propofol is unknown (14). But there are some proposed methods for prevention of Propofol injection pain studied are site of injection (use of large vein), use of non- steroidal anti-inflammatory drugs, premedication with an opiate, speed of injection of Propofol, speed of carrier intravenous fluid, the use of local anesthetic (lidocaine), dilution of Propofol, different temperatures, metoclopramide, glyceryl trinitrate, thiopentone and ketamine. (15, 16, 17) clonidine, cholinesterase inhibitors (18)

Lidocaine is the most commonly used local anesthetic it has a relatively short duration of action which limits its postoperative analgesic effect (19). Pain on injection induced by propofol has been found to be reduced by a preceding injection of lidocaine (21) Lidocaine pretreatment is the most popular method for reducing this pain.

A potential pharmacokinetic interaction between propofol and lidocaine was explored by evaluating plasma levels of propofol at the end of the infusions (21). The exact mechanism by which lidocaine reduces pain on injection of propofol is unknown, but there is a possibility that lidocaine, a local anesthetic, reversibly blocks peripheral nerve pathways through the action on excitable membranes (9).

Tramadol was first manufactured in Germany in 1970 to relieve post-surgical and chronic pains. It is currently the most commonly prescribed opioid in the world its main acting mechanism is the increase in serotonergic neural conduction; therefore, its analgesic effects can be averted by simultaneous administration of a serotonin-receptor antagonist (21).

1.2 Statement of the problem

Pain on injection of Propofol has been reported and is an important limitation of its use and 30% patients have severe pain on injection of Propofol (19, 20). Propofol, a widely used drug for induction, often causes local pain when administered into a peripheral vein. Many patients experience mild to moderate pain or even excruciating pain during Propofol injection (20). This can lead to hemodynamic variations due to pain (21) which a man is always trying to alleviate and conquer since ages (22).

The incidence of pain induced during Propofol injection has been reported to range from 85-100% (1, 10, 23). Pain on injection induced by Propofol has been found to be reduced by a preceding injection of lidocaine (24). Lidocaine pretreatment is the most popular method for reducing this pain. However, the failure rate is between 32% and 48% and thus lidocaine can not entirely control Propofol induced pain (25).

A potential pharmacokinetic interaction between Propofol and lidocaine was explored by evaluating plasma levels of Propofol at the end of the infusions (26). The exact mechanism by which lidocaine reduces pain on injection of Propofol is unknown, but there is a possibility that lidocaine reversibly blocks peripheral nerve pathways through the action on excitable membranes (7).

Tramadol inhibits the action of epinephrine carrier and is a weak agonist for μ receptor; its structure is a methyl-morphine resembling that of codeine and it will only be partially antagonized by naloxone the analgesic effects of Tramadol are mostly independent of its effects on μ receptor (27, 28). It is currently the most commonly prescribed opioid in the world (7).

Tramadol is a centrally-acting drug which is effective in the treatment of moderate to severe pain. According to this action, pretreating the vein with IV Tramadol has proved to be effective in preventing Propofol injection pain in adults and the incidence of Tramadol treated patients was 23% (4).

This study is aimed to compare the effectiveness of intravenous lidocaine and Tramadol in reducing the incidence and severity of pain on Propofol injection.

1.3 Significance of the study

Propofol has become the intravenous drug of choice for many forms of anesthesia, especially when rapid and complete awakening is desired. Indeed, awakening is more rapid and complete with Propofol than with all other drugs used for induction of anesthesia.

However, its use is associated with pain or discomfort on intravenous injection. Propofol pain is one of the most ignored, under diagnosed and untreated medical problems particularly in our setup. The question posed regarding the effect of Lidocaine and Tramadol pretreatment has been studied in developed countries by many investigators over the years.

There is a controversy regarding the treatment of Propofol injection pain. Some have shown Lidocaine pretreatment is superior to that of tramadol (18). Some have shown Tramadol pretreatment is also as effective as lidocaine for prevention of Propofol injection pain (1).

Even though the effect of Lidocaine and Tramadol pretreatment in attenuating Propofol injection pain has been studied in developed countries by many investigators, there is a difference in population as well as hospital setup in TASH and this may results in different out come from the study done before. And there is an individual variability in pain perception, recognition and assessment is affected by social, cultural, cognitive, genetic factor, religious and cultural beliefs about recognition and endurance of pain (29).

In our country as far as the researchers' knowledge and search, there is no similar research done and there has no published evidence on the same topic in the same area. So that, it can be used as a source of information for further researchers and a sole input to the literature.

This study is also helpful for program planners and policy makers so as to devise different strategies which help to improve and select appropriate pre medication in attenuating the pain caused due to Propofol injection.

Chapter two: Literature Review

Propofol nowadays became popular because of its amazing qualities of quick, smooth induction and rapid recovery without any residual effects of anesthesia. Besides, its high safety profile, minimal side-effects, Propofol has almost taken over all the other anesthetic drugs for the induction as well as maintenance of anesthesia and is currently the most popular intravenous anesthetic agent among anesthetists all over the world (2, 3,18). In spite of all these advantages, there are a few factors that have limited the usefulness of this wonderful drug. These include hypotension and pain on its injection. Pain on injection is the most common side effect of Propofol, associated with high recall rates even in the post-operative period (18).

A randomized clinical trial conducted by Canbay.O.et.al in Turkey in 2007 a total of One hundred and fifty ASA I and II patients undergoing general anesthesia were randomly allocated into three groups. Groups I, II, and III were pretreated with 40 mg of lidocaine in saline, 50 mg of intravenous acetaminophen, and 5 ml of saline, respectively. The occlusion was released after 2 min and one-fourth of the total propofol dose was injected into the vein over a period of 5 second. They found that the incidence of pain on injection of propofol in control, intravenous acetaminophen, and lidocaine groups was 64%, 22% and 8%, respectively with (P, 0.05). And the total severity of pain in lidocaine group was mild pain 6% and 2% of moderate pain and has no severe pain (11).

Another Prospective, Randomized, Double-Blind Study conducted by Kaya.S.et.al in Turkey in 2008 aged 18 to 45 years, classified as American Society of Anesthesiologists physical status I or II, who were scheduled to undergo elective surgery under general anesthesia induced with propofol, were randomly assigned to five groups: group one, 2% lidocaine 20 mg in saline in a total volume of 10 mL and no venous occlusion; group two, 2% lidocaine 20 mg in saline in a total volume of 10 mL plus venous occlusion for 15 seconds; group three, 2% lidocaine plus venous occlusion for 30 seconds; group four, 2% lidocaine plus venous occlusion for 60 seconds; and group five, saline 10 mL and no venous occlusion. they found the incidence of pain on propofol injection in patients pretreated with 20 mg lidocaine without venous occultation was 45% as compared with 20 mg lidocaine with venous occultation for 15, 30 and 60 seconds with the incidence of 30%, 35% and 10% respectively (16).

RCT study done by Borazan H. et.al in Turkey in 2012 in 120 patients to Compare the effectivness of Pre- treatment with Tramadol (1 mg/kg) and Propofol-Lidocaine Mixture (180 mg 1% Propofol with 2 ml %1 lidocaine) found the incidence of Propofol injection pain was 35 % (14 of 40) in Tramadol group and 25% (10 of 40) in lidocaine group and they found Pretreatment with Tramadol were equally effective with lidocaine mixture in attenuating pain during iv injection of Propofol and there was no significant difference between these groups ($p>0.05$). This study also found that 14 (35.9 %) in control group, 6 (17.5 %) in Tramadol group and 4 (10 %) patients in lidocaine group had moderate pain with no statistically difference found among groups. Additionally, no patient had an experience of severe pain in Tramadol and lidocaine groups so there was no statistically significance between these two groups with respect to severe pain (12).

A Prospective Randomized Open labeled Placebo Controlled Study conducted in 2011 by Bashir A et al. in India in 120 patients admitted for different elective general surgical procedures found the incidence of pain which was assessed on a four point scale (0=none, 1=mild, 2=moderate, 3=severe) in patients received intravenous Propofol 2mg/kg only, 1% lidocaine 0.5mg/kg, Tramadol 1mg/kg ,normal saline 2ml was 100.0%, 30.0%, 26.7%, and 96.7% respectively. And they found there was significant reduction in incidence of pain in received lidocaine and received Tramadol and both Tramadol and lidocaine reduced the severity of pain, with no patient complaining of severe pain. This study concluded Lidocaine and Tramadol are equally effective in reducing both incidence and severity of pain due to Propofol injection (1)

Another randomized, double-blind, prospective trial study conducted in India by Reyhan Polat, et.al in 2012 a total of 250 patients ASA physical status I and II patients undergoing elective surgery with general anesthesia were randomly allocated into five groups each of 50 patients. Group R received 2 mL (0.02 mg) of remifentanil, Group L received 2mL (40 mg) of lidocaine Group M, 2 mL (10mg) of metoclopramide Group K received 2mL (100 μg/kg) of ketamine and 2 mL of saline. They found that the incidence of pain associated with propofol injection was 62%, 24%, 24% and 42% remifentanil, lidocaine, metoclopramide and ketamine respectively it was seen that pain was reduced significantly in pretreated with lidocaine 2mL (40 mg) and 2 mL (10mg) of metoclopramide given the incidence of pain associated with Propofol injection 24% in both lidocaine and metoclopramide group with p value <0.001 (25).

Another Open label observer blind prospective randomized controlled study was done by Nadkarni M et.al in India 2016 a total 300 patients were randomly assigned into three groups. Group I received 2 ml pre-treatment with 4 mg ondansetronin normal saline, group II received 2 ml pre-treatment with 50 mg tramadol in normal saline, and group III received pre-treatment with 2 ml normal saline. They found that the incidence of pain was 82.2% in the saline group, 13.3% in the tramadol group, and 24.4% in the ondansetronin group. The severity of pain in tramadol group was 12% had mild pain 2% experienced moderate, none had severe pain (P=0.001) (2).

A prospective, randomized double blinded study conducted by Madan HK et.al. in India in 2016 in 100 adult patients belonging to ASA I and II scheduled for elective surgery under general anesthesia with Propofol 2.5 mg/kg at the rate of 0.5 ml/sec as an inducing agent found the incidence of pain on Propofol injection after lidocaine (60 mg) pretreatment and Tramadol 50 mg pre-treatment was 24% with a mean VAS of 0.72 $\pm$ 1.62 and 28% with mean VAS of 0.96 $\pm$ 1.65 respectively (10).

Double blind randomized study was conducted by Ajay Kumar et.al in India in 2017 on hundred and fifty adult female age 18-50 ASA physical status I and II patients were randomly assigned into three groups of 50 each. Group N received 2 mL of 0.9% saline, Group L received 2% lidocaine (40 mg) and Group T received thiopental 0.5 mg/kg. they found that the incidence of pain associated with propofol injection in saline group was 72% (36/50) as compared to 20% (10/50) in lidocaine group and 24% (12/50) in thiopentone group in lidocaine group the incidence of pain associated with Propofol injection 20% and the severity of pain associated with Propofol injection mild pain 14% moderate pain 4% severe pain 2% with ($P < 0.05$) (17).

A prospective randomized double blind study conducted by Zahoor1 I. et.al in India in 2017 in a total of 180 patients belonging to ASA I and II, of either sex, aged between 21 to 50 years under general anesthesia undergoing elective surgery found the incidence of pain in lidocaine group received 2ml of 2% (40mg) was 8.3% of which all patients had mild pain only while in tramadol group received 1mg/kg of Tramadol was 25% of this 18.3% had mild pain, 6.7% had moderate pain and 0% had severe pain. Overall, they found lidocaine showed the best efficacy in attenuating Propofol injection pain. In addition to reducing the incidence of pain, it also reduced its severity, with majority of patients experiencing only mild pain (18).

A randomized clinical trial study conducted by Syed et.al in Pakistan in 2016 in 100 Patients divided in two equal groups of 25 patients: Group A receiving 50 mg of Tramadol intravenously and Propofol at dose of 2 mg/kg, and 25 % of this dose was given at rate of 1 ml/second and Group B was given 2 ml (2%) lidocaine found that pain was present in 14% patients in group A as compared 22%patients in group B. But this study found there was no significant statistical difference between Pretreatment with Tramadol and Lidocaine [P value=0.298] (30).

Another prospective randomized double-blind study was conducted by H. Khouadja et.al in Tunisia in 2014, 180 patients, ASA I or II status, they were randomly assigned to one of the three groups of 60 each. Groups I, II, III were pretreated with 40 mg of lidocaine in saline, 100 mg of paracetamol and 10 ml of saline, respectively. They found that the incidence of pain was 85% in the control group, 21.7% in the lidocaine group and 36.6% in the paracetamol group. The incidence and severity of pain on injection of Propofol in lidocaine groups was 21.7% with mild pain 11.7%, moderate pain 8.3 % and severe pain 1.7% with ($p < 0.05$) (23).

2.2 Hypothesis testing

1. **HO:** there is no statically difference in incidence of pain on Propofol injection after intravenous lidocaine verses Tramadol premedication.

   HA: there is statically difference in incidence of pain on Propofol injection after intravenous lidocaine verses Tramadol premedication.
2. **HO:** there is no statically difference in severity of pain on Propofol injection after intravenous lidocaine and Tramadol premedication.

   HA: there is statically difference in severity of pain on Propofol injection after intravenous lidocaine and Tramadol premedication.

Chapter Three: Objectives

3.1 General objective

To assess the effectiveness of intravenous lidocaine and Tramadol in reducing the incidence and severity of pain on Propofol injection for adult elective surgical patient in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia from February 1, 2018- March 30, 2018.G.C

3.2 Specific objectives

- To compare the incidence of pain on Propofol injection after intravenous lidocaine verses Tramadol premedication.
- To compare the severity of pain on Propofol injection after intravenous lidocaine and Tramadol premedication.

CHAPTER FOUR: METHOD AND MATERIALS

4.1. Study Area and period

The study was conducted Tikur Anbessa specialized hospital which is the largest hospital, multi-specialist tertiary care teaching hospital located in Addis Ababa, Ethiopia, opened since 1972 and in 1998 transferred to school by FMOH since then it became a university teaching hospital. It offers diagnosis and treatment for approximately 370,000-400,000 in a year.

TASH is now the main teaching hospital for clinical and preclinical trainings of most disciplines. It is also an institution where specialized clinical services that are not available in other public or private institutions are rendered to the whole nation. It has about 800 beds, it had about 17 operation theatre and approximately 7000-9000 patents undergo surgery in a year including emergency surgery. More than 900 health professionals in the different specialties dedicated to providing health care services, and the various departments' residents under specialty training in the school of medicine also provide patient care in the hospital from February 1, 2018- March 30, 2018.G.C

4.2. Study design

Comparative cross sectional study design was employed.

4.3. Population

4.3.1. Source Population

The source population were all adults elective surgical patients (18- 60 age) at Tikur Anbessa specialized hospital.

4.3.2. Study Population

The study populations were all adult elective surgical patients who underwent their surgical procedure under general anesthesia induced with Propofol in the study period who fulfilled inclusion criteria.

4.4. Eligibility criteria

4.4.1. Inclusion criteria

All patients scheduled for elective surgery underwent general anesthesia with induction of Propofol either pretreated with lidocaine or tramadol:

- ✓ Age between 18-60 years
- ✓ ASA grade I and II

4.4.2. Exclusion criteria

Patients with the following conditions were excluded:

- ✓ Patients with difficult communication,
- ✓ Premedicated Patients with analgesics
- ✓ Premedicated Patients with sedatives
- ✓ Patients with history of neurological or psychiatric disease.
- ✓ Patient refusal

4.5 Sampling Technique and Sample Size Determination

4.5.1 Sample size determination

The sample size was calculated using Comparison of two proportions with equal sample size formula based on previous study done in India in 2017 (18) which showed that the incidence of Propofol injection pain in tramadol group was 25% and in lidocaine group was 8.3% and using 80% power:

$$n1 = n2 = \frac{[za\sqrt{(1+\frac{1}{r}).\bar{p}\bar{q}}}{(p1-p2)^2} + \frac{z\beta\sqrt{\frac{p1q1}{r}+p2q2\quad}]^2}{(p1-p2)^2}$$

Where;

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

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

p1= the incidence of pain in tramadol group=0.25; **q1**= 1-p1=0.75

p2 = the incidence of pain in lidocaine group= 0.083; **q2**= 0.917

n1=sample for those patients premedicated with tramadol

n2=sample for those patients premedicated with lidocaine

r = allocation ratio of the sample size = n2/n1= 1

$\mathbf{p}^{-}$ (change) = (p1+rp2)/1+r= 0.1665

$\mathbf{cq}^{-}$ (change) = 1- p^{-}=0.8335

$$n1=n2=\frac{[1.96\sqrt{1+\frac{1}{1}.0.1665*0.8335}}{(0.25-0.083)^2}+\frac{0.84\sqrt{\frac{0.25*0.083}{1}+0.083*0.917\quad}]^2}{(0.25-0.083)^2}=\mathbf{78}$$

Therefore; a total of 156 adult elective surgical patients were involved in the study.

4. 5. 2 sampling technique

A study participant was selected using systematic random sampling technique using skip interval from the daily operation in the OR in those patients induced with Propofol and premedicated with lidocaine or tramadol which was used as a sampling frame.

In situational analysis done for one month, seven patients per day or 147 patients per month were undergo surgery induced with Propofol in TASH on average.

Thus, 294 patients were operated per the study period (2 month). The sampling interval; K was determined using the formula: K=N/n; where, n = total sample size, N = population per 2 month. K= 294/156 ≈2

Therefore, the sampling interval was two and the first study participant (random start) was selected using lottery method from the daily operation schedule list. Then, every second cases from the operation schedule were included in the study during the study period.

4.6. Study variables

4.6.1. Dependent Variables

- ✓ Propofol injection pain

4.6.2. Independent Variables

- ✓ Age
- ✓ Sex
- ✓ ASA status
- ✓ dose of Propofol
- ✓ Type of premedication
- ✓ Dose of premedication
- ✓ Concentration of Propofol

4.7. Data Collection

Data was collected using pretested adapted structured questionnaires by two degree anesthetist and supervised by one MSc anesthetist. One day training was given for data collectors on the assessment of pain. After providing training for data collectors, verbal informed consent was taken and data was collected using a structured questionnaire. Socio- demographic data like the patient's age, sex, and ASA physical status, associated coexisting illness was recorded from the chart. The patients were trained on the response of pain using the eleven Point NRS score 0 to 10 in the morning of operation day in the operation room before taking induction agent. After routine monitoring (electrocardiogram, noninvasive blood pressure, and pulse oxmeter) patients were pretreated with 2ml of 2% lidocaine and 1mg/kg tramadol and simultaneously patients were induced with 2.5mg/kg of propofol. Propofol injection pain and severity of pain at induction period was assessed using numeric rating score as per the protocol prescribed Adopted from South African acute pain guideline scores (31). Pain scores were assessed during injection of propofol until the patient asleep. It was based on the patient's complaint.

4.8 Data Processing and Analysis

Data was checked manually for completeness and then coded and entered in to epi info version 7 then transferred to SPSS version 20 computer program for analysis. Descriptive statistics was used to summarize by central tendencies, count, frequency tabulation (frequency and cross-tabulation), tables and figures. The data were cheeked the normality level with different tests (plot, skewness and kurtosis, curve with histogram and normality test using Shapiro-Wilk and Kolmogorov-Smirnov. however, the data was not normally distributed when checked using all tests and plots. Therefore, non-parametric alternative, Mann –Whitney U Test was used to compare the pain severity ,Chi-square (x^2)test was used to analyze the homogenous categorical independent variables and incidence of propofol injection pain between these two groups, but the data was homogeneous as tested by Levene's test of equality of variance. Continuous data was presented as median (IQR) and categorical data was presented by frequencies (percentages), p-value < 0.05 was considered as statistically significant.

4.9. Data Quality Control and Assurance

Data was collected using structured questionnaire prepared in English addressing the objective of the study. Pretest was done on 5% of the sample size at Zewiditu Memorial Hospital. Data collectors and Supervisors were trained on each items included in the study tools, objective, relevant of study, right of respondents. During data collection, regular supervision and follow up was made. Investigator cross checked for completeness and consistency of data on daily basis. Double entry was made on 10% of sample size.

4.10. Dissemination plan

This study on completion could serve as a reference material to researchers, experts and policy makers for intervention. To reach these bodies the completed paper will be submitted to College of Health Sciences, Department of anesthesia. In addition, a copy of this material will be given to TASH, Addis Ababa University student research office, Ethiopian Association of Anesthetists, Ethiopian ministry of health. The result will also be disseminated through publication in peer reviewed local and international journals and through presenting it in related workshops and seminars.

4.11. Operational definitions

Elective Surgery: Scheduled surgeries included non-emergent surgical cases ordered to surgery.

Propofol Injection pain: its pain caused after administration of intravenous Propofol.

Numeric Rating Scale: Is a valid pain intensity assessment tool that involves asking a patient to rate his or her pain from 0-10(11point scale) with the understanding that 0 equal to no pain and 10 equal to the worst possible pain (31).

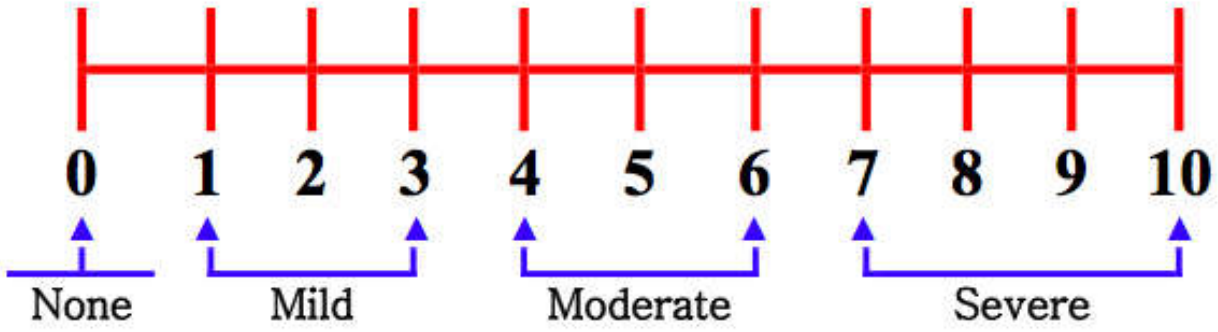

Figure 1 Adopted from South African acute pain guideline

4.12. Ethical Consideration

Prior to the study, ethical clearance was obtained from the Departmental Research and Ethics Review Committee (DRERC) of Department of anesthesia, School of Medicine, college of Health Sciences of Addis Abba University and the acquiescence was also obtained from the study institutions (Tikur Anbessa specialized Hospital). Moreover, full clarification about the purpose of the study was made to the Authorized person of the health facilities. A formal letter of cooperation was obtain from Tikur Anbessa specialized Hospital. The purpose of the study was explained to the patient who included in the study. Verbal consent from the patients was asked and Confidentiality of the information was assured by using code numbers and keeping questionnaires locked.

Chapter five: Result

5.1 Socio-demographic characteristics of study participants

A sample of 156 patients included in this study within the age of 18 – 60 years. 85 participants were female and 71 were male. American society of Anesthesiologists' (ASA) status, 113 patients was ASA I; and 43 patients were ASA II. And with regard to body mass index, 15 patients had a BMI of less than 18.5 kg/m^2, majority of the participants (118) had a BMI of between 18.5-24.9 kg/$m^2$and 23 patients had a BMI of between 25-29.9 kg/m^2(table 1).

Table 1 Socio demographic Characteristic of study participants in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia from February 1, 2018- March 30, 2018.

Variables		Frequency	(%)
Sex	Male	71	(45.5%)
	Female	85	(54.5%)
BMI	<18.5 kg/m^2	15	(9.6%)
	18.5-24.9 kg/m^2	118	(81.4%)
	25-29.9 kg/m^2	23	(9%)
ASA status	ASA I	113	(75.8%)
	ASA II	43	(24.2%)
Age in year		median	Inter quartile
		38	28-50

5.2 Distribution of the study participant in between the group

The study participant was comparable in terms of socio demographic characteristic such as age, sex, and BMI and ASA statues with no stastically significant difference between lidocaine and tramadol group (table 2).

Table 2. Type of pre treatment drugs for prevention of propofol injection pain in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia from February 1, 2018- March 30, 2018

VARIABLE		Lidocaine	Tramadol	P -VALUE
Age in year M(IQR)		37.5(26-50)	39(29-55)	0.148
Sex	Male n (%)	37 (47.4%)	34(43.6%)	0.630
	Female n (%)	41 (52.6%)	44(56.4%)	
BMI	<18.5 kg/m^2 n (%)	9 (11.5%)	6(7.7%)	0.109
	18.5-24.9 kg/m^2 n (%)	62 (79.5%)	56(71.8%)	
	25-29.9 kg/m^2 n (%)	7 (9%)	16(20.5%)	
ASA status	ASA I n (%)	59 (75.6%)	54(69.2%)	0.370
	ASA II n (%)	19 (24.4%)	24 (30.8%)	

Hint M(IQR) =median and intrequartile range, n(%) =number proportion, Mann –Whitney U test and x2 test was used, p-value < 0.05 is significant.

5.3 Type of surgery for propofol Injection

In both groups majority of patients (59.6%) underwent general surgery and there was no statistically significant difference in the type of surgical procedures done between the groups with p-value 0.856 (figure 2).

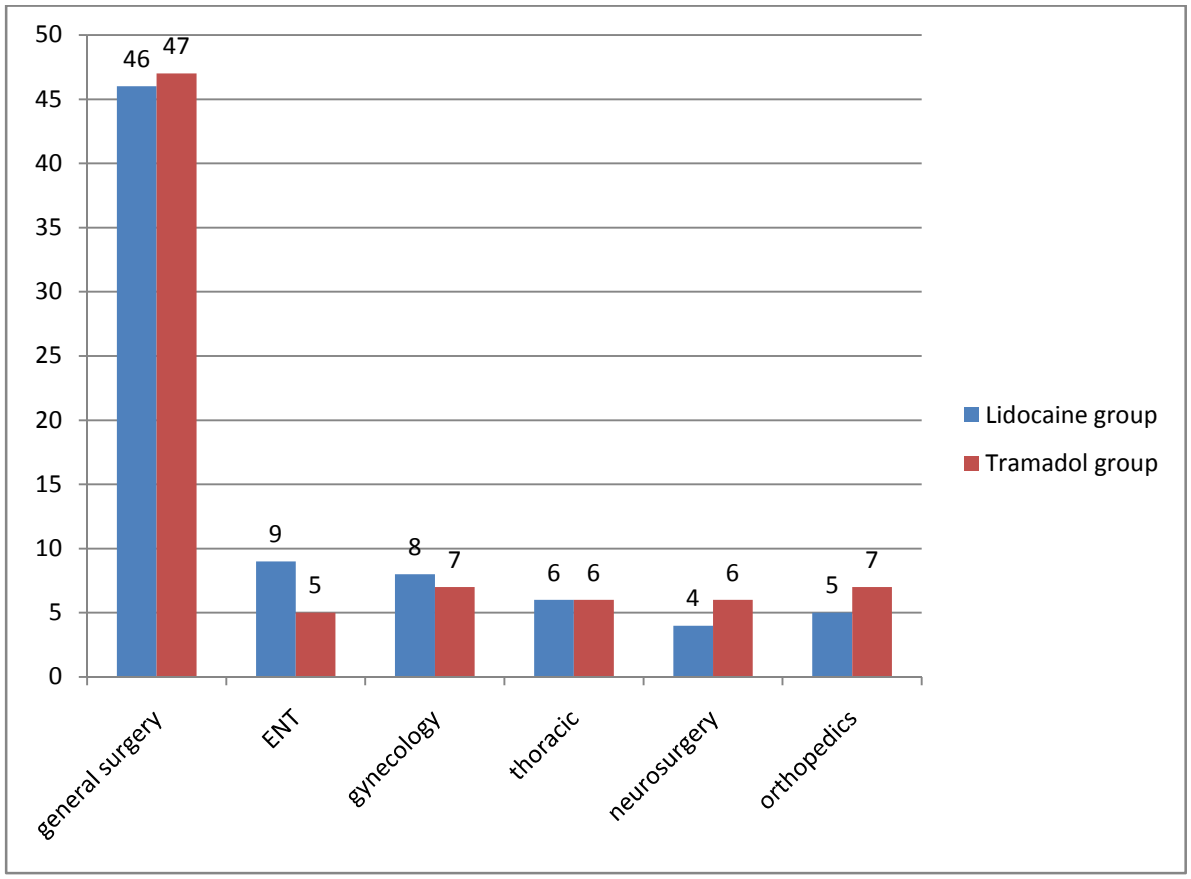

Figure 2: Type of procedures done in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia from February 1, 2018- March 30, 2018

5.4 Incidence of Propofol injection pain

The incidence of Propofol injection pain after pretreatments with lidocaine (n=78) was 23.1% and the incidence of Propofol injection pain after pretreatments with tramadol (n=78) was 34.6% with no statistically significant difference. (p- value 0.112)

The overall total incidence of Propofol injection pain was 28.8% after pretreatments of both lidocaine and tramadol group (n=156). Of this the incidence of Propofol injection pain in lidocaine group was (n=18) 11.5% and tramadol group was (n=27) 17.3%

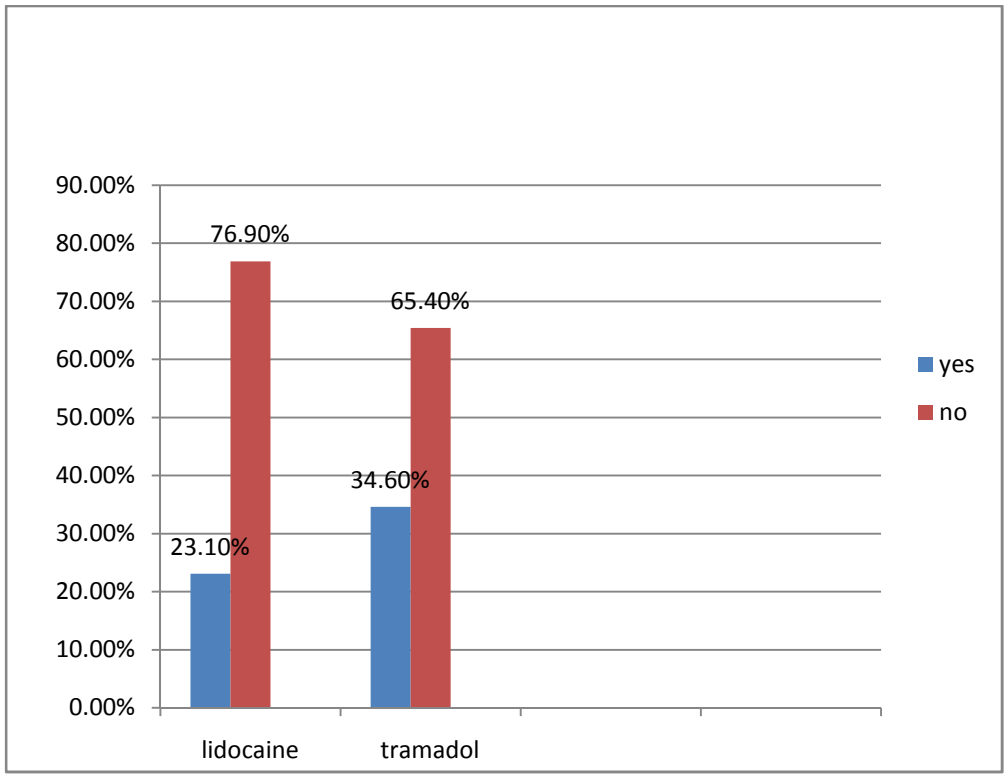

Figure 3 The incidence of Propofol injection pain in lidocaine and tramadol group in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia from February 1, 2018- March 30, 2018

5.5 Severity of Propofol injection pain

The Mann Whitney U test showed that the median and intrequartile range of NRS score were 0(0-2.25) in lidocaine group and 0(0-3) in tramadol group which was comparable between lidocaine group and tramadol group with no statistically significant difference between two group with (P 0.669) (figure 4).

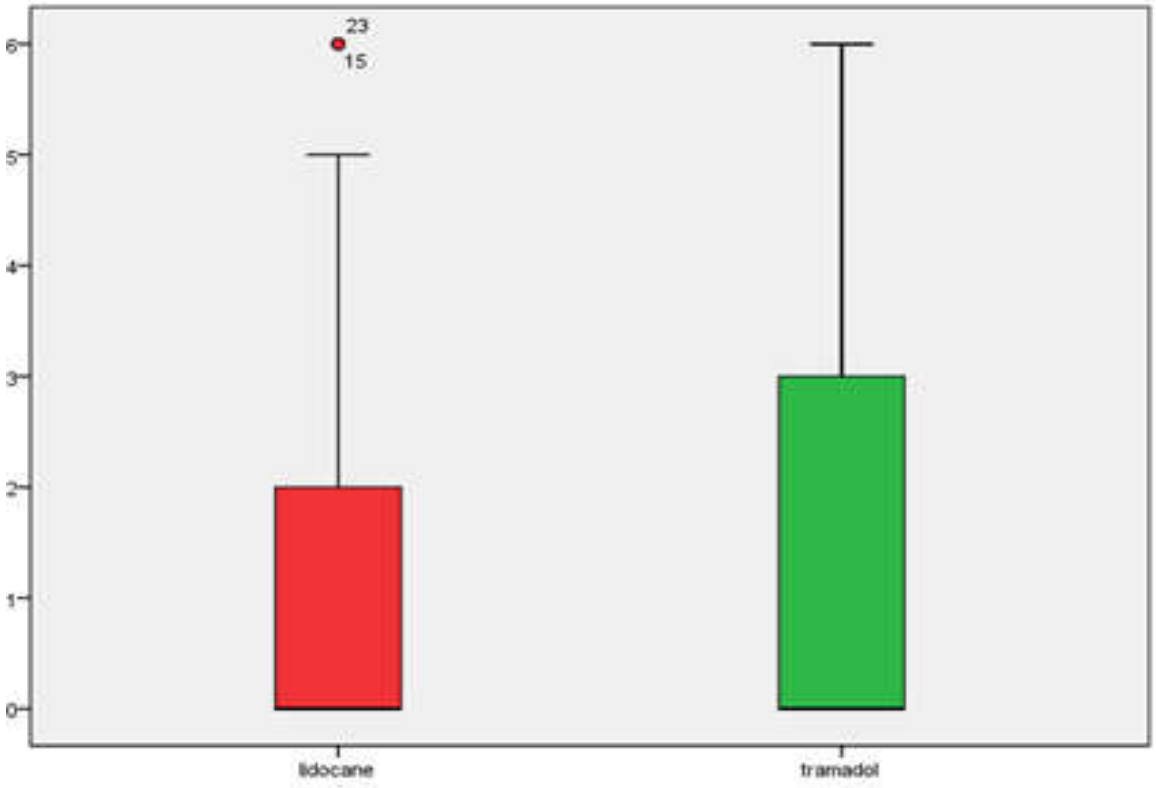

Figure 4 The severity of propofol injection pain measured by NRS in lidocaine and tramadol group in Tikur Anbessa Specialized hospital, Addis Ababa Ethiopia from February 1, 2018-March 30, 2018

Chapter Six: Discussion

Propofol has almost taken over all the other anesthetic drugs for the induction as well as maintenance of anesthesia and is currently the most popular intravenous anesthetic agent of quick, smooth induction and rapid recovery without any residual effects of anesthesia (18). In spite of all these advantages, it can cause pain on injection which is the most common side effect of Propofol and the incidence in most previous studies has been reported from 85-100% (1, 10, 23). To resolve this issue most previous studies have assessed the efficacy of lidocaine and tramadol in reducing the incidence of Propofol induced pain (1, 10,18).

In Our study there was no statistical significant difference in the incidence of Propofol injection pain after pretreatments with lidocaine and tramadol group which was 23.1% and 34.6% respectively (p=0.112) and there was reduction in incidence of pain compared with previous studies reported incidence of propofol injection pain ranging from 85-100% (1, 10, 23).

Our result was in line with a prospective randomized open labeled placebo Controlled Study conducted by Bashir A. et al. found the incidence of pain in patients receiving lidocaine 0.5mg/kg was 26.7% and in patients receiving Tramadol 1mg/kg was 30 % and there was significant reduction in incidence of pain and they concluded that both are equally effective in reducing incidence of propofol induced pain ($p = 0.720$) (1).

Similarly our study is comparable with another study done by Khouadja H. et.al found the incidence of pain in lidocaine group receiving 40 mg was 21.7% with ($p > 0.05$) (23) and it was also similar with study done by Madan. H. et.al. found the incidence of pain in lidocaine group receiving 60 mg and tramadol group receiving 50 mg was 24%and 28% respectively (P-value >0.1) (10).

And the incidence of pain in lidocaine group in our study was comparable with a randomized clinical trial study conducted by Syed et.al found that the incidence of pain in lidocaine group given 40 mg was 22%, but the incidence of pain in tramadol group in our study was higher compared with the incidence of pain in tramadol group receiving 50 mg in Syed et.al study which was 14 % even though there was no statistical significant difference between the groups in their study (P value=0.298) (30). The possible reason might be for applied tourniquet for venous occlusion for 60 seconds.

Our study was inconsistent with a prospective randomized double blind study conducted by Zahoor1 I. et.al found statistically significant difference in the incidence of propofol injection pain in patients receiving 2% of 40mg lidocaine and patients receiving tramadol 1mg/kg which was 8.3% and 25% respectively ($p< 0.05$(18). The possible explanation for inconsistency might be Zahoor1 I. et.al applied tourniquet for venous occlusion for 60 seconds.

In contrast to our study there was lower incidence of propofol injection pain according to research study by Canbay O. et.al found the incidence of propofol injection pain in lidocaine group pretreated with 40 mg of lidocaine in saline was 8% with P value< 0.05 (11). The differences might be due to tourniquet application for venous occlusion for two minutes and titration of propofol.

Our study was also inconsistent with another prospective randomized controlled study done by Nadkarni M. et.al found the incidence of propofol injection pain in patients received pre-treatment with 50 mg tramadol in normal saline with venous occlusion was13.3% compared with control group (P=0.001) (2). The decrement in the incidence and severity of pain in this study probably due to application of tourniquet and venous occlusion for two minute after giving of the pretreatment drugs, intermittent injection and titration of propofol.

In our study the incidence of pain in lidocaine group was lower compared with prospective, randomized, double-blind study conducted by Kaya.S.et.al found the incidence of pain on propofol injection in patients pretreated with 20 mg lidocaine without venous occultation was 45% and there was a statistical significant difference in incidence of pain in this study ($p= 0.05$) (16). The likely explanation for the difference could be due to the lower dose of lidocaine they administered.

In our study there was no statistical significant difference in the severity of Propofol injection pain after pretreatments with lidocaine and tramadol group in which the median and intrequartile range of NRS score were 0(0-2.25) in lidocaine group and 0(0-3) in tramadol group which was comparable between group with(P 0.669)

This result in line with a prospective randomized study conducted by bashir A. et al and Khouadja H. et.al. Found there was no statistical significant difference between lidocaine and tramadol group in severity of propofol injection pain ($p = 0.720,>0.05$) (1) (23).

Our study was inconsistent with a prospective randomized double blind study conducted by Zahoor1 I. et.al found statistically significant result in the severity of propofol injection pain in patients receiving 2% of 40mg lidocaine and patients receiving tramadol 1mg/kg. ($p < 0.05$(18). The possible explanation for inconsistency might be Zahoor1 I. et.al applied tourniquet for venous occlusion for 60 seconds.

In contrast to our study also there was lower severity of propofol injection pain according to research done by Canbay O. et.al in their study on the severity of propofol injection pain found stastically significant difference (P value < 0.05 (11). And our study was also inconsistent with another prospective randomized controlled study done by Nadkarni M. et.al found stastically significant difference 50 mg tramadol in normal saline with venous occlusion compared with control group (P=0.001) (2). The decrement in the incidence and severity of pain in these studies probably due to application of tourniquet and venous occlusion after giving of the pretreatment drugs, intermittent injection and titration of propofol.

In our study the severity of pain in lidocaine group was lower compared with Prospective, Randomized, Double-Blind Study conducted by Kaya.S.et.al in Turkey found the severity of pain on propofol injection in patients pretreated with 20 mg lidocaine without venous occultation (p= 0.05) (16). The likely explanation for the difference could be due to the lower dose of lidocaine they were administered.

6.1 Strength of the Study

To the researchers knowledge this is the first study in our study area that specifically assesses the effectiveness of intravenous lidocaine and Tramadol in reducing the incidence and severity of pain on Propofol injection for adult elective surgical patient; so it can be used as a baseline data for researchers.

6.2. Limitation of the Study

Lack of blind technique for data collectors and do not use of control group.

Chapter seven: Conclusion and Recommendation

7. 1 Conclusion

The result of this study indicated that both lidocaine and tramadol reduced both incidence and severity Propofol injection pain. The choice of agent should be individualized with due consideration to the cost effectiveness and benefit to the patient.

7.2 Recommendation

Based on the finding of the study the following recommendations were drawn.

 Anesthetist can use both lidocaine and tramadol as pretreatment for the attenuation of propofol injection pain.

 Researcher should conduct further research.

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Annexes

Annex: I Assurance of principal investigator

I the undersigned agree 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 principal investigator: Metages Hunie

Date: December, 2017 Signature _____

Name of the advisor: Wosenyeleh Admasu

Date: December, 2017 Signature _____

Annex: II Information sheet

Hello.

My name is _____. I Am a researcher and I have been attending postgraduate program in the field of Anesthesia at Addis Ababa university. I am going to conduct research on the effectiveness of intravenous lidocaine and Tramadol in reducing the incidence and severity of pain on Propofol injection in black lion specialized hospital for all adult elective surgical patients from, December 1- January 30 Addis Ababa Ethiopia, The information going to be obtained will help the government and other responsible bodies to decrease in morbid adverse events after surgery and patent satisfaction. Your participation is very valuable for the success of this project. Also be mindful that whatever we will get here is for research purposes only and the information will not be used by any other person apart from this research and therefore, confidentiality can be guaranteed. However, your names will not be mentioned or be attached to anything that you say.

Do you want to continue yes---------- No---------- (Thank you in advance for your help!)

Name and contact address of investigators

Metages Hunie Email huniemetages@gmail.com Cell phone +251-921782168

Identification card no. ----------

Annex III: Amharic information sheet

አድስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ፣ ህክምና ትምህርት ቤት፣የአንስቴቫርያ ትምህርት ክፍል

የመጠይቅ ፈቃደኛነት ቅጽ

ስሜ _____ ይባላል፡፡እኔ በአዲስ አበባ ዩኒቨርሲቲ በአንስቴዝያ ትምህርት ክፍል የምርምር ቡድን ዉስጥ አንድ አባል ነኝ፡፡የዚህ መጠይቅ አላማ ከኦፕራሲዎን በፊት የአንስቴቫርያ መድሃኒት ፕሮፖፎል መዉሰድን ተከትሎ ስለሚከሰተዉ ኅመም ለመቀነስ ትራማዶል እና ሊዶኬን የተባሉ መድሃኒት በመስጠት እና የህመም መንሴዎች ምርምር/ጥናት /መረጃ ለመሰብሰብ ነው፡፡ እርስዎን አንድ የጥናቱ ክፍል አድርጌ ስመርጠዎ አስፈላጊ የሆኑ መረጃዎችን እንደሚሰጡኝ በማሰብ ነዉ፡፡በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ከእርስዎ የሚገኘው ማንኛውም መረጃ በሚስጥር ይጠበቃል፡፡ለዚህም ሲባል የእርስዎሥምም ሆነ አድራሻ አይገለጽም፡፡ የእርስዎ ፈቃደኛነት ከኦፕራሲዎን በፊት፣የአንስቴቫርያ መድሃኒት ፕሮፖፎል መዉሰድን ተከትሎ ስለሚከሰተዉ ህመም እና መንሴዎች ለሚደረገው ምርምር/ጥናት / በከፍተኛ ሁኔታ ያግዛል፡፡እንድሁም ከጥናቱ በኋላ ኦፕራሲዎን ለሚደረግላቸዉ ታካሚዎች ከኦፕራሲዎን በፊት፣በኦፕራሲዎን ጊዜ ተከትሎ ስለሚከሰት የህመም መጠን መቀነስ ተገቢ የሆኑ እርምጃዎችን ለመዉሰድ ይረዳል፡፡

የቃል ሥምምነት

የዚህ ጥናት ዓላማው ገብቶኝ በጥናቱ ለመሣተፍ

ሀ. ፈቃደኛ ሆኛለሁ ለ. ፈቃደኛ አይደለሁም

በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ቃለመጠይቁን መቀጠል ይቻላል፡፡

ፈቃደኛ ከሆኑ የመጠይቁ መለያ ቁጥር_____መጠይቁ የተካሄደበት ቀን _____

የጠያቂው ሥምና ፊርማ _____

የሱፐርቫይዘር ስምና ፈርማ _____

ጥናቱን በተመለከተ ማንኛዉም አይነት ጥያቄ ካላችሁ የሚከተለዉን አድራሻ ተጠቀሙ::

በዋናነት ምርምሩን የሚያካሂዉ ሰዉ ስም፡ መታገስ ሁኔ

ስ.ቁ.፡ 0921782168 ኢሜል፡ huniemetags@gmail.com

Annex: IV Data collection tool

Date ____/___/____

Structured Check list **Code _____**

Data collection tool (questionnaire) for patient who will have taken general anesthesia induced by Propofol all adult patient at black lion specialized hospital January 2017.

Instructions:

A. Fill the blank space provided.

B. Encircle the alternatives when necessary.

C. Check the questions for completeness.

Part: I Question on socio-demographic characteristics:

1.1. ward _____

1.2. Diagnosis_____

1.3. Patient MRN_____

1.4. Age (in year) _____

1.5. Sex: A. Male

B. Female

1.6. Body weight _____Kg

1.7 Height _____ meter

1.8 BMI _____kg/m^2

1.9 ASA status: A. I B. II

Part II: Question on type of premedication and induction drug, Propofol

2. Which premedication drugs with induction time?

A. lidocaine

B. Tramadol

2.1 premedication _____dose (mg)

2.2 concentration of propofol_____%

2.3 concentration of lidocaine_____%

Part III: Question about Propofol injection pain

3.1. Did the patient feel pain during injection of Propofol?

A. yes

B. No

3.2. If yes, what is severity of this pain as measured by numeric reting scale (NRS) during injection of Propofol?

Appendix I English Version of Numeric Rating Scale (NRS)

The scale was used to assess propofol injection pain patient was asked to rate their pain was assessed and recorded at induction of anesthesia with propofol pretreated with the study drugs The patient was asked one of the following questions:

A. What number on a 0 to 10 scale would you give your pain right now?

B. When the explanation suggested above is not sufficient for the patient, further explanation or conceptualization of the scale will be done:

- 0 = no pain
- 1-3 = mild pain (nagging, annoying, interfering little with ADLS)
- 4–6 = moderate pain (interferes significantly with ADLS)
- 7-10= severe pain (disabling; unable to perform ADLs)

Appendix II አማርኛትርጉምበቁጥርአምሳያመለኪያ (NRS)

በዚህ መለኪያ በሽተኛዉየሚጠየቃቸዉጥያቄዎችአሁንየሚሰማዎትንህመምበየትኛዉቁጥርይወክሉታል;

ሀ) ከዜሮእስከአስርካሉትቁጥሮችአሁንየሚሰማዎትንህመምየትኛዉቁጥርይገልፀዋል.

ለ) ከላይየተሰጠዉማብራሪያበቂሳይሆንሲቀር፣ለበሽተኛዉየበለጠመረጃመስጠትአስፈላጊሆኖይገኛል

- 0- ምንምህመምየለም
- 1-3 - ትንሽህመምአለ
- 4-6 - መካከለኛህመምአለ
- 7-10 - ከባድህመምአለ