



Addis Ababa University

College of health sciences

To Compare the Effectiveness of prophylactic intravenous ketamine 0.5mg/kg and pethidine 0.5mg/kg for postoperative shivering in elective surgical patients under general anesthesia at Tikur Anbessa specialized hospital, Addis Ababa Ethiopia, from January 01 to April 30, 2018: A Prospective observational Cohort study

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Declaration

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.

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Lists of acronym and abbreviations

AAU	Addis Ababa university
ASA	American society of anesthesiologists
BMI	Body mass index
BP	Blood pressure
Bsc	Bachelor of sciences
DBP	Diastolic blood pressure
ECG	Electrocardiography
GA	General Anesthesia
GP	General Practitioner
HR	Heart rate
IV	Intravenous
MAP	Mean Arterial pressure
NE	Nerephinephrine
NMDA	N-methyl-D aspartate
Msc	Masters of sciences
SBP	Systolic blood pressure
TURBT	Transurethral resection of bladder tumor
OR	Operation room
PACU	Post anesthesia care unit
PAS	Post-anesthesia shivering

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Abstract

Background: Post anesthesia shivering is one of the potential complications of anesthesia which may increase patient's morbidity. Nowadays, it has become a common phenomenon with the increasing number of surgeries. Various pharmacological and non-pharmacological methods had been employed to control postoperative shivering. Warming the patient and other alternative methods has been employed over several years, but it was more expensive.

Objectives: to compare the effectiveness of intravenous ketamine 0.5mg/kg and pethidine 0.5 mg/kg for post-operative shivering after general anesthesia at black lion specialized hospital from January 1 to April 30, 2018.

Methods and materials: an observational cohort study was conducted at black lion specialized hospital from January 1 to April 30, 2018. The study involved 76 ASA I and II patients aged 18-65 years, undergoing elective surgery under general anesthesia. The patients in the two groups took either ketamine 0.5mg/kg and pethidine 0.5 mg/kg 20 minutes before completion of the surgery. The incidence and severity of post-operative shivering were compared between the two groups every 10 minutes until one hour postoperatively. Categorical data were analyzed with the Chi-Square test and fisher exact test. Parametric data between groups were analyzed using independent samples t-test and non-parametric data were analyzed with Mann-Whitney U test. A p value of <0.05 was considered as a statistically significant.

Results: The incidence of shivering between the ketamine and pethidine groups in PACU were (28.2%) and (35.9%) respectively ($p=0.467$). Grades of shivering were not significantly different between the two groups ($p=0.893$). Comparison of HR and MAP at different time intervals intraoperatively was found to be comparable between the groups ($p>0.05$). The scores of axillary temperature at different time intervals during intraoperative and postoperative period have shown comparable values.

Conclusion and Recommendation: This study showed that prophylactic low dose IV ketamine reduced postoperative shivering as effectively as pethidine. The study also showed a clinically better outcome in favor of ketamine. We recommend prophylactic low dose IV ketamine 20 minutes before completion of surgery to prevent postoperative shivering.

Key words: ketamine, pethidine, general anesthesia, postoperative shivering, elective surgery

Chapter One: Introduction

1.1 Background of study

Shivering after an operation is a very common problem but varies in severity. It can sometimes cause a great deal of discomfort. A large study in UK showed that despite preventive measures, patients still develop moderate shivering: one in seven patients taking general anesthetics. [1]

Postoperative shivering is a frequent complication of surgery in developing countries and there is no satisfying method to treat it. It is one of the unpleasant complications during recovery from anesthesia manifesting as involuntary oscillatory mechanical movements and can be characterized as clonic movements starting from 5 to 30 minutes after the cessation of general anesthesia. [2, 3] The incidence of shivering varies from 50% to 65% with general anesthesia, while it occurs in 57% and 30% of cases following regional and epidural anesthesia, respectively. [4]

The etiology of PAS is multi-factorial and not completely understood. Patients undergoing surgery were subject to hypothermia due to exposure to cold operating room environments, vasodilation resulting in core to peripheral heat loss, and impairment of normal thermoregulatory mechanisms by anesthetic agents. [5, 6] Core body temperature can decrease as much as 0.5 to 1.5°C during the first hour of anesthesia. Furthermore, it decreases gradually in linear fashion then after 2-3 hours of anesthesia and comes almost to a steady after about 3-4 hours of anesthesia. [7]

Though it is generally accepted that PAS is a normal thermoregulatory response to hypothermia, shivering can also occur in patients who are normothermic. [6, 7] This suggests that mechanisms other than heat loss may play a role in the development of PAS, including pain, inflammation, and the anesthetic agents themselves. [7, 8] It occurs frequently i.e. 40 to 60 % after volatile anesthetics, but still it remains poorly understood. Shivering occurs in approximately 40% of unwarmed patients who are recovering from general anesthesia and in about 50% of patients with a core temperature of 35.5 degree centigrade and in 90% of patients with a core temperature of 34.5 degree centigrade. Normal thermoregulatory shivering remains by far the most common cause of postoperative shivering. Some shivering may not be thermoregulatory, thus making the management of PAS complex. [1, 6] [8, 9]

The risk of shivering was reported to be increased in younger patients and during long operations, no opioid analgesics and core hypothermia. [6]

Apart from the obvious discomfort, post anesthesia shivering is associated with a number of potentially deleterious sequelae. This includes increased oxygen consumption and carbon dioxide production, catecholamine release, increased cardiac output, tachycardia and hypertension, may decrease arterial oxygen saturation, and may be associated with an increased risk of myocardial ischemia, intraocular and intracranial pressure. Furthermore, shivering occasionally impedes monitors such as pulse oximetry and ECG. [10]

Universally many attempts have been made to treat after shivering had occurred rather than to prevent it. Various pharmacological and nonpharmacological methods had been commenced in the past to control shivering that occurs intraoperatively and postoperatively. [11]

Some of nonpharmacological methods usually employed clinically to reduce shivering are covering bare part of the patients' body, using warm IV fluids, and heating machine if available. Also, different pharmacological agents that are believed to have an antishivering property had been used. Although various pharmacological agents have been used to prevent or treat the post-operative shivering, including alfentanil, sufentanil, ketanserin, physostigmine, nefopam, urapidil, doxapram, tramadol, nalbuphine, and pethidine, the ideal drug for this query has not been found.[12, 13]. Among these drugs, pethidine has been shown to be the most effective drug. Nevertheless, some disadvantages including nausea, vomiting, hallucination and respiratory depression have been reported following the use of pethidine. [13]

At a number of levels, N-methyl-d-aspartate (NMDA) receptor antagonists are likely to modulate thermoregulation. Ketamine, NMDA receptor competitive antagonist, has different characteristics such as cerebral vasodilatation, induction of relaxation of bronchial smooth muscle, amnesia, ability to increase intra-cranial pressure, cause transient, and marked increase of blood pressure by sympathetic system stimulation, and analgesia. Ketamine can likely control shivering, as a prophylactic agent. [2, 5, 15]

Different studies have reported different way of controlling shivering following anesthesia. This study therefore compared the effectiveness of ketamine 0.5 mg/kg I.V, one of an IV anesthetics as a way of preventing post anesthetic shivering with 0.5 mg/kg I.V pethidine which is a gold standard drug for shivering control.

1.2 Statement of the problem

It is widely accepted that complications related to surgery and delivery of anesthesia care are inevitable. Post anesthesia shivering is one of the potential complications of anesthesia which may increase patient's morbidity. Nowadays, postoperative shivering has become a common phenomenon with the increasing number of surgeries. [15] In fact, it occurs among 50-65% of patients in the awakening state of general anesthesia and more than 33% of patients under local anesthesia. [5, 16, 17]

Shivering usually initiates in the PACU and following the return of muscle tone and can be distressing to the patient and has been cited as one of the primary causes of discomfort during the postoperative period. [8, 18]

The exact etiology of postoperative shivering is still not fully understood. There are a number of risk factors such as decreased core body temperature, young age, volatile anesthetics, and long surgery duration. It is associated with many adverse events post operatively such as postoperative pain, increased oxygen consumption, postoperative hypoxemia and disturbs monitors. Moreover, it might be associated with increased catecholamine release and a consequent increase in cardiac workload and postoperative hypertension. [10, 18]

Since its etiologies were not fully identified, it was difficult to manage post-operative shivering and no satisfied method had been utilized. Various pharmacological and nonpharmacological methods had been commenced in the past to control shivering that occurs intraoperatively and postoperatively. [11] Non-pharmacological methods to maintain normothermia are effective but may be expensive hence, are not practical in all settings. Pharmacological methods using various drugs have been tried. However, these are associated with adverse events like nausea and vomiting, respiratory depression, bradypnea, and arterial oxygen desaturation. Pethidine was believed to be most effective in controlling shivering that occurs after anesthesia and surgery. [12] Though pethidine is the gold standard used for its management, its use has become limited due to unavailability in most clinical set ups. [21] Thus, as it had been mentioned in many studies, ketamine IV at low dose can provide this purpose. Therefore, this study was aimed at comparing the effectiveness of low dose (0.5mg/kg) ketamine with pethidine 0.5mg/kg as a way of preventing postoperative shivering.

1.3 Justification of the study

Shivering is one of deleterious post anesthetic complication associated with many adverse effects such as postoperative pain which increases analgesic demand, wound dehiscence, graft failure, doubling or tripling of oxygen demand and become potential to hypoxia, increases postoperative protein catabolism, increases intraocular and intracranial pressures.

The effective and ideal method of controlling postoperative shivering was still questionable. Infact, both non pharmacological and pharmacological methods were employed in the past but they had had their own limitations.

Many studies were conducted to compare the antishivering effect of ketamine against various drugs, I.e. pethidine. But they used to compare different doses of either drug. There are controversies concerning effective doses of ketamine to prevent postoperative shivering with fewer side effects. Some literatures recommend small doses of ketamine while others showed small doses are not effective and they recommend large doses for prevention of postoperative shivering. [24, 25, 27] Many scholars in their critical review had tried to discuss about the side effects of pethidine even though it had become a novel drug for many years to control post anesthetic shivering. [22, 23] And it is not easy to find pethidine in most of our clinical set ups. But ketamine is readily available in operation theatre therefore it doesn't need any further prescription or impose any additional cost on the patient. Taking all these side effects into account, it warrants searching for another alternative approach for preventing postoperative shivering without jeopardizing the patients' physiology.

This study was conducted by considering the population of study area is different from others where previous studies carried out using different drugs, susceptibility to hypothermia and average body weight related to dietary habit and economic status.

Furthermore, this study will add quality in an education and clinical practice. The study will also be a baseline for those who conduct a research on similar issues and an indicator for those who are going to implement the result of the project.

Chapter Two: Literature Review

Post anaesthesia shivering (PAS) was first described over fifty years ago with a worldwide incidence of 20-60%. [29] Postoperative shivering incidence in patients recovering from general anesthesia has been estimated to be as high as 50%- 60% before several methods have been taken to maintain intraoperative normothermia in recent years. [30] A large study in UK showed that despite preventive measures, patients still develop moderate shivering: one in seven patients taking general anesthetics. [1]

However, postoperative shivering is also a quite frequent complication of surgery in developing countries lacking enough facilities to maintain normothermia, and the overwhelming majority of cases present with a core temperature $<36^{\circ}\text{C}$. [31] One study conducted in university of Gondar, Ethiopia reported that the overall incidence of postoperative shivering was very high, i.e. 26%. The study identified age, long duration of surgery, low axillary temperature and no opioid analgesia as a major risk factors for PAS. Their study also suggested making a possible intervention to prevent and treat postoperative shivering if focus on patients less than sixty five years old, long duration of anesthesia, and low axillary temperature to reduce the incidence.

Opioid administration is also recommended. [32]

The origin of postoperative shivering is unclear. Several hypotheses have been raised to explain its occurrence. Perioperative hypothermia is the primary cause, which sets in due to anesthetic induced inhibition of thermoregulation; however, the muscular activity may be increased following anesthesia even in nonhypothermic patients. [1, 20] [22, 24]

Both of anesthesia and surgery can cause perioperative hypothermia. General anesthesia inhibits thermoregulation in a dose-dependent manner, and induces vasoconstriction and shivering. Other factors that contribute to a decrease in body temperature during surgery are ambient temperature $<21^{\circ}\text{C}$, administration of unwarmed intravenous fluids, decreased basal metabolic rate, and heat required to humidify inhaled dry gases.[22, 33]

Shivering can be very unpleasant and physiologically stressful for the patients after enjoying the comforts of modern anesthetics. Mild shivering increases oxygen consumption to a level that is produced by light exercise, whereas severe shivering increases metabolic rate and oxygen consumption up to 100-600%. It may induce arterial hypoxemia, lactic acidosis, increased IOP and ICP and interferes with ECG monitoring, pulse rate, blood pressure etc. [20]

While patients find shivering very uncomfortable, it causes artifacts in monitors and increases postoperative pain, heart rate, cardiac output, oxygen consumption by fivefold and metabolic rate by 600%. [8, 12, 34] Vasoconstriction and increased vascular resistance leading to inadequate circulation especially in patients with atherosclerosis and therefore, aggravated cardiac ischemia are other complications following the condition. [35] In a survey on 33 clinical problems, anesthesiologists ranked postoperative shivering 8th when its frequency was considered and 21st when asked about the importance of preventing this complication. [36]

Various strategies such as the use of reflective blankets, cutaneous forced-air warming devices, warm humidified anaesthetic gases and radiant heat are adopted to lower the incidence of the condition. [37] Equipments to maintain normothermia are effective in preventing shivering, but may be expensive and not practical in all settings. [38] Therefore, shivering should ideally be prevented or treated pharmacologically which is the most popular approach in clinical practice. Therefore, many scholars have been trying to overcome this ill effect of postoperative thermal discomfort using various pharmacological agents. The use of drugs such as Nefopam, Tramadol, Physostigmine, Morphine, Fentanyl, and Pethidine are considered as an alternative but effective solution; it, however, is associated with side-effects such as nausea, vomiting and respiratory depression. [11, 39, 40]

Pethidine was thought as a standard antishivering drug. It is a combined μ - and κ -receptor agonist. Although its mechanism of anti-shivering effect has yet to be fully established, it was indicated in a study in which naloxone was used that pethidine may act via the κ -, rather than μ -opioid, receptors. The anti-shivering action of pethidine was inhibited by high-dose naloxone, which blocked both the μ - and κ -receptors, but not by low dose naloxone which only blocked the μ -receptors. [41] Activation of the κ -opioid receptors decreased the shivering threshold twice as much as the vasoconstriction threshold. [42] However, pethidine probably acts directly on the thermoregulatory center and not only through receptor activation. [43] Disadvantages of meperidine: excessive sedation, respiratory depression and postoperative nausea and vomiting, which may be stimulated with previously administered opioids or anesthetics. [24]

Ketamine, a noncompetitive NMDA receptor antagonist, has been shown to inhibit postoperative shivering. Secondary to an inhibition of norepinephrine uptake post ganglionic sympathetic endings, it has been shown that ketamine has the ability to decrease core- to- peripheral

redistribution of heat. Moreover, NMDA receptor antagonists also modulate thermoregulation at multiple levels. In addition to being a noncompetitive NMDA antagonist, it has several other pharmacological properties; i.e. opioid agonist, blocking amine uptake in descending inhibitory monoaminergic pain pathway, having a local anesthetic action and interacting with muscarinic receptor. Therefore, it controls shivering by nonshivering thermogenesis either by acting on hypothalamus or by β -adrenergic effect on norepinephrine.[2, 5][44, 45]

In the study conducted in Turkey Ankara in 2011 by Kose A and colleagues in their prospective randomized double-blind study which involved 150 ASA I and II patients undergoing general anesthesia, the efficacy of ketamine at the doses 0.1, 0.25, and 0.5 mg/kg was evaluated for prophylaxis against postoperative shivering. The result showed that the number of patients shivering 10 minutes after operation and in the recovery room was less in the group which took ketamine 0.5mg/kg and pethidine 25 mg than the group that took ketamine 0.1 and 0.25 mg/kg ($p < 0.001$ and $p=0.001$). They concluded as ketamine 0.5 mg/kg was found to be effective in preventing postoperative shivering and ketamine 0.1 mg/kg and 0.25 mg/kg had less prophylactic effect. Also they suggested that ketamine 0.5 mg/kg and 0.75 mg/kg exhibited the same effect with side effect delirium and hallucination. [2, 5] In their study, three patients still had grade >2 shivering after ketamine prophylaxis and were treated with i.v. pethidine.

In their prospective, randomized double-blind study conducted in 2008 in Turkey Ankara involving 90 ASA I and II patients, Kose A et al. compared the efficacy IV 0.5mg/kg and 0.75mg/kg against pethidine 25 mg IV in controlling postoperative shivering after general anesthesia. Their study also compared body temperature and implied that there is no statistically significant difference in tympanic temperature among the groups ($p=0.587$). Their result showed that Shivering grades for the first 4 min after treatment were lower in the ketamine groups; however, nystagmus and feeling like “walking in space” was experienced with both doses of ketamine. Nystagmus and feeling like walking in the space were experienced more frequently in groups ketamine 0.5 and ketamine 0.75 ($P = 0.001$ and $P = 0.001$, respectively) compared with group pethidine. They reported in conclusion that ketamine 0.5 and 0.75 mg/kg to be effective and more rapid than pethidine 25 mg for the treatment of post anesthetic shivering but some side effects including nystagmus and a feeling like “walking in space” were seen. [2]

In their randomized clinical trial conducted in 2014 in Iran, Mashhad which involved one hundred and thirty-five patients undergoing elective abdominal surgery under general anesthesia,

T.Masoomeh et al compared the effect of IV ketamine and pethidine on postoperative shivering. They compared the incidence and severity of postoperative shivering between the groups. The result showed that the rate of postoperative shivering was significantly less different in the pethidine and Ketamine groups than the Normal Saline group. Shivering was more frequently seen in the normal saline group all the time. However, no significant difference was seen between the pethidine and Ketamine groups ($p=0.15$). [28]

A study to compare 0.5mg/kg ketamine, 3mg gransetron and combination of both was conducted by O. Sagir et al to find out their prophylactic effect in prevention of shivering during regional anesthesia was conducted on 160 ASA I and II patients in which after 15 minutes of giving spinal anesthesia, prophylactic dose of one of drugs was given. Shivering was graded subjectively into four different levels. The difference between groups was found significant. Result clearly concluded that ketamine was more effective in prevention of shivering during spinal anesthesia. [47]

A randomized, double blind placebo, controlled study conducted in India by Dar AM. et al compared ketamine 0.5 mg/kg, pethidine 20 mg and placebo for the efficacy in preventing postoperative shivering after general anesthesia in 90 ASA I and II patients undergoing elective surgery under general anesthesia. In this study, hemodynamic parameters, body temperature and severity of shivering were compared between the groups. The results of this study showed that the number of patients shivering at T0 and subsequently at T10 and T20 was significantly less in Group K and Group P than in Group S ($p\text{-value} < 0.005$). However, they reported no difference between Group P and Group K ($p\text{-value} > 0.005$). Finally they concluded that Ketamine was found to be as effective as pethidine in preventing post anaesthetic shivering without increasing the risk of side-effects. [48]

A prospective, randomized, double-blind controlled trial, conducted in Alexandria University, Egypt, by Ashraf Arafat Abdelhalim which involved 120 ASA I and II patients, undergoing ENT surgery under general anesthesia, evaluated the preventive effects of ondansetron, ketamine or combination of both on post anesthetic shivering. The study compared the efficacy of combination of ondansetron 4mg plus ketamine 0.25 mg/kg (Group OK), ondansetron 8mg (Group O), ketamine 0.5 mg/kg (Group K), and normal saline as the control group (Group C), after giving intravenously 20 minutes before the end of surgery. The result showed that Shivering was observed in 12 patients (40%) in Group C, 3 patients (10%) in group OK, 4

patients (13.3%) in groups O and 3 patients (10%) in group K; however, the difference between group C and all other groups was statistically significant ($P < 0.001$). The number of patients with a shivering grade of 3 was significantly higher in Group C compared with other groups ($P=0.001$). The sedation score was significantly higher in group K than the other groups ($P = 0.021$). The incidence of nausea or vomiting in the ondansetron group (8mg) was 6.7%, which was significantly less compared to other groups ($P = 0.0162$). [49]

In the study conducted in Amman, Jordan in 2005, which involved eighty patients, who undergo elective trans urethral resection of prostate under general anesthesia, Khaldi HA et al compared ketamine 25 mg IV against placebo in prevention of postoperative shivering. They compared postoperative hemodynamic parameters and showed no difference among the groups. They also compared the incidence of severity of shivering and their result showed 64% and 13% of patients from placebo and group Ketamine respectively developed shivering with grade ≥ 2 and treated with pethidine. Their result showed that Ketamine significantly reduced the incidence and severity of post-anesthetic shivering in comparison with placebo, on arrival in the recovery room and at regular intervals postoperatively. [50]

Chapter Three: Objectives

3.1 General objective:

- To compare the effectiveness of ketamine 0.5 mg/kg IV and pethidine 0.5 mg/kg IV for prevention of postoperative shivering in elective surgical patients under general anesthesia at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia from January 1 to April 30, 2017/18.

3.2 Specific objectives:

- To compare the incidence of post-operative shivering between the groups
- To compare the severity of post-operative shivering between the two groups
- To compare hemodynamic changes at 5, 10, 15 and 20 minutes after administration of ketamine or pethidine prophylaxis for post-operative shivering

Chapter Four: Methods and materials

4.1 Study design and period

An institutional based prospective observational cohort study was conducted at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia in operation room and PACU from January 1 to April 30, 2017/18.

4.2 Study area

Addis Ababa is the capital city of Ethiopia with a population of 3,475,952 according to the 2007 population census with annual growth rate of 2.7%. The city has ten administrative sub cities and 99 Kebeles. Addis Ababa has 39 Hospitals (11 public and 28 Non-Governmental Organization (NGO) and private), 29 health centers, 122 health stations, 37 health posts and about 382 modern private clinics.

Tikur Anbessa specialized hospital is located in Addis Ababa; Ethiopia and is a university affiliated biggest teaching and referral hospital in the country. It is located in Lideta subcity, around Ethiopian national theatre. It is bordered in front of Fana broadcasting corporation main building to north and national forensic investigation and emigration directorate office to south. The hospital has about 800 beds and provides a regular service to many subspecialties, i. e surgical services (neurosurgery, general surgery, pediatric surgery, and orthopedic surgeries), intensive care medicine, gynecology and obstetrics, internal medicine and pediatrics. Currently, the hospital has about 13 operation theatre and two recovery rooms.

There are about two hundred specialists, about 400GPs, 40 anesthetists and 20 anesthesiologists, and 10 nurses/PACU nurses.

4.3 Populations

4.3.1 Source population: All patients scheduled to undertake elective surgery under general anesthesia at Tikur Anbessa specialized hospital.

4.3.2 Study population: All patients who underwent elective surgery under general anesthesia and who fulfill the inclusion criteria from January 1 to April 30, 2018.

4.4 Eligibility criteria

4.4.1 Inclusion criteria

All patients scheduled for elective surgery under general anesthesia who gave consent to be involved in the study.

4.4.2 Exclusion criteria

Age <18 and >65 years old

Induction with ketamine

TURBT and endoscopic urologic procedure

Neurosurgical patients

ENT surgery

BMI >30

Body temperature less than 35⁰ c and greater than 38⁰ c

Thyrotoxicosis

Intra operative use of tramadol and dexamethasone

Psychiatric problem

Intra operative Blood transfusion

History of hypertension

Surgery duration more than 3 hours and less than 1 hour

4.5 Sample size and Sampling techniques

4.5.1 Sample size

Sample size for the study was calculated using double population proportion formula for comparison of two proportions based on the following assumptions: significance level 5% ($\alpha=0.05$), power of study ($1 - \beta$) of 80%, from previous study, the effectiveness of pethidine 0.5mg/kg and ketamine 0.5 mg/kg in preventing postoperative shivering was found to be 88.9% and 62.2% respectively [51], thus it's computed as follows:

$$n_1=n_2 = \frac{p_1(1 - p_1) + p_2(1 - p_2) \times (z_\alpha + z_\beta)^2}{(p_1 - p_2)^2}$$
$$= \frac{(0.889)(0.111)+(0.622)(0.378) \times 7.84}{(0.889-0.622)^2} = 37 \text{ per each group. Where,}$$

n_1 = number of clients to take pethidine

n_2 = number of clients to taken ketamine

Z= 95% confidence interval =1.96

F (α , β) = the power function at 80%= 7.84

P1=Efficacy in percentage for pethidine (88.9%), Q1 is 1-P1 (11.1%)

P2= Efficacy in percentage for ketamine (62.2%), Q2 is 1-P2 (37.8%)

By considering a contingency of 5%, the study will involve 39 individuals. Thus, the total sample for both groups will be $39 \times 2 = 78$. Therefore, 78 participants were involved in this study.

4.5.2 Sampling Technique

From situational analysis Tikur Anbessa specialized hospital has provided 400 elective surgical services under general anesthesia in three months duration. Seventy eight patients were involved in the study using systematic random sampling technique. Thus, to obtain every k^{th} patient into the study, $K=400/78 \approx 5$. Therefore, every 5th case selected to participate in the study.

By considering a consecutive patient scheduled to undergo elective surgery under general anesthesia, every 5th patient was selected to be included into the study. The first patient was

selected using lottery method from the first five cases to indicate where to start our sampling. The first selected number was 2 so that case number two was our random start. Then after, every 5th patient from the random start number was included into the study until the desired sample size reached. Thus, we selected as case number 2, 7, 12... and so on until we get desired sample size.



Figure 1: a study flowchart for enrolment of patients undergoing elective surgery under GA in Tikur Anbessa specialized Hospital from January 1 to April 30 2017/18.

Patient management in Tikur Anbessa specialized hospital was routine hospital practice. The professionals involved in the management were Bsc anesthetists, Msc anesthetists and anesthesiologists. As routine practice patient came for surgery were assessed for being candidate for anesthesia and surgery. Then premedicate with the respective medication and anesthetic induction accordingly with the induction agent and muscle relaxants available. Intraoperatively anesthetic maintenance was also as routine practice with available medications. About 20 minutes to complete surgery, either ketamine 0.5 mg/kg or pethidine 0.5 mg/kg given as shivering prophylaxis. At the end of operation, patient took reversal for neuromuscular blockade and tracheal extubation take place. The patients then transferred to PACU to monitor for full recovery from anesthesia.

4.5.3 Method and procedure of Data collection

Data collectors were trained before data collection and supervised by a principal investigator. Two MSc candidates and two trained senior BSc anesthetists were involved for data collection process. Data was collected by using questionnaire and checklist prepared in English. Observation was used as a method of data collection. Data collectors observe for occurrence of post-operative shivering in PACU and record in the respective grade. They also measure and record post-operative body temperature for one hour in PACU.

4.6 Study Variables

4.6.1 Dependent variables

- Incidence of post-operative Shivering
- Severity of post-operative shivering
- Intraoperative hemodynamic parameters

4.6.2 Independent variables

- Sociodemographic characteristics (age, sex, weight, height, BMI, ASA)
- Preoperative Body temperature
- Baseline hemodynamic parameters
- Type of surgery

Duration of surgery

Blood loss

Fluid intake

Exposure variables- Ketamine and pethidine prophylaxis

4.7 Data quality assurance

To assure the quality of the data, data collectors were trained and supervisor had made a regular supervision and follow up. In addition, regular checkup for completeness and consistency of the data was made on daily basis. After the data had been collected and checked for completeness, consistency and accuracy, it was sorted, categorized and summarized.

4.8 Operational definitions

ASA I-A normal healthy patient

ASA II-A patient with mild systemic disease

Elective surgery- procedures which is done in program according to schedule

General anesthesia-a complete state of unconsciousness, muscle relaxation and analgesia

Hypertension- consistently elevated systolic blood pressure above 160 and diastolic pressure above 110.

Hypothermia- a core body temperature less than 35⁰c

Intracranial pressure-a pressure within a cranial vault

Intra ocular pressure-a pressure within the eye ball or globe.

Intraoperative- an event or time when a surgery is going on

Ketamine- an intravenous anesthetic agent

Myocardial ischemia- a state of decreased blood supply to the heart

Normothermia- the range of normal body temperature

Pethidine- a synthetic opioid that used for analgesic purpose

Post anesthetic shivering- shivering occurring within one hour after cessation of anesthesia

Postoperative- the time of event until one hour after surgery has been complete

Tachycardia- heart rate greater than 100

Volatile anesthetics- anesthetics that are administered to the patient as anesthetic vapour.

Shivering grade using a four-point scale [51].

Grade 0: no shivering,

Grade 1: piloerection or peripheral vasoconstriction but no visible shivering,

Grade 2: muscular activity in only one muscle group,

Grade 3: muscular activity in more than one muscle group but not generalized and

Grade 4: shivering involving the whole body or generalized shivering

4.9 Data processing and analysis

The collected data was entered into Epi info version 7 and exported to Statistical Package for the Social Sciences (SPSS) version 20 computer program for analysis after it is cleaned and coded.

Descriptive statistics were used to summarize data, tables and figures to display results.

Shapiro wilks and Levene's test for equality of variances were used to check normality of data and homogeneity of variances respectively. For statistical analysis, student independent t-test statistics and Mann-Whitney U test were used for quantitative data that was distributed normally and nonnormally respectively. Chi square test and fisher exact test (when appropriate) were used to compare difference in categorical data. P value less than 0.05 was considered as a statistically significant.

4.10 Ethical consideration

Before data collection, Ethical clearance and approval was obtained from Addis Ababa university ethical Review Board (REC, Research Ethics Committee,). Official support letter has been written to the selected Hospital and permission for data collection was obtained from the

hospital authorities. The purposes and the importance of the study were explained and verbal informed consent was obtained from each participant. There was no coercion and or no incentives for participating in the study. Confidentiality was maintained at all levels of the study by using nameless questionnaire and locking the questionnaires securely. In addition, all the responses were kept confidential and used only for the purpose of the study.

4.11 Dissemination plan of the results

The copy of the results of the study will be disseminated to concerned bodies:

Addis Ababa University, college of health sciences, department of anesthesia as part of Msc thesis, Federal Ministry of Health, Ethiopian Association of Anesthetists (EAA), and Johns Hopkins Program for International Education in Gynecology and Obstetrics (JHPIEGO).

Chapter Five: Results

Seventy six ASA I and II patients completed the study, grouped into two; 38 patients in each group to compare the effectiveness of low dose ketamine and pethidine as a way of preventing post-operative shivering.

5.1 Sociodemographic characteristics

The distribution of demographic characteristics (age, sex, height, weight, BMI) and operative values like ASA were compared between ketamine and pethidine groups. The result showed us no significant difference between the two groups. [Table I]

Table I: Demographic characteristics and operative values of elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital, Addis Ababa Ethiopia, from January 1-to- April 30, 2017/18.

	Ketamine group (n=38)	Pethidine group (n=38)	P value
Age	42.95±11.82	41.74±12.49	0.663
Gender(M/F)	20/19	21/18	0.821
Height	166.15±5.52	167.36±5.80	0.350
Weight	62.23±8.31	64.26±5.48	0.208
BMI	22.47±2.36	23.02±1.17	0.196
ASA(I/II)	24/15	21/18	0.492

ASA and gender analyzed using chi-square test. Others analyzed using independent t-test. The values are presented as mean±SD, gender and ASA presented in numbers, SD: standard deviation.

5.2 Intraoperative parameters

Haemodynamic parameters (heart rate and mean arterial pressure) and body temperature were measured and recorded continuously at different time intervals during intraoperative period.

Heart rate and MAP of the participant was recorded during intraoperative period. It was recorded before a study drugs, 5 minutes after giving study drugs, 10 minutes after giving a study drugs, 15 minutes after giving a study drugs and 20 minutes after giving a study drugs. There was no statistically significant difference between the two groups in this regard. [Table II].

Table II: Intraoperative Heart rate and MAP of elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital, Addis Ababa Ethiopia, from January 1-to-April30, 2017/18.

Variable		Ketamine group (n=38)	Pethidine group (n=38)	P value
Heart rate (BPM)	Baseline heart rate	87(7)	84(13)	0.551
	Before study drugs given	83.18±8.26	84.10±6.70	0.590
	5 minutes after drugs given	84(8)	83(9)	0.984
	10 minutes after drugs given	82.23±7.66	82.72±4.23	0.729
	15 minutes after drugs given	81.67±7.54	80.31±7.65	0.432
	20 minutes after drugs given	82.05±4.08	81.26±5.81	0.487
Mean arterial pressure	Baseline MAP	96(13)	98(10)	0.117
	Before study drugs given	86.87±2.90	87.49±3.80	0.391
	5 minutes after drugs given	88.33±4.79	88.69±8.31	0.816
	10 minutes after drugs given	88.62±2.33	89.41±4.36	0.319
	15 minutes after study drugs	88.87±4.73	89.67±2.87	0.372
	20 minutes after drugs given	90.79±3.60	89.90±3.61	0.276

Independent t-tests and Mann Whitney U test. the values were expressed as mean±SD. And median (interquartile range), SD: standard deviation, BPM; beat per minute

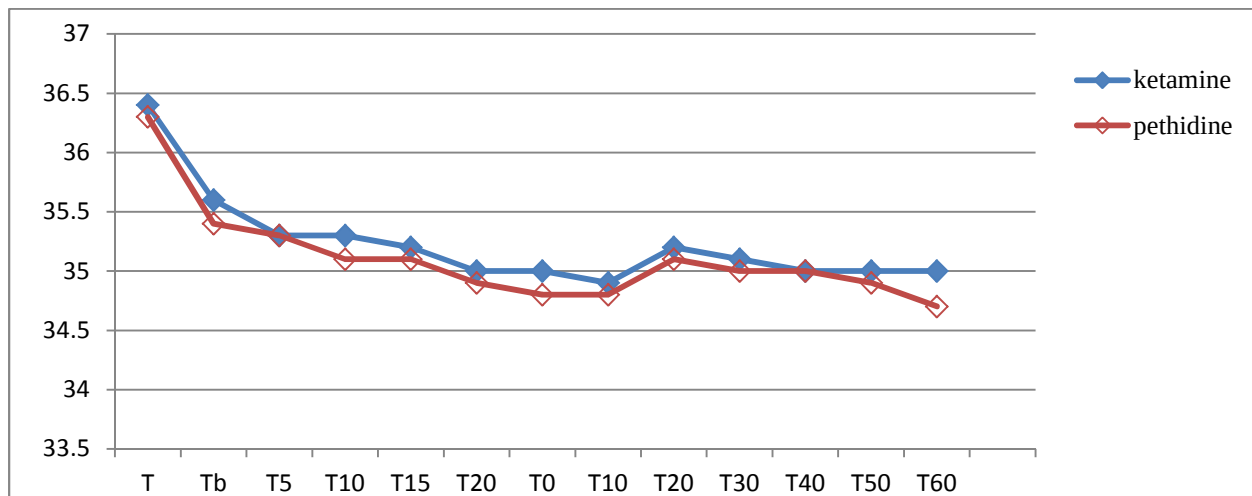
Body temperature was measured and recorded at different time intervals intraoperatively and postoperatively. The recorded value was compared between ketamine and pethidine group. The two groups were comparable except temperature at one hour post operatively. [Table III).

Table III: Perioperative Body Temperature of elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital, Addis Ababa Ethiopia, from January 1-to-April 30, 2017/18.

Variables		Ketamine group	Pethidine group		
		(n=38)	(n=38)	P value	
Body temperature (°c)	Operation	Baseline	36.32±0.26	36.27±0.27	0.332
		Before the study drugs given	35.58±0.49	35.41±0.54	0.143
		5 minutes after the drugs given	35.33±0.53	35.26±0.46	0.571
		10 minutes after drugs given	35.27±0.50	35.10±0.56	0.160
		15 minutes after drugs given	35.18±0.58	35.09±0.36	0.452
		20 minutes after drugs given	34.99±0.37	34.90±0.39	0.288
	PACU	T0	35.09±0.56	34.9±0.45	0.106
		T10	34.93±0.53	34.74±0.48	0.101
		T20	35.16±0.41	35.07±0.26	0.295
		T30	35.14±0.33	35.04±0.23	0.129
		T40	34.98±0.42	35.01±0.36	0.752
		T50	35.00±0.24	34.89±0.32	0.810
		T60	35.01±0.51	34.71±0.48	0.007

Independent t-test. The Values are expressed as mean±SD.

Perioperative axillary temperature record was shown in the line graph below.



T: baseline body temperature, Tb: temperature before study drugs given, T5: temperature at 5 minutes after study drugs given, T10: temperature 10 minutes after drugs given, T15: temperature at 15 minutes after drugs given, T20: temperature at 20 minutes after drugs given, T0: temperature at immediate arrival into recovery room, T10: temperature at 10 minutes after arrival, T20: temperature at 20 minutes in PACU, T30: temperature 30 minutes in PACU, T40: temperature at 40 minutes in PACU, T50: temperature at 50 minutes in PACU, T60: temperature at 60 minutes in the PACU. PACU: post anesthesia care unit

Figure 2: change in axillary temperature in intraoperative and postoperative period in elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital from January 1 to April 30, 2018

5.3 Intraoperative exposure variables

Type and duration of surgery, amount of blood loss and total fluid given were all compared between the groups. The two groups did not showed a significant difference with this regard. [Table IV]

Table IV: Intraoperative exposure variables in elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital from January 1-to-April 30, 2017/18.

variables	Ketamine (n=38)	Pethidine(n=38)	P value
Type of surgery			
Abdominal	14	12	0.932
Gynecologic	10	11	
Orthopaedic	10	11	
Urologic	5	4	
Duration of surgery(minute)	124.51±24.27	130.25±30.45	0.360
blood loss(ml)	343.33±93.51	327.95±109.1	0.506
Total fluid given(ml)	2425.64±619.73	2450±672.68	0.868

Types of surgery analyzed by Chi-square and others by independent t-test. Type of surgery presented as numbers, others in mean±SD.

5.4 Incidence and severity of shivering

Patients were observed for shivering in post anesthesia care unit for one hour. The occurrence of shivering and the time to develop shivering were compared between two groups. There was no statistical difference regarding this with p values greater than 0.05. [Table V]

Table V: The number of shivering patients and time to develop shivering in the elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital from January 1 -to-April 30, 2017/18.

Variable	Ketamine (n=38)	Pethidine(n=38)	P value
Shivering			
Yes	11(28.2%)	14(35.9%)	0.467
No	28(71.8%)	25(64.1%)	
Time to shiver(minutes)			
0 /10/20/30/40/50/60	4/3/4/0/0/0	6/5/3/0/0/0	0.774*
Severity of post-operative shivering			
Grade 1/2/3/4	7/3/1/0	9/3/2/0	0.874*

*The values are presented as numbers (percentages), chi square test, *-fisher exact test.*

The incidence of post-operative shivering between the two groups was 28.2% and 35.9% in ketamine and pethidine groups respectively as shown below.

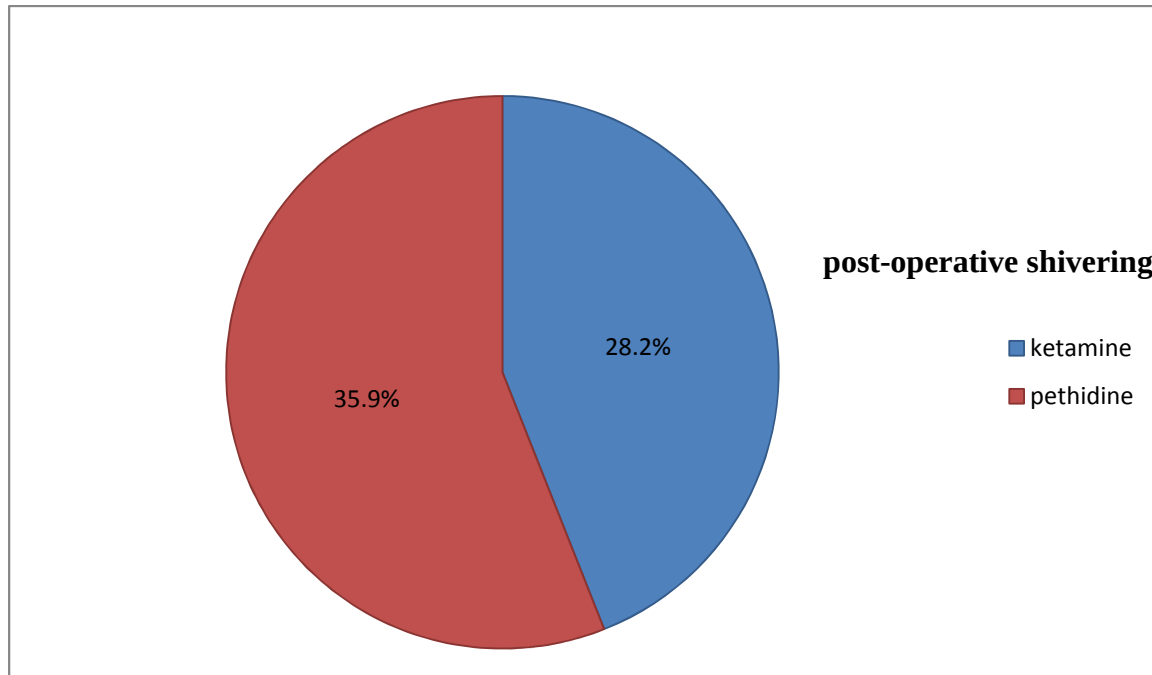


Figure 3: Pie chart displaying Incidence of postoperative shivering in ketamine and pethidine groups in elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital from January 1 to April 30, 2017/18

The severity of post-operative shivering among ketamine and pethidine groups was shown on the bar graph below.

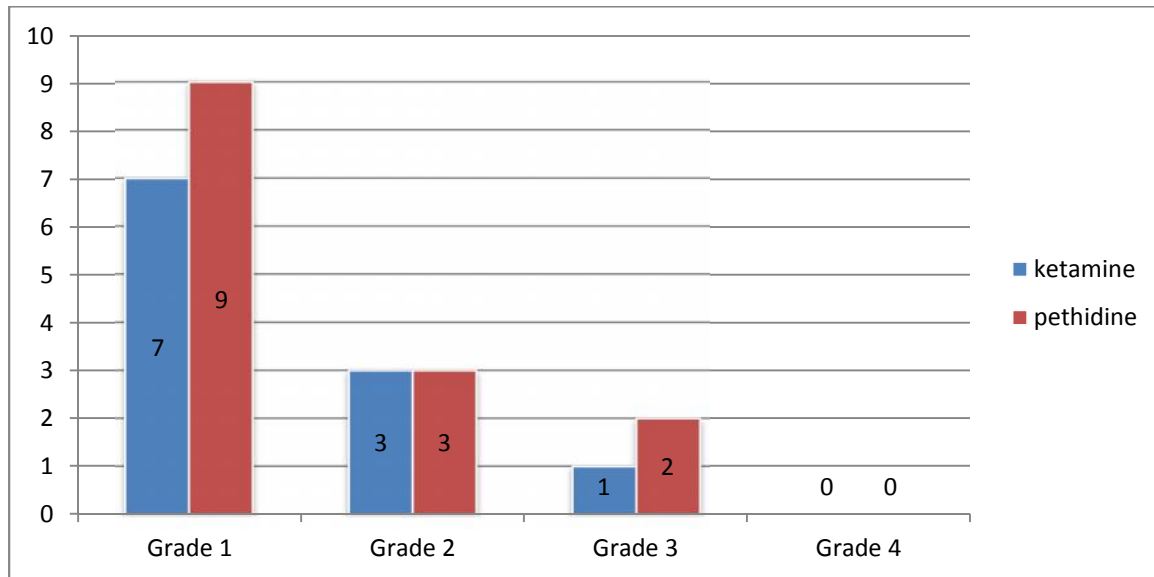


Figure 4: Bar graphs showing grades of post-operative shivering in elective surgical patients under general anesthesia in Tikur Anbessa specialized hospital from January 1 to April 30, 2017/18.

Chapter Six: Discussion

Post-operative shivering had remained one of common adverse events in the patients recovering from general anesthesia. Furthermore, it is associated with a major deal of discomforts to both the patients and medical care team. Moreover, there were several speculations about its origin yet exact etiology is still in question. This had made management of post-operative shivering more complex but several pharmacologic and nonpharmacologic methods had been employed. This prospective observational study compared the effectiveness of prophylactic intravenous ketamine 0.5mg/kg and pethidine 0.5mg/kg in elective surgical patients under general anesthesia.

The antishivering effect of pethidine was suggested by several reports. Its antishivering effect pertains to *k*- opioid receptor but not due to μ -receptor mediated. [5, 44, 51] even though, it had been a novel antishivering drug, side effects related pethidine may preclude its utilization in some situations. [24]

The preventive effect of ketamine for post-operative shivering was realized in many studies. However, its mechanism of action became difficult to predict due to pharmacological complexity of the drug. The possible speculation for its antishivering effect would be its action on thermoregulatory center via NMDA antagonism. Inhibition of NE reuptake at post ganglionic fiber by ketamine induces peripheral vasoconstriction which in turn decreases core to peripheral redistribution of heat. [43, 44, 51]

In this study, factors like age, gender, preoperative body temperature, type and duration of surgery, amount of blood loss and total fluid intake which were considered as a risk factors for perioperative hypothermia and shivering [6], were all comparable between the two groups ($p>0.05$).

This study compared preoperative (baseline) Mean arterial pressure and heart rate between the two groups and the result showed a statistically insignificant difference with $p>0.05$. The study had also compared intraoperative hemodynamic parameters at different time intervals i.e. before study drugs, 5, 10, 15 and 20 minutes after a study drugs. The result showed that no statistically significant difference observed in each variable with $p>0.05$. These results were supported by a randomized; placebo double-blind study conducted previously conducted by Dar AM, et al. in

India, Sher-i-Kashmir Institute of Medical Sciences. Their study has shown that the comparison of hemodynamic parameters of the study groups at regular intervals showed no difference ($p > 0.05$). [48] Similarly our result was also supported by a prospective randomized double-blind study conducted in Ankara, Turkey by D. Dal, et al. in 2005. [5] However, the limitation to their study might be they didn't put their results in an identifiable clear time intervals.

Body temperature of the patients in the two groups was recorded and compared in the operation theatre and in the PACU and was found to be statistically insignificantly different ($p > 0.05$) except the record at one hour in PACU ($p = 0.007$). The factor for the difference at one hour had not been discovered. However, the patient factor might have contributed for this. Also, temperature management protocol in PACU might differ among the two groups. Another possible explanation for this could be the variation on the extent of surgical incision between the two groups. In this study, the mean axillary temperature was lower during intraoperative time compared to baseline score in both groups. The drop between the two groups was not significantly different ($p > 0.05$). There might have a clinical significance for this difference and could be due to anesthetic induced impairment of thermoregulatory center, decreased metabolic heat production, core to peripheral redistribution of heat and heat transfer through an exposed surgical wounds. This result conforms to previous study conducted in Babol University of medical sciences, Iran which compared the efficacy of meperidine and low doses of doxapram and ketamine in the prevention of post anesthesia shivering and showed there was no significant difference in respect to drop core body temperature among the groups after anesthesia. [26] Another study conducted by Zabareh et al also revealed no difference in perioperative body temperature among the patients who took ketamine and pethidine. [51] However, the scores in our result were slightly lower when compared to the values of their study. The probable reason could be due to controlled room temperature ($22-25^{\circ}\text{C}$) in their study, but our study lack to control ambient temperature.

In this study the overall incidence of post-operative shivering was 32.1%. This rate is higher than the report from the study conducted in Isfahan University of medical sciences, Iran by Zabareh SMHT et al. In their study, over all shivering rate was 26.7% which is smaller than the rate of our study. [51] The cause for this might be variation in intraoperative and postoperative patient

management. Another speculation could be Intraoperative use of fentanyl which also has antishivering effect, and higher operation room ambient temperature in their study.

The most important outcome of interest in this study was an incidence of post-operative shivering in ketamine and pethidine groups. In our study, the number of shivering patients in ketamine and pethidine groups was not statistically significant (11(28.2%) and 14(35.9%) respectively for ketamine and pethidine group, ($p=0.467$). Although it was statistically insignificant, it seems practically better outcome. This finding is in line with the study conducted in India which involved 90 ASA I and II patients by Dar AM, et al. Their study showed no statistically significant difference found between ketamine and pethidine groups ($p>0.05$). [48] This might be due to utilization of the same dose of the study drugs. Another study conducted in Mashhad, Iran by Masomeh et al also reported pethidine and ketamine can similarly reduce post-operative shivering [28]. Our study result also supported by a study in Tabriz University of Medical Sciences, Iran by Eydi M. et al in 2014. [54] The result of their study showed that ketamine and pethidine are both equally effective in reducing post-operative shivering. This could be due to similar study design. Also another study, conducted by Ayatollahi V et al in Iran had reported similar finding to our study. Their study reported prophylactic use of low doses of intravenous ketamine (0.3 or 0.5 mg/kg) was found to be effective to prevent postanesthetic shivering. However, administration of 0.3 mg/kg ketamine lowered the rate of hallucination as compared with 0.5 mg/kg. [24] This might be related to different drug response.

A prospective RCT conducted in Isfahan University of medical sciences, Iran by Zabareh SMHT et al reported a contradictory finding in favor of pethidine. They said pethidine seems to be the most appropriate choice for preventing postoperative shivering. [51] The difference in the study design could have contributed for this discrepancy.

Another prospective randomized study conducted by Emine Arzu et al in Hacettepe University, Turkey showed ketamine in doses of 0.5-0.75 mg/kg had better reduced post-operative shivering than pethidine. But ketamine 0.75 mg/kg associated with more hallucination [25]. This might be caused by higher dose of ketamine. Another contradictory result to our finding was reported by the study conducted in Motahari Hospital in Jahrom (Iran), by Zabetian H, et al in 2016. This study reported as although ketamine can control shivering, pethidine was still better choice for shivering control. [53] The possible explanation for this could be the small dose of ketamine and different anesthetic technique I.e. spinal anesthesia in their study.

The severity of post-operative shivering was another interest of this study. It was compared between the two groups and the difference was not statistically significant ($p=0.874$). A randomized double blind study conducted by Dar AM showed similar finding to our study. In their study, severity of post-operative shivering was not significantly different between ketamine and pethidine groups ($p>0.05$).

The number of patients with grade 1 and 2 shivering in our study was 7 and 3 respectively in ketamine group and 9 and 2 respectively in pethidine groups. This result was in line with the prospective randomized clinical trial conducted by Masomeh et al. In their study, while only one patient in ketamine group developed grade 1 shivering, no patient has developed either grade 2 or 3 shivering. But their finding for pethidine group was similar to the result of our study. In their study, the number of patients who developed grade 1 and 2 shivering was 3 and 3 respectively. [28] This is higher number compared to ketamine counterparts. It could be due to less dose pethidine used to prevent postoperative shivering. Our study was also consistent with a randomized study conducted by Dar AM, which showed the number of patients with grade 1 and 2 shivering were 4 and 3 in both ketamine and pethidine groups respectively ($p>0.05$).

In our study, the number of patients with grade 3 shivering and took pethidine 25 mg rescue treatment was 1 and 2 in ketamine and pethidine group respectively. However, this result might be comparable to previous study conducted in India by Neethika M, et al. In their study, the number of patients with grade 3 shivering and treated with pethidine 25 mg was 1 and 1 in ketamine and pethidine group respectively. [52] Meanwhile, our result was in contrary to previously conducted randomized study by Dar AM, in which no patient developed postoperative shivering >2 . This could be due to difference in perioperative patient management.

6.1 Strength of the study

Study participants were homogenous

First study in our country

Involved participants from different surgery types

6.2 Limitation of the study

Temperature of operation room and intravenous fluids was not controlled.

Not having a control group because of time constraints.

Most of the results were compared with randomized clinical trial study.

Confounders are still possible

Chapter Seven: Conclusion and Recommendation

7.1 Conclusion

Based on the result of our study, the incidence and severity of post-operative shivering were not significantly different between ketamine and pethidine groups. There was no statistically significant difference observed between ketamine and pethidine groups regarding haemodynamic parameters. Based on these findings prophylactic low dose ketamine can prevent post-operative shivering as effectively as pethidine. But low dose ketamine has shown a practically better outcome than pethidine. Therefore, prophylactic low dose intravenous ketamine could be an ideal alternative to control post-operative shivering.

7.2 Recommendation

The result of this study showed that both low dose ketamine and pethidine were found to be similarly effective in preventing post-operative shivering. We recommend anesthetists in our clinical area to use ketamine 0.5 mg/kg before the end of operation for prevention of post-operative shivering. We also recommend prophylactic low dose ketamine for prevention of post-operative shivering because it is cheap and easily available in the operation room and cost effective. We also recommend future randomized study with this baseline data.

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Annexes:

I. Consent and questionnaire.

Addis Ababa University College of health Sciences, School of graduate studies, department of anesthesia

Questionnaire prepared to compare the effectiveness of ketamine 0.5 mg/kg and pethidine 0.5 mg/kg as a way of preventing postoperative shivering in elective surgical patients under general anesthesia.

This questionnaire was used as a guide to collect information for the data collectors.

Hello! My name is -----, I am one of the members of the research team. The purpose of this questionnaire is to gather information on how much the prevention of shivering is effective between ketamine and pethidine. I have identified you as a study participant hoping that you would be willing to help me by providing with some information. I have some questions which I would like to ask you, if you have the time and are willing. The interview will take about 5 minutes of your time. All information you provide will be kept confidential. I will not include such as your name or exact address. Only honest answers would contribute to improvement of health planning. Your role in the success of the research is important and I appreciate your contribution to the research.

First of all, I would like to thank for your cooperation and willingness!!!

Would this be okay with you?

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

A. Agree B. disagree

If Respondent agrees to be interviewed, the interview will be started.

Questionnaire Code _____ Starting time _____

አድስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ፣ህክምና ትምህርትቤት፣በድህረ-ምረቃፕሮግራም

የአንስቴዥያ ትምህርት ክፍል

የመጠይቅ ፈቃደኛነት ቅጽ

እንደምንነዎት! ስሜ _____ይባላል።እኔ በአዲስ አበባ ዩኒቨርሲቲ በአንስቴዥያ ትምህርት ክፍል የምርምር ቡድን ውስጥ አንድ አባልነኝ ። የዚህ መጠይቅ አላማ በኦፕራሲዎን ወቅት ሊሰጧችሁ የሚችሉትን ከታሚንና ፕቲዲን የተሰኙትን መደሐኒቶች ወጤታማነት ለመለካት መረጃ ለመሰብሰብ የሚያገለግል ነው። እርስዎን አንድ የጥናቱ ክፍል አድርጌ ስመርጠዎ አስፈላጊ የሆኑ መረጃዎችን እንደሚሰጡኝ በማሰብ ነው።በጥናቱ ለመሳተፍ ስለፍቃደኛነትዎ ከወዲሁ እያመሰገንኩ 5 ደቂቃዎችን ብቻ እንዲሰጡኝ እጠይቃለሁ። ከእርስዎ የሚገኙ ማንኛውም መረጃዎች በሚስጥር ይጠበቃሉ።ለዚህም ሲባል የእርስዎ ሥምምሆነ አድራሻ አይገለጽም። ለመመለስ ፈቃደኛ ያልሆኑትን ማንኛውንም ጥያቄ አለመመለስ ይችላሉ። በማንኛውም ሰዓት የጥያቄ እና መልሱን ሂደት ማቋረጥ ይችላሉ። ነገር ግን ቀደም ሲል እንደተገለጸው እርስዎ የሚሰጡት እውነተኛ ምላሽ በኦፕራሲያን ጊዜ ሊሰጧችሁ የሚችሉትን ከታሚንና ፕቲዲን የተሰኙትን መደሐኒቶች ወጤታማነት ለመለካት ለሚደረገው ጥናት/ምርምር በከፍተኛ ሁኔታ ያግዛል።እንድሁም ከጥናቱ በኋላ ኦፕራሲዎን ለሚደረግላቸው ታካሚዎች ወጤታማ የሆነውን መደሐኒት በተገቢው ጊዜ በመስጠት ተገቢ የሆነውን እርምጃ ለመውሰድ ይረዳል።

የቃል ሥምምነት

የዚህ ጥናት ዓላማው ገብቶኝ በጥናቱ ለመሳተፍ

ሀ. ፈቃደኛሆኛለሁለ. ፈቃደኛ አይደለሁም

በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ ቃለ መጠይቁን መቀጠል ይቻላል።

ፈቃደኛ ከሆኑ፤

የመጠይቁ መለያ ቁጥር-----መጠይቁ የተካሄደበት ቀን ----- የተጀመረበት ሰአት-----

የጠያቂው ሥምና ፊርማ-----የሱፕርቪዘር ስምና ፊርማ-----

ጥናቱን በተመለከተ ማንኛውም አይነት ጥያቄ ካላችሁ የሚከተለውን አድራሻ ተጠቀሙ።

ምርምሩን በዋናነት የሚያካሂደው ሰው ስም፡ገረሱገበየሁ

Instruction: for each of the following questions, please fill the appropriate responses in the space provided.

Section I: Socio demographic and operative characteristics of the clients

- 100. MRN:_____
- 101. Age: _____
- 102. Sex:_____
- 103. Height:_____
- 104. Weight:_____
- 105. BMI:_____
- 106. ASA PS_____

Section II: Baseline Hemodynamic parameters

- 200. Heart rate: _____
- 201. Blood pressure: _____
- 202. Temperature: _____

Section III: Intra operative: anesthesia technique

- 300. Premedication: _____
- Mode of Induction_____induction agent_____dose_____
- Muscle relaxant_____dose_____
- Maintenance_____
- Others: _____

Intra operative Hemodynamic parameters:

- 301. Blood pressure: Before administering the study drugs_____

: After administering the study drugs every 5 minutes interval until the patient goes to PACU. -5 minutes____10 minutes____15 minutes____20 minutes

301. Heart rate: Before administering the study drugs_____

: After administering the study drugs every 5 minutes interval until the patient goes to PACU 5minutes____10 minutes____15 minutes____20 minutes__

302. Temperature: Before administering the study drugs_____

: After administering the study drugs_____

-5 minutes____10 minutes____15 minutes____20minutes

303. Any method used to warm the patient intra operatively? Yes___ No___ if yes, specify_____

304. Type of surgery: _____

305. Duration of surgery: _____

306. Blood loss_____

307. Amount of fluid given_____

Section IV: Post-operative period

403. Does the patient shiver?

YES (T0____, T10____, T20____T30____T40____T50____T60____) NO____

404. If yes, grade (1____2____3____4____)

405. Does the patient take treatment for shivering?

406. TemperatureT0____T10____T20____T30____T40____T50____T60____)

REMARKS:

T0-immediate admission into PACU

T10-ten minutes after admission into PACU

T20-twenty minutes after admission into PACU

-
-
-

T60-sixty minutes after T0.

Name of the data collector_____ **signature**_____

Name of the supervisor_____ **signature**_____

Date:_____