COLLEGE OF HEALTH SCIENCE AND MEDICINE

DEPARTMENT OF ANESTHESIA

A COMPARATIVE STUDY ON THE EFFECTIVENESS OF ONDANSETRON VERSUS PETHIDINE FOR THE PREVENTION OF POSTOPERATIVE SHIVERING IN PARTURIENTS UNDERGOING ELECTIVE CESAREAN SECTION UNDER SPINAL ANESTHESIA IN SELECTED GOVERNMENTAL HOSPITALSIN ADDIS ABABA ,ETHIOPIA.A PROSPECTIVE COHORT STUDY,2025 GC.

Principal Investigator: Kassahun Yimer (BSc in Anesthesia, MSc Candidate)

Name of Advisors: Mr.Adugna Aregawi (MSc, Assistant Professor in AAU)

Mr.Hirbo Samuel (MSc in Anesthesia)

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Principal Investigator	**Kassahun Yimer(BSc, MSc Student)**
Advisors	Mr.AdugnaAregawi (Assistant Professor). Mr.Hirbo Samuel (Msc in Anesthesia).
Research Topic	A Comparative study on the effectiveness of ondansetron versus pethidine for prevention of post-operative shivering in parturients undergoing elective cesarean section under spinal anesthesia in selected governmental hospitals, Addis Ababa, Ethiopia: A prospective cohort study.
Duration of the project	January1-Aprill 30, 2025 GC.
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Total cost of the project	42,288 ETB
Address of the investigator	Kassahun445@gmail.com Phone number;0912266125/0925016600

Declaration

I the undersigned confirm that this thesis is my own workto partiallyfillfill the advanced clinical anesthesia MSc requirementsand I agreedthat plagiarism would not be accepted and I made sure that every source I used for this thesis was properly cited

Primary Investigator: Kassahun Yimer

Signature_____

Date_____

Approval of Advisors

Name Sign Date

1._____

2._____

Internal Examiner

Name Sign Date

1._____

External Examiner

Name Sign Date

1._____

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List of Abbreviations

ASA	American Society of Anesthesiologist
BMI	Body Mass Index
BP	Blood Pressure
CS	Cesarean Section
ECG	Electrocardiography
GA	General Anesthesia
GMH	Gandhi Memorial Hospital
ICU	Intensive Care Unit
IV	Intravenous
KG	Kilo Gram
MAO	Mono Amino Oxidase
MAP	Mean Arterial Pressure
MG	Milli Gram
NS	Normal Saline
PACU	Post Anesthesia Care Unit
PAS	Post Anesthesia Shivering
RA	Regional Anesthesia
RCT	Randomized Control Trial
RR	Respiratory Rate
SA	Spinal Anesthesia
SPO2	Saturation of Arterial Oxygen
TASH	Tikur Anbesa Specialized Hospital
ZMH	Zewuditu Memorial Hospital

Abstract

Background: Postoperative shivering is a common adverse of spinal anesthesia after a cesarean delivery, causing serious complications such as increased oxygen consumption, carbon dioxide production, and increased risk of myocardial ischemia. Pethidine is widely used for shivering prevention and treatment, but it has serious side effects. Ondansetron has been suggested in several studies to prevent shivering with minimal side effects, although there are limited studies and its effectiveness compared to pethidine remains controversial, particularly in cesarean section cases.

Objective: To compare the effectiveness of ondansetron versus pethidine for the prevention of postoperative shivering in parturients who underwent elective cesarean section under spinal anesthesia in governmental hospitals in Addis Ababa, Ethiopia.

Methods: A prospective cohort study was conducted in selected governmental hospitals in Addis Ababa, Ethiopia, from January 1 to April 30, 2025 GC; involving 172(86 for ondansetron and 86 for pethidine) parturients who underwent elective cesarean sections under spinal anesthesia selected using a systematic sampling technique. Data were collected by a pretested structured questionnaire and analyzed using SPSS version 27.Difference in categorical data were compared by Chi-square and Fisher exact test ,while continuous data non parametric data were analyzed by Mann-Whitney U test.A P-value < 0.05 taken asstatistically significant difference.

Result:The incidence of postoperative shivering was 15.1% and 11.6% in ondansetron and pethidine groups respectively (p-value=0.502). Grades of shivering were comparable betweengroups, with no grade 3 shivering (p =0.796). There was a statistically significant difference in the incidence of nausea and vomiting in the two groups, which was 2.3% in the ondansetron group and 32.6 % in the pethidine group, with a p-value < 0.001.

Conclusion: This study showed that ondansetron 8 mg intravenous has no significant difference with pethidine 0.4 mg/kg intravenous in preventing postoperative shivering but fewer side effects from ondansetron, and the researchers recommend the use of ondansetron 8mg as a safer alternative to pethidine for the prevention of postoperative shivering in parturients undergoing elective cesarean section under spinal anesthesia.

Keywords: Cesarean Section, Nausea and Vomiting, Ondansetron, Pethidine, Shivering

CHAPTER ONE: INTRODUCTION

1.1. Background

Postoperative shivering (POS) is an involuntary, spontaneous, and rhythmic fasciculation of one or more groups of the skeletal muscles longer than 15seconds(1). It is a physiologic compensatory mechanism for hypothermia in order to raise metabolic heat production after peripheral vasoconstriction(2).

Post-operative shivering (POS) is a complex and poorly understood issue. Spinal anesthesia causes increased heat loss, impairing sensory input ,loss of thermoregulatory vasoconstriction below the block level and decreasing the threshold of shivering, causing distressing post-anesthesia shivering, even worse than surgical pain (3).Postoperative shivering is a frequent problem that varies in severity, ranging from isolated facial or muscle group fasciculations to full-body involvement, and affects 50-65% of parturientscoming for cesarean sections, and it is the sixth most common perioperative complication(4).

Post-operative shivering can cause discomfort, anxiety, and interference in monitoring, leading to potential lethal consequences like increased oxygen consumption (100-600%), carbon dioxide production, tachycardia, hypertension, postoperative pain, and increased risk of myocardial ischemia. Therefore shivering may be detrimental in parturients having cardiorespiratory disease (5).

A study in Iran found that postoperative shivering can be caused by factors such as age, sex, lower BMI, procedure length, and patient comorbidity(6).A core temperature of 33°C to 35°C is consideredhypothermia, while 35.5°C is the shivering threshold for patients who are not sedated. The normal interthreshold range, or hypothalamic set point, is raised when anesthetic drugs increase the heat response thresholds and reduce the cold response thresholds(7).

Postoperative shivering management is crucial for patient comfort and prevents complications. Non-pharmacological methods include warm irrigation and IV fluid, warm clothing, radiant heat warmer, and temperature adjustment, while pharmacological methods include ,pethidine,dexmedetomidine,serotonin 5-HT3 receptor antagonists(8,9).

The body's temperature is regulated by neurotransmitters. Serotonin, also known as 5-hydroxytryptamine (5-HT), is one of these regulating neurotransmitters in the brain and spinal cord. Serotonin receptor antagonists have gotten a great of deal attention as prevention for post spinal shivering (10).Ondansetron,primarily used to prevent emesis, can be used to treat shivering that occurs perioperatively with less adverse effects. Ondansetron will reduce shivering by inhibition of serotonin reuptake in the anterior hypothalamic preoptic region, affecting both heat production and loss pathways (11).

Pethidine, a potent analgesic, has been regarded as a gold standard for managing perioperative shivering. The mechanism of action is not clearly understood, but its agonist effect at κ-opioid receptors is strongly linked to the prevention of shivering(12).However, limited comparative studies have been conducted to determine which drug is more effective to prevent and treat postoperative shivering in parturients undergoing cesarean section in Ethiopian healthcare settings. This study was conducted to provide evidence-based recommendations that will improve patient care and efficient utilization of resources in these hospitals

Therefore this study aimed to compare the effectiveness of ondansetron and pethidine in preventing postoperative shivering in parturients who underwent elective cesarean section under spinal anesthesia in selected governmental hospitals in Addis Ababa.

1.2. Statement of the problem

Postoperative shivering is a prevalent problem worldwide, with a high incidence rate, particularly in parturients undergoing cesarean section under spinal anesthesia (SA). It occurs in 50-65 % of parturients undergoing cesarean section under spinal anesthesia(13).In a study conducted in Sub-Saharan tertiary hospital Uganda found the incidence of post spinal shivering was 8.1%(2).A study conducted in Northwest Ethiopia on the incidence of post-spinal shivering found 51.8%(14).

Post-operative shivering leads to decreased mother-to-child bonding, increased pain, prolonged hospital stays,dissatisfaction,increased health care costs, delayed wound healing and hemodynamic instability(15). Some studies show that babies born to hypothermic mothers may be at increased risk of low body temperature, low Apgar score, and lower umbilical pH at birth (16).Postoperative shivering(POS)after cesarean section(CS) usually occurs when the effect of anesthesia starts to wears off and the body starts to restore its normal thermoregulatory balance and when the muscle tone returns(17).Predisposing factors for POS in cesarean sections include stress, cold temperatures, skin disinfection, heat redistribution and loss of warm amniotic fluid(11,12,18).InEthiopia, poor temperature control and resource limitations exacerbate this problem (19,20).

Despite various pharmacological and non-pharmacological methods for shivering prevention and management, no novel treatment options are available.Non-pharmacological methods like warming fluid and controlling operating room temperature are listed, but they are not available and functional all the time in our resource-limited setup. Pethidine, the leading agent, has lots of adverse effects like nausea and vomiting, sedation, neonatal depression and cost-related issues make it unsuitable for usage in pregnant women.So we need to find an alternative drug that has less adverse effect, easily available and cost effective(21–23).

Ondansetron is a preferred antiemetic drug, has fewer adverse effects on pregnant mothers, cost-effective can be used in preventing and treating postoperative shivering even though there are some controversies(23–25).But direct comparison of its effectiveness for shivering with pethidine in parturients undergoing cesarean section is limited. Ethiopia lacks standardized guidelines for POS prevention and management, leading to medication choice based on availability and physician preference, potentially causing ineffective shivering management. So

the purpose of this study was to fill this gap by comparing the effectiveness of pethidine and ondansetron in preventing postoperative shivering and its consequences in these populations.This study would improve clinical practices by identifying a safer, more effective drug for preventing POS in cesarean section, thereby promoting evidence-based anesthesia management. In addition, it will offer useful information for developing guidelines and policies in Ethiopian healthcare settings. As well, determining the more effective medication will also have economic benefits by reducing the need for additional interventions, or extended hospital stays. This can lead to more efficient use of healthcare resources in obstetric settings. Furthermore, this study will also provide baseline information for future researchers.

In general, this study aimed to enhance the quality of care for obstetric mothers undergoing cesarean sections, ensuring a more comfortable and safer postoperative experience which is essential for both the mothers' health and her ability to care for her newborn baby.

1.3. Justification of the study

Post-operative shivering in cesarean section after spinal anesthesia is challenging to prevent, despite the use of pharmacological and non-pharmacological approaches, which are not always available or applicable and may have side effects for parturients (10,19).

Pethidine, the preferred drug for shivering, faces limitations in its usage due to cost, unavailability, and potential side effects like neonatal depression, sedation, nausea, vomiting, and respiratory depression (26). So it needs to search other alternative drug to prevent shivering which is cost effective, easily afforded and minimal side effect. According to some research, even though there are some controversies, ondansetron isan effective drug to treat shivering that is easily available, cost effective, and has minimal side effects, so this study aimed to investigate it in our setup(27,28).

Despite the fact that ondansetron and pethidine have been investigated for prevention of postoperative shivering, comparison of their effectiveness in terms of cesarean section under spinal anesthesia is not well established. Existing studies has shown conflicting results and they recommend further investigations (23,29). No published Ethiopian study exists, necessitating this study, since it is difficult to generalize with findings from other countries due to differences in management approach that result from resource-limited settings and economic and technological disparities. This study, conducted across multiple centers, employed a large sample size and long-term follow-up. It will provide evidence-based recommendations for improving patient comfort, reducing complications, and enhancing recovery. It will offer valuable data for developing cost-effective strategies for managing postoperative shivering in Ethiopian hospitals and serve as a baseline for future research.

CHAPTER TWO: LITERATURE REVIEW

Perioperative shivering following SA is a frequent complication that can occur in approximately 40–80% of cesarean sectionleading to discomfort, delayed wound healing, increased myocardial oxygen consumption and carbondioxide production (19).

A cross sectional study done in Ethiopia showed the incidence of shivering in parturients taking spinal anesthesiafor cesarean sections (CS)was 51.8%. A number of variables, including the length of the procedure, hypothermia and hypotension contributed to shivering after administration of spinal anesthesia(14).Various intervention have been explored for the prevention and treatment of shivering with ondansetron and pethidine being the study drugs. This literature review compares the effectiveness of ondansetron and pethidine in preventing postoperative shivering in parturients undergoing cesarean section under spinal anesthesia.

2.1. Intravenous Ondansetron

Ondansetron,a 5-HT3 antagonist, reduces shivering by inhibiting serotonin reuptake at the pre-optic anterior hypothalamic region, which plays a key role in thermoregulation.Zhang.et al.and M. Li et al. in 2016 have been shown that ondansetron reduces the occurrence and severity of post anesthetic shivering. However some studies failed to demonstrate a reduction in PAS with ondansetron administration(4,18,30).

2.2. Intravenous pethidine

Pethidine is a synthetic opoid widely used for shivering and its effect is thought to be mediated through its effect on κ-opioid receptor, monoamine reuptake inhibition, and N-methyl-d-aspartate receptor antagonism. It can be used through both intrathecal and intravenous routes(31). Its effectiveness in preventing and treating postoperative shivering is well documented; however, its use is often limited by its side effects. While both ondansetron and pethidine act on different mechanisms of action to prevent postoperative shivering, their effectiveness in this context varies.

2.3. Intravenous Ondansetron versus Intravenous Pethidine

Different studies have compared ondansetron and pethidine for their effectiveness in the prevention of POS after spinal anesthesia, and different controversies are also seen. Further studies are needed to resolve these controversies(23).

A RCT done in 2018 in India by Gupta R, *et al* compared pethidine(25mg), ondansetron 4mg administered immediately after SA, and placebo on the prevention of shivering after spinal anesthesia in patients undergoing cesarean section. Their study finding showed that there was no significant difference in the incidence of postoperative shivering in the ondansetron and pethidine groups after thirty minutes of anesthesia (4.6% and 18.2%, respectively), but there is a significant difference with the placebo group (71.5%) (32).

A comparative study done in Bangladesh in 2021 on the comparison of ondansetron 8mg IV and pethidine 0.4mg/kg for prophylaxis of post-spinal shivering in cesarean sections found the incidence of shivering was 53.33%, 13.33%, and 26.66% in the control, ondansetron, and meperidine groups, respectively. The number of patients with a shivering grade of 3 & 4 was very highly significant ($p<0.001$) in control group compared with other groups at 15 min & 20 min after the block. They conclude ondansetron was a more effective and hemodynamically stable drug(33).

Another double-blinded randomized controlled trial (RCT) done in Iran compared 4mg ondansetron, 8mg ondansetron, and 0.4 mg/kg pethidine for the treatment of POS in patients who had shivering after general anesthesia. The shivering cessation after ten minutes was 59%, 81%, and 86% for each group, respectively ($p = 0.01$), with no significant difference in the intensity of shivering. There was a significantly lower incidence of nausea and vomiting in the 4mg ondansetron (11%) & 8mg ondansetron (0%) groups than in the 0.4 mg/kg pethidine group (34%) ($p=0.01$)(24).

Based on a double blind clinical trial done in Iran in 2017 on comparison of the effect of pethidine and ondansetron in prevention of shivering in patients undergoing cesarean sections under spinal anesthesia in three groups of patients ondansetron (O) 4mg, pethidine (P)25mg, and placebo (N) 2ml normal saline. No significant difference was found between the ondansetron and pethidine groups in the incidence of shivering (p value > 0.05)(34).

Another cross-sectional study conducted in Iran in 2021 on the comparison of the effects of 8mg of ondansetron and 0.4 mg/kg of pethidine in the prevention of postoperative shivering in parturients having operative delivery under spinal anesthesia showed that the incidence of postoperative shivering was 11.4% in the ondansetron group and 8.6% in the pethidine group, and the mean intensity of shivering between the ondansetron and pethidine groups was 0.22±0.68 and 0.34±0.49, respectively, with ondansetron having the advantage of reducing the incidence of postoperative nausea and vomiting(35).

Different studies compared these medications in different patient populations.AnRCT study done in Egypt compared pethidine and ondansetron for postoperative shivering prophylaxis in lower abdominal surgery patients. Their results showed 5% and 15% incidence of shivering and 20% vs 0% incidence of nausea and vomiting respectively(23).Another RCT done in India compared ondansetron, ketamine, and pethidine to prevent perioperative shivering in patients having knee replacement surgery under spinal anesthesia and found incidences of shivering as 16%, 7.84%, and 7.69% of patients, respectively. The incidence of grade three shivering was 12%, 3.9%, and 1.9% respectively(36).

A double-blind clinical trial study done in Iran in 2021 compared dexmedetomidine, pethidine, and ondansetron for prevention of postoperative shivering in patients having abdominal surgery under GA and demonstrated the incidence of shivering was 12.5% in the dexmedetomidine group and 31.3% in the ondansetron and pethidine groups(37).Another double-blind, randomized, non-controlled study done in Egypt in 2019 compared pethidine and ondansetron for preventing post-spinal shivering in hysterectomy patients showed the incidence of shivering 16% in both groups(10).

A randomized, double-blinded controlled trial done in East Africa in 2019 found that a weight-based dose of ondansetron (0.1 mg/kg actual body weight) reduced the incidence of PAS by half compared to a 4 mg dose (11.3% vs 22.6%)(38).A study done by Tubog and Bramble in 2022 showed a significant reduction in PAS with 8 mg doses but not with 4 mg doses compared to placebo but may be associated with side effects with rapid bolus injection(39).

2.4. Risk Factors for Postoperative Shivering

Postoperative shivering is the common complication after spinal anesthesia and several risk factors contribute to the development of postoperative shivering particularly in cesarean section after spinal anesthesia. Emergency case, cold operating room, cold intravenous fluid, longer surgeries, low BMI,extreme of age ,preoperative anxiety, lower core temperature at the end of surgery significantly associated with postoperative shivering(2,40,41).

According to some of the reviewed literature, ondansetron may be a good alternativeto pethidine in preventing postoperative shivering in parturients having operative delivery under spinal anesthesia. Even though some studies did not show that ondansetron was effective in preventing POS. Further studies are required to clearly establish the comparison of the effectiveness of ondansetron and pethidine in preventing POS.

No studies were conducted in our country on the comparison of effectiveness of ondansetron and pethidine for prevention of postoperative shivering in parturients undergoing cesarean section under spinal anesthesia, so this study aimed to provide relevant datato optimal management strategies for postoperative shivering by comparing these two medications, particularly in these population groups.

Conceptual framework on factors affecting the comparison of ondansetron(8mg intravenous) and pethidine 0.4mg/kg intravenous for prevention of postoperativeshivering (incidence and severity, post-operative nausea and vomiting) as dependent variable and patient factor ,surgical and anesthetic factors taken as independent variable which is extracted from previous studies as shown below(2,14,29,42–45).

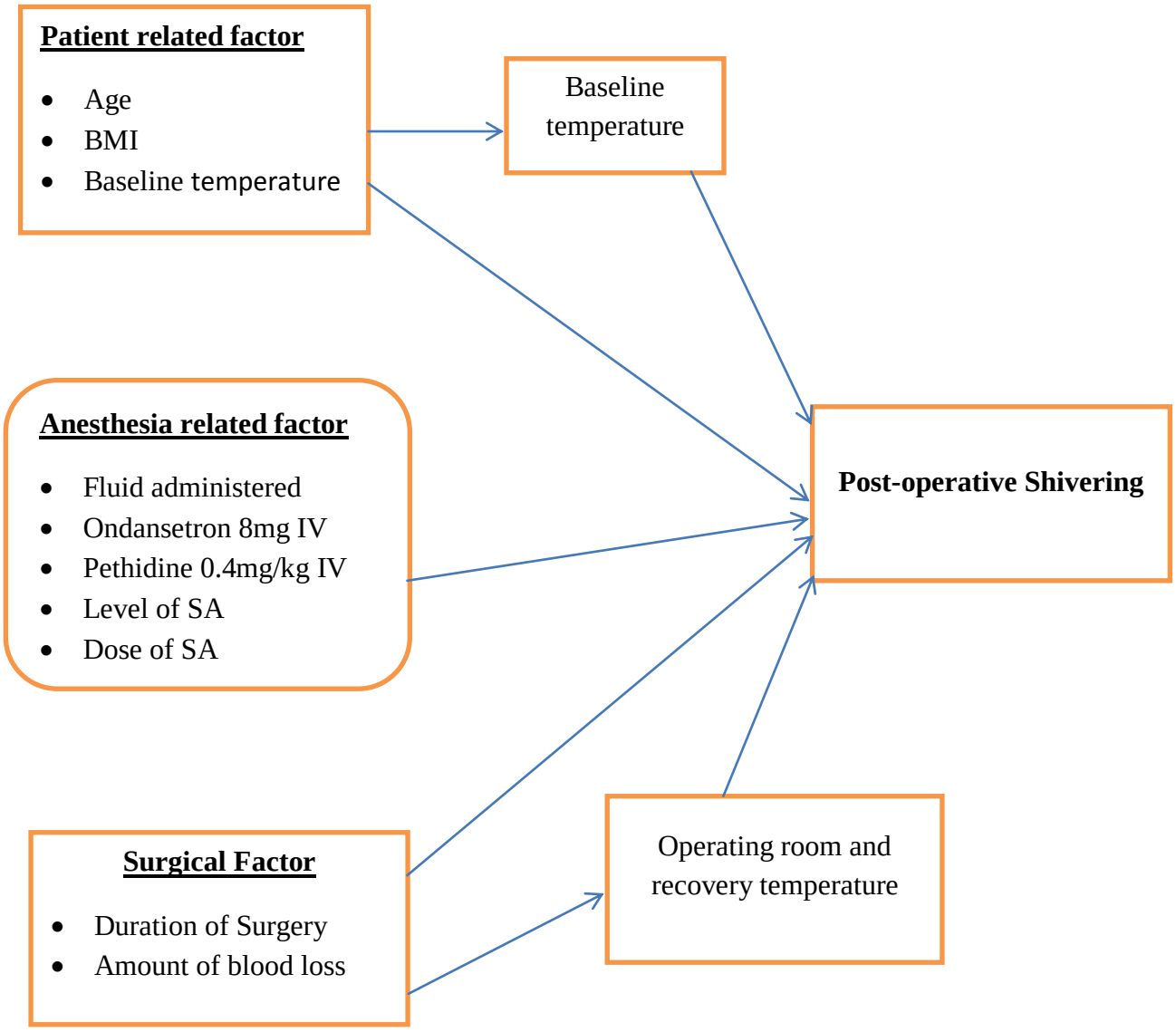

Figure 1: Conceptual framework on factors affecting postoperative shivering

CHAPTER THREE: OBJECTIVE

3.1. General Objective

- To compare the effectiveness of ondansetron and pethidine in preventing postoperative shivering in parturients who underwent elective cesarean sections under spinal anesthesia at Ghandi Memorial Hospital, Zewuditu Memorial Hospital, and Tikur Anbesa Comprehensive Specialized Hospital (TASH) in Addis Ababa, Ethiopia.

3.2. Specific Objectives

- To compare the incidence ofpost-operative shivering (POS)amongparturients receiving ondansetron and those receiving pethidine who underwent cesarean section under spinal anesthesia in Ghandi Memorial Hospital, Zewuditu Memorial Hospital and TASH,Addis Ababa, Ethiopia.
- To compare the severity ofPOS between ondansetronand pethidine groups in parturients whounderwent elective cesarean section under spinal anesthesia in Ghandi Memorial Hospital, Zewuditu Memorial Hospital and TASH, Addis Ababa, Ethiopia.
- To compare incidence of nausea and vomitingbetween parturients receiving ondansetron and those receiving pethidine who underwent elective cesarean section under spinal in Ghandi Memorial Hospital, Zewuditu Memorial Hospital and TASH,Addis Ababa, Ethiopia.

Research Hypothesis

H0:There is no a statistically significant difference in the incidence of postoperative shivering between the ondansetron and pethidine groups of parturients undergoing elective cesarean section under spinal anesthesia

HA: There is a statistically significant difference in the incidence of postoperative shivering between the ondansetron and pethidine groups of parturients undergoing elective cesarean sections under spinal anesthesia.

H0:There is no a statistically significant difference in the severity of postoperative shivering among the ondansetron and pethidine groups of parturients undergoing elective cesarean section under spinal anesthesia

HA: There is a significant difference in the severity of postoperative shivering among the ondansetron and pethidine groups of parturients undergoing elective cesarean sections under spinal anesthesia

H0:There is no a significant difference in the incidence of nausea and vomiting among ondansetron and pethidine groups of parturients undergoing elective cesarean section under spinal anesthesia.

HA: There is a significant difference in the incidence of nausea and vomiting among ondansetron and pethidine groups of parturients undergoing elective cesarean section under spinal anesthesia

CHAPTER FOUR: METHODS AND MATERIAL

4.1. Study Area and Period

Addis Ababa is the capital and biggest city of Ethiopia, with a populationof 5,704,000 in 2024,a 4.45% increase from 2023, and it is growing very rapidly like many African cities, which have an area of 527square kilometers.Addis Ababa has 13 public hospitalsas of 2023. From them, Tikur Anbesa Specialized Hospital (TASH), Ghandi Memorial Hospital, and Zewuditu Memorial Hospital serve many societies in Ethiopia at different departments; The Obstetric and Gynecologic department is one of them. TASH wasestablished in 1964 E.C, at Lideta sub-city and it is Ethiopia's largest referring hospital. TASH has two major operation tables for cesarean section, 31 post natal beds, and they perform an average of 67 elective CS per month.

Gandhi Memorial Hospital is a governmental hospital in Kirkos, Addis Ababa, Ethiopia that specializes in maternity services. It opened on 7th March 1997.Womens reproductive obstetric and gynecological health care is the hospital main focus. With 153 post-partum beds and four operating rooms this hospital performs 116 elective cesarean sections on average per month. Zewuditu Memorial Hospital is the other leading hospital in central Addis Ababa, Nifas Silk Lafto Sub City, Ethiopia. It was openedduring the Derg regime in 1976. This hospital has 36 beds in gynecological and obstetrics. This hospital has 2 major operation tables for elective cesarean sections, and they perform an average of 56 CS per month.

Therefore, these study areas were selected after situational analysis was done and cesarean sections were mostly undergone in these hospitals and also their level using convenient sampling techniques.

This study was conducted from January 1-April 30, 2025 GC.

4.2. Study Design

A prospective cohort study was conducted

4.3. Population

4.3.1. Source Population

All parturients scheduled for elective cesarean sections atTASH, Gandhi Memorial Hospital, and Zewuditu Memorial Hospital.

4.3.2. Study Population

All systematically selected parturients scheduled for elective cesarean sections during the study period and fulfill the inclusion criteria at TASH, Gandhi Memorial Hospital, and Zewuditu Memorial Hospital.

4.4. Eligibility Criteria

4.4.1. Inclusion Criteria

ASA II and aged 18-40 years full term gestational age (37-42 weeks of gestational age) parturients undergoing elective cesarean section under spinal anesthesia during a study period.

4.4.2. Exclusion Criteria

A history of sensitivity to the study drugs, Parturients who have taken opoid and ondansetronpremedication, History of drug abuse, Parturients having neuromuscular disease and neurologic disturbance, Electrolyte disturbance and cardiac disease, Havingbaseline body temperature <36 and > 38^0C, Combined spinal and epidural patients, Taking alpha2 agonists,Tricyclic antidepressant and mono-amino-oxidase (MAO) inhibitors, Those who take tramadol, Intrathecal opoid and dexamethasone, Complicated pregnancy(eclampsia,abruption placenta and placenta previa), Failed SA ,Those who are sedated or received with small dose ketamine, Parturients who transfused blood and those who have history of hyperthyroidism or hypothyroidism.

4.5. Sample Size Determination and Sampling Technique

4.5.1. Sample Size Determination

The sample size for this study was determined by using double population proportion formula for comparing two independent proportion by using Epi info 7 and manually by using incidence of shivering as primary outcome variables based on the following assumption; Significance level 5% (α=0.05), power of study (1 – β) of 80%, from previous study which is done inIndia, the incidence of shivering in ondansetron group was 4.6% and pethidine was 18.2%(32).

To calculate the required sample size for comparing two population proportions, we used the following formula;

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 \cdot (p_1(1-p_1) + p_2(1-p_2))}{(p_1 - p_2)^2}$$

- p1….Proportion of shivering in parturients in pethidine group
- p2 …..Proportion of shivering in parturientsin ondansetron group
- p1 and p2 are the two population proportions.
- Zα/2 is the Z-score corresponding to the significance level (α=1.96 for a 5% significance level).
- Zβ is the Z-score corresponding to the desired power of the test (1−β=0.84 for 80% power).
- α is the significance level (0.05 for 95% confidence).
- β is the Type II error rate (0.20 corresponding to 80% power)

The required sample size is 82 per each group.

By taking a contingency of 5%, the sample size becomes 86 individuals per each group.

Thus, the total sample for both groups was 86x2= 172. Therefore 172 participants were involved in the study.

4.5.2. Sampling Technique

By taking the prevalence of cases done within one year, an average prevalence of three months was taken to avoid seasonal variations. From this situational analysis of the three hospitals, total of N= 717 parturients underwent elective cesarean sections under spinal anesthesia, and from sample size n=172.Systematic random sampling techniques was used for this study and the sample interval was calculated as Kth = N/n= 717/172 ≈ 4.Since the random sampling interval is about 4, after randomly picking the first study participant using a lottery method from the numbers 1 to 4 and the chosennumber was three, data were collected every fourth interval until the required sample size was reached during the study. The required sample size for each hospital was calculated by proportional allocation from a total sample size using this formula (sample size/population size) x hospital size.

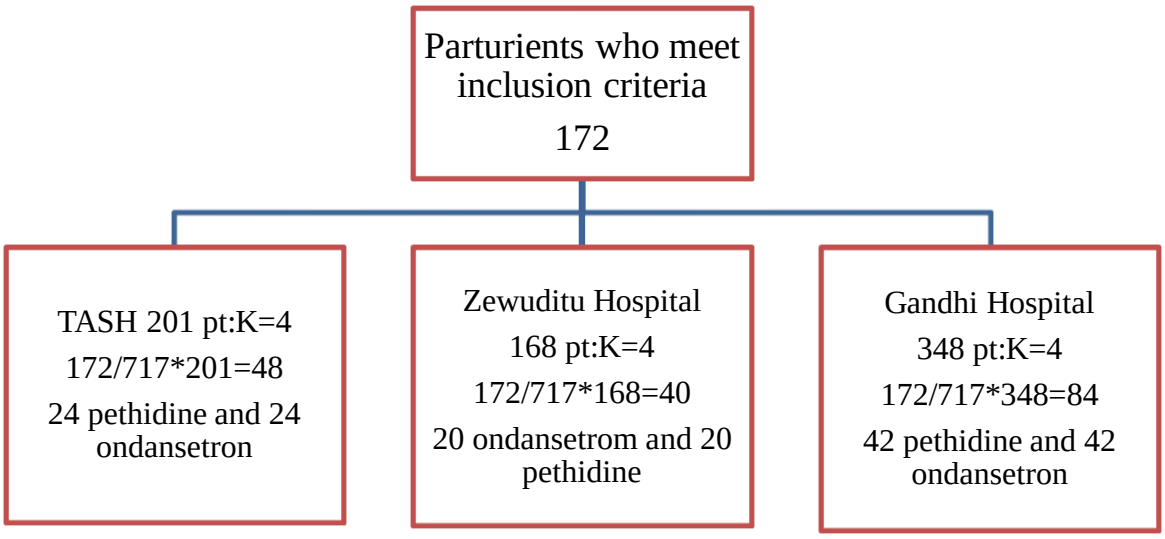

Figure 2: Schematic representation of sampling procedure for comparison of incidence of shivering in ondansetron and pethidine groups.

4.6. Study Variable

4.6.1. Dependent Variables

- Incidence of shivering after spinal anesthesia
- Severity of shivering after spinal anesthesia
- Incidence of post-operative nausea and vomiting

4.6.2. Independent Variables

- Socio-demographic data
    - Age
    - BMI(body massindex)
    - Height
- Surgical factors
    - Blood loss
    - Duration of surgery
- Anesthetic factors
    - Fluid intake
    - Level of sensory block of SA
- Base line body temperature
- Room temperature

4.7. Operational Definitions

Post-operative shivering: shivering that occurs within the first one hour post-surgery and assessed as yes or no in this study

The Bedside Shivering Assessment Score (BSAS) is used to grade the severity of shivering(46).

Grade 0: None: No shivering noted on palpation of the masseter, neck, or chest wall.

Grade 1: Mild: Shivering localized to the neck and/or thorax only.

Grade 2: Moderate: Shivering involves gross movement of the upper extremities (in addition to the neck and thorax).

Grade 3: Severe: Shivering involves gross movements of the trunk and upper and lower extremities

Parturients- a pregnant woman at term undergoing elective cesarean section under spinal anesthesia

Nausea -a sensation of urge to vomit after a study drug assessed as mild and severe nausea

Vomiting –forceful expulsion of gastric contents after a study drug assessed as mild and severe

Pethidine group –Parturients who received pethidine 0.4mg/kg after delivery of the baby.

Ondansetron group – Parturients who received ondansetron 8mg IV after delivery of the baby

4.8. Data Collection Procedure and Tool

All parturients scheduled for elective cesarean sections at selected hospitals that fulfill the inclusion criteria were assessed after written informed consent was taken. After the parturient entered to the operation room (OR) and lay on the table, standard anesthesia monitoring (blood pressure (BP), electrocardiography (ECG), and arterial oxygen saturation (SPO2) pulseoximetry was attached, and baseline vital signs were recorded in the left lateral position, and the parturients were orally informed for axillary temperature measurement. After that double intravenous line (IV) line placements were assured and metoclopramide 10 mg IV was given for aspiration prophylaxis for both groups. The parturient was resuscitated with 15 ml/kg crystalloid which was warmed to 37◦.Then; the parturient was positioned for spinal anesthesia.After possible aseptic technique was done spinal anesthesia was given with 2-3 ml of 0.5% hyperbaric bupivacaine alone between the lumbar L3-L4 interspace and normal saline fluid was given intraoperatively. The parturients were positioned supine with their heads and shoulders supported on a pillow and tilted to a 15-degree left lateral position. Level of anesthesia was assessed by cold sensation using alcohol, pinprick, and the Bromage scale for autonomic, sensory, and motor block. Immediately after delivery of the baby, the responsible anesthetist gave 8 mg of ondansetron or 0.4 mg/kg of pethidine.This drug dosage was chosen based on prior studies' recommendations for the prevention of postoperative shivering in parturients undergoing cesarean section under spinal anesthesia while also minimizing postoperative nausea and vomiting. Also, they are appropriate doses for maternal and fetal well-being(35,47). Here, if the responsible anesthetist didn’t give either of these drugs or this specific dose, those parturients were excluded from the study. The data collectors observed the parturient every ten minutes after administration of the study drug up to postoperative one hour for the incidence of shivering and recorded the onset

time of shivering, the grade (severity) of shivering, the temperature, and any side effects such as nausea and vomiting, as well as any medication given for the treatment of shivering, including the dose.The parturient that develops shivering grade ≥ 2 was given tramadol 50mg IV and those who develop frequent vomiting were given 10mg IV metoclopramide.

The above procedures were regular practices in anesthesia in selected hospitals.Data were collected by BSc and MSc anesthetists and PACU nurses at the workplace.

4.9. Data quality control and assurance

After training was given for data collectors and supervisors about the proper usage of the study tool and the significance of the study, datawere collected with standardized questionnaire. Pretest was given in 5% of the calculated sample size and the results of the pretest were not included in the final analysis.The supervisor and investigator assessed the data's accuracy, completeness, and clarity.

4.10. Data Analysis

Data were entered into EpiData 3.1 and transferred into SPSS version 27.To summarize the data, tables, and figures, descriptive statistics were employed and homogeneity of variance was tested by using Levene's test for continuous data. Categorical data were analyzed using chi-square (incidence of shivering, incidence of nausea and vomiting and Parity) and Fisher's exact test (severity of shivering), and the result was displayed asnumbers and percentages.The Mann-Whitney U test was used to analyze quantitative data that were not normally distributed, and the results were displayed as median and (IQR). A difference was considered statistically significant if the p-value was less than 0.05.

4.11. Ethical Considerations

Before we start the study, ethical clearance was obtained from anesthesia department and Addis Ababa Public Health Research and Emergency Management ethical clearance committee.Additionally, a formal letter of support was sent to the responsible personnel at TASH, ZMH, and GMH to obtain permission for data collection. The appropriate authorities granted permission to collect the data.Every voluntary participant in the study was fully informed about the goal and significance of the research and we obtained written and informed consent. There were no incentives or compulsion to take part in the study. By employing a nameless

questionnaire and securely locking it, confidentiality was preserved throughout the whole trial. Only research purposes were served by theresponses.

4.12. Dissemination Plan

The result of the study will be presented to Addis Ababa University, College of Health Sciences and Medicine,Department of Anesthesiaas part of a partial fulfillment of a Master'sof Science degree in anesthesia.It will also be submitted to Addis Ababa University Library, Addis Ababa Public Health Research and Emergency Management Directorate, Tikur Anbesa Specialized Hospital, Zewuditu Memorial Hospital and Gandhi Memorial Hospital. The manuscript will be submitted to a peer reviewed journal for publication

CHAPTER FIVE: RESULT

A total of 172parturients (86 parturients in each group) were included based on whether they received ondansetron 8mg IV or pethidine 0.4mg/kg IV a response rate of 100%.

5.1. Sociodemographic Characteristics

Note: Age, Body Mass Index (BMI) and Height presented as Median ± IQR tested by Mann-Whitney U. Parity presented as number and percentage tested by Chi-square test. P- Value < 0.05 was taken as statistically significant different. IQR –Interquartile range

Table 1: Demographic characteristics between ondansetron and pethidine groups in TASH, ZMH and GMH, Addis Ababa, Ethiopia,January 1 to April 30, 2025 GC

Variables		Ondansetron (n=86)	Pethidine (n=86)	p-value
Age(Year)		28.00±7	27.00 ±7	0.801
BMI(kg/m2)		26.00±3.00	26.00±3.00	0.923
Height(m)		1.68±0.05	1.68±0.05	0.549
Parity	**Nulliparous**	28(32.6%)	31(36%)	0.630
	Multiparous	58(67.4%)	55(64%)	

5.2. Baseline hemodynamic variables comparison between the ondansetron and pethidine groups

Hint: Values are presented by; Median ±IQR, Mann-Whitney U test and p value <0.05 is statistically significant different.

Table 2: Baseline variables of ondansetron and pethidine groups in TASH, ZMH and GMH, Addis Ababa, Ethiopia, Jan 1 _ April 30, 2025 GC

Baseline hemodynamic Variables	Ondansetron group	Pethidine group	p-value
Axillary body temperature(0C)	36.30±0.10	36.30±0.10	0.406
Heart rate(bpm)	88.00±4	87.00±5	0.209
Mean arterial pressure(mmHg)	90.00 ±7	90.00±7	0.916
SPO2 (%)	98±1	98±1	0.110

There was no significant difference in length of the procedure, the degree of SA block, dose of SA, the volume of fluid given, and the estimated blood loss inboth groups astested by Mann-Whitney U test in the two groups(p-value > 0.05).

Axillary and operation theater temperature were recorded during the procedure and for one hour postoperative. The median body temperature decreased in each group, but the difference was not statistically significant (p > 0.05)between the groups as Mann-Whitney U test.

There was no statistically significant difference between the groups, as tested by the Mann-Whitney U test with p-value in various frequently recorded hemodynamic variablesp-value > 0.05.

5.3. Incidence of shivering comparisons in the ondansetron and pethidine groups

Hint: Results are displayed as: numbers & percentages, Chi-square test was used with p-value 0.502& $p < 0.05$ was considered statistical significant different.

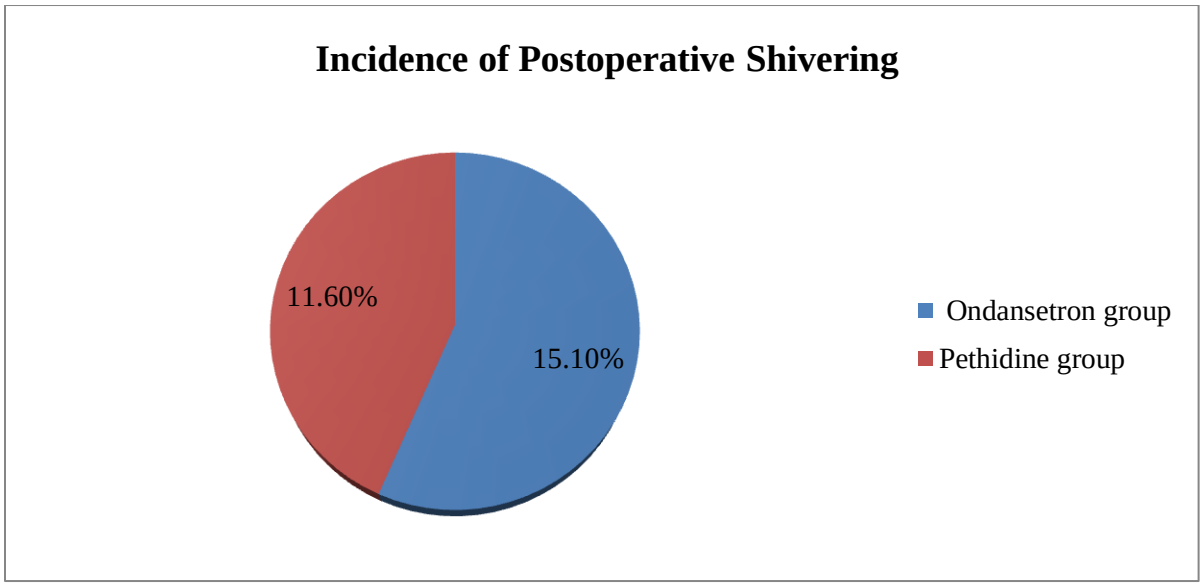

Figure 3: Comparison of Incidence of postoperative shivering between ondansetron and pethidine groups in TASH, GMH and ZMH Addis Ababa, Ethiopia, from January 1-April 30,2025 GC.

5.4. Severity of shivering comparison in the ondansetron and pethidine groups

Results are displayed by percentages, analyzed by Fisher exact testtest& p <0.05 was considered statistically significant different. P value=0.796

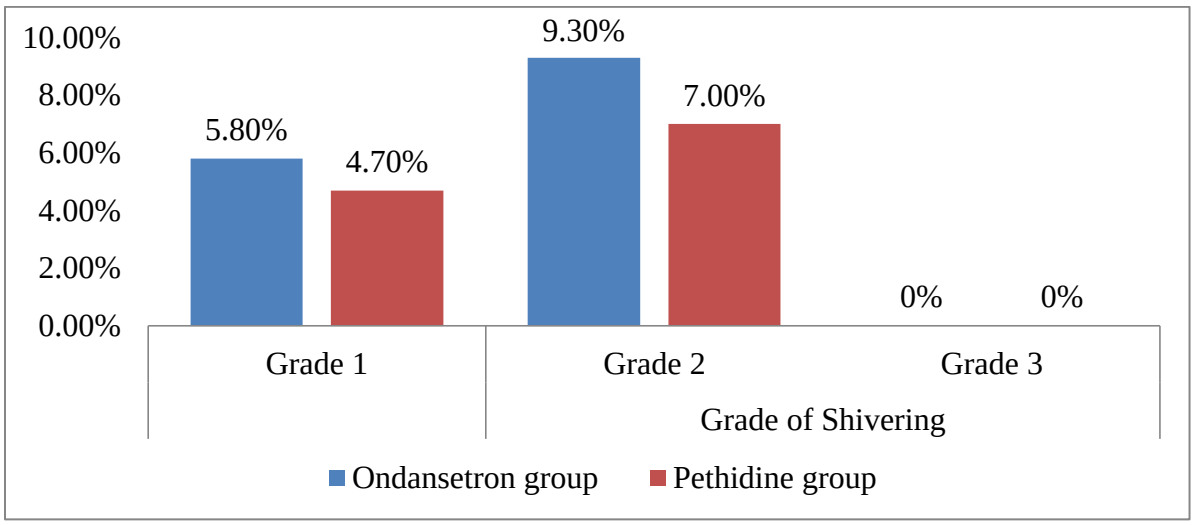

Figure 4: Comparison of severity shivering in ondansetron and pethidine in TASH, ZMH and GMH, Addis Ababa, Ethiopia,January 1 to April 30, 2025 GC

5.5. Incidence of Nausea and Vomiting comparison in the ondansetron and pethidine groups

In the incidence of nausea and vomiting there was a statistically significant difference in the ondansetron and pethidine groups with a p-value < 0.001.

Tested by Chi-square test, results are displayed by percentages by taking p < 0.05 a statistically significant different-.

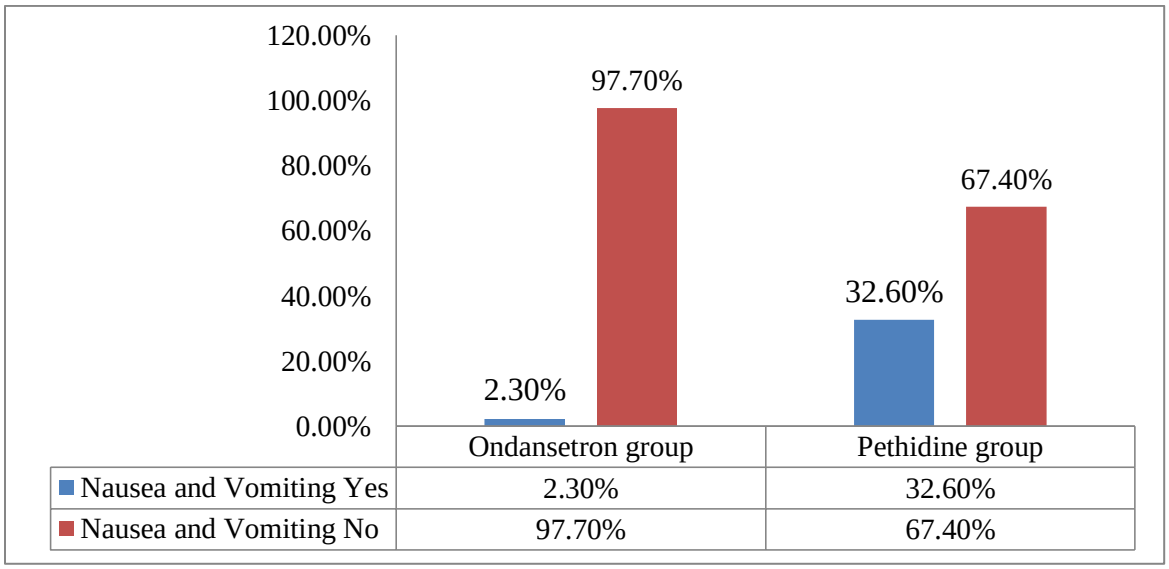

Figure 5: Comparison of incidence of nausea and vomiting in ondansetron and pethidine groups in TASH, ZMH and GMH, Addis Ababa, Ethiopia, January 1 to April 30, 2025 GC

CHAPTER SIX: DISCUSSION

Postoperative shivering is a common and troubling complication after spinal anesthesia especially in obstetric mothers(30). The study compared ondansetron and pethidine for preventing postoperative shivering in elective cesarean sections under spinal anesthesia. Results showed no significant difference in shivering incidence and severity (p-value 0.502, and 0.79 respectively), but ondansetron significantly reduced nausea and vomiting (p-value <0.001.

Increased heat loss due to lower limb vasodilatation, impairing sensory input, loss of thermoregulatory vasoconstriction below the block level and decreasing the threshold of shivering due to spinal anesthesia mainly contribute to shivering(41).

Ondansetron will prevent shivering by inhibiting serotonin reuptake in the anterior hypothalamic preoptic region, affecting both heat production and loss pathways(37). Pethidine antishivering effect is not clearly understood, but its agonist effect at κ-opioid receptors is strongly linked to the prevention of shivering(48).Ondansetron, 5-HT_3 receptor antagonist, inhibits serotonin-mediated emetogenic signals by acting peripherally on vagal nerve terminals in the gastrointestinal tract and centrally at the chemoreceptor trigger zone (CTZ)(49).

Pethidine induces nausea and vomiting by acting on μ-opioid receptors and stimulating the CTZ, slowing gastric emptying, and enhancing vestibular sensitivity(3). In obstetric anesthesia, minimizing nausea and vomiting is crucial for maternal comfort and satisfaction. Due to physiologic changes of pregnancy, parturients undergoing cesarean section are vulnerable to these side effects(50). Ondansetron, with a lower emetogenic profile, may be better suited for preventing shivering in these populations.

In line with the current study, a cross-sectional study done in Iran by Arash Karimi et al. on the comparison of the effects of 8 mg of ondansetron, 0.4 mg/kg of pethidine, and control (2 ml normal saline) in the prevention of postoperative shivering in parturients undergoing operative delivery under spinal anesthesia showed that postoperative shivering incidence was 11.4% in ondansetron group, 8.6% in pethidine , and 40% in the control group, which was significantly less in ondansetron and pethidinein comparison to control group (p = 0.03).Both studies support the use of ondansetron and pethidine as prophylactic agents against postoperative shivering, even

though pethidine has a greater effect. This consistency may be due to similar study populations, types of anesthesia and the same drug dosages(35).

In line with our result a study done in Bangladesh on comparison of control group, ondansetron and pethidine for prophylaxis of postoperative shivering in elective and emergency cesarean sections foundhighly significant difference the incidence of shivering in control group (53.33%) compared with ondansetron 8mg IV(13.33%) and pethidine 0.4mg/kg IV group(26.66%)($p<0.001$).The high incidence of shivering in the control group in Bangladesh study shows the significance of ondansetron for prevention of postoperative shivering. The disparity in the incidence of shivering in the two studies may be due to differences in study design, population (includes emergency), or perioperative management strategies. The consistency of the findings in both studies supports ondansetron is the non-opioid alternative of pethidine for prevention of shivering in parturients undergoing cesarean section(33).

In consistent with our study, another RCT conducted in 2018 in India by Gupta R. et al. compared pethidine (25mg), ondansetron(4mg), and placebo on the prevention of shivering after spinal anesthesia in parturients undergoing cesarean section. Their study finding showed that there was no significant difference in the incidence of postoperative shivering in the ondansetron and pethidine groups (p-value < 0.05). The consistency of the result of the two studies may be due to similar populations and types of anesthesia. The slight difference in the incidence of shivering in the two studies may be due to drug dosage, study design, and environmental conditions. However, both studies support the use of ondansetron as an alternative to pethidine for the prevention of shivering in parturients undergoing cesarean section under spinal anesthesia(32).

The results of this study align with a double-blinded RCT study conducted in Egypt in 2017 by Badawy et al. in parturients who underwent elective cesarean section under spinal anesthesia, which compared ondansetron 8 mg IV with a control group, and the result found ondansetron significantly reduced post-spinal shivering (26%) in parturients undergoing elective cesarean delivery compared with the control group (51%) ($p< 0.007$. The consistency in the study may be attributed to the same study population, anesthesia type, and drug dosage. The difference in the incidence of shivering in the two studies may be due to the timing of administration, sample size, study design, and environmental conditions. Both studies consistently support ondansetron as a

non-opioid alternative to pethidine for preventing shivering in parturients undergoing cesarean section (16).

Our results align with another RCT study done in India on the comparison of the efficacy of 8 mg of ondansetron with a control group for the prevention of post-spinal shivering during lower-segment cesarean section, which reported the incidence of shivering was 10% in the ondansetron group, which is statistically significantly different (p-value = 0.001). These consistent results in the two studies may be due to similar populations, similar drug dosages, and similar types of anesthesia and suggest ondansetron is effective in preventing postoperative shivering. The slight difference in the incidence of shivering in the two studies despite similar doses may be due to the timing of administration (before spinal anesthesia in the India study), study design, and environmental conditions. Both studies support ondansetron effectiveness in preventing postoperative shivering in parturients undergoing cesarean section under spinal anesthesia(51).

Our study is in contrast with a prospective RCT done in Egypt by Shabana et al. in 2018, who studied 100 parturients who underwent elective cesarean section under spinal anesthesia and found no significant differences in the incidence of shivering between ondansetron and placebo: 96% for the ondansetron group and 100% for the 0.9% saline group (P = 0.49), suggesting ondansetron was ineffective in preventing shivering. The difference in the study result may be due to the timing of administration (before spinal in the Egypt study), drug dosage (4 mg in the Egypt study), environmental conditions, sample size, and study design(52).

In contrast with this study, another RCT conducted in Egypt in 2016 by Khouly and Meligy comparing ondansetron 4 mg with placebo in parturients undergoing elective cesarean section showed that there was no significant difference in the incidence of shivering between the two groups: ondansetron (0%) and placebo (4%) (p=0.49). The discrepancy in the outcome may be due to environmental conditions, drug dosage (4 mg in Egypt's study vs. 8 mg in our study), and the study design (53).

The severity of postoperative shivering was another interest of this study. It was compared between the groups, and the difference was not statistically significant (0.796). The result showed that ondansetron and pethidine reduce the severity of shivering with complete absence of severe (grade 3) shivering.

In agreement with our study another RCT comparedondansetron 8mg and pethidine 0.4mg/kg in cesarean section under spinal anesthesia showed that they prevented sever shivering (grade 3) p>0.05.The consistency may be due tosimilar population, drug dosage and type of anesthesia. The consistency of the two results suggests ondansetron and pethidine not only reduce the incidence of shivering but also the grade of shivering(54).

This study also showed that the incidence of nausea and vomiting was 2.3% in the ondansetron group and 32.6% in the pethidine group which is statistically significant different (p-value < 0.001).This result shows the antiemetic advantage of ondansetron over pethidine when used for the prevention of shivering in parturients.

Our results align with another cross sectional study done in Iran by Arash Karimi et al. in 2021 on the comparison of the effects of ondansetron 8 mg and pethidine 0.4mg/kg for the prevention of shivering in parturients undergooperative delivery under spinal anesthesia, showed that the incidence of nausea and vomiting was significantly less in the ondansetron group (2.9%) p=0.03 than in the pethidine group (31.4 %). This parallel finding suggests the antiemetic advantage of ondansetron over pethidine in addition to reducing the incidence and severity of shivering. This consistent result may be due to the same population, drug dosage, and type of anesthesia(55).

In line with our result, another RCT study done in India on the efficacy of 8 mg of ondansetron for the prevention of post-operative shivering in parturients undergoing cesarean showed the incidence of nausea and vomiting (5%), which is statistically significantly different compared to placebo (47.5%) (P-value = 0.0001) .The parallel findings of the two studies suggest the effectiveness of ondansetron not only in the prevention of shivering but also in reducing the incidence nausea and vomiting. The consistency in the two studies may be due to similar population, type of anesthesia, and drug dosage(51) .

In agreement with our study, another RCT done by Rasheda Azzam et al. on the comparison of prophylactic intravenous pethidine versus intravenous ondansetron in the prevention of post-spinal shivering in hysterectomy showed that the incidence of nausea was 10% in ondansetron (4mg) group, and vomiting was 6.7%, while in the pethidine (0.4 mg/kg) group the incidence of nausea was 36.7% and vomiting was 26.7%, which is a statistically significantdifference. Both studies suggest that ondansetron not only reduces the incidence and severity of shivering but also

reduce the incidence of nausea and vomiting, which may be due to its 5-HT3 receptor antagonist effect. Whereas, pethidine has a tendency to activate the chemoreceptor trigger zone (CTZ), which is linked to a higher risk of nausea and vomiting(31).

Strength of the study

The study participants were comparable in terms of sociodemographic and baseline hemodynamic parameters and the same type of procedure, and it was the first of its kind in our country and was conducted in a multicenter setting.

Limitation of the study

Confounding variables that could directly or indirectly contribute to shivering are not controlled since this is not an RCT study. Due to variations in study design and degree of evidence, the comparability of results may be limited because the majority of studies utilized for comparison are RCTs.We did not assess maternal satisfaction.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.1. Conclusion

This study showed that both ondansetron 8 mg and pethidine 0.4 mg/kg effectively reduce the incidence and severity of shivering in parturients undergoing elective cesarean section under spinal anesthesia. Even though there is a slight difference in the incidence of postoperative shivering in the two groups, it was not statistically significant .Both drugs significantly reduced the incidence of severe (grade 3) shivering. Additionally, ondansetron contributed to a statistically significant decrease in the incidence of nausea and vomiting compared to pethidine. This shows ondansetron has an additional advantage as an antiemetic, which enhances postoperative obstetric mothers' comfort and satisfaction.

7.2. Recommendations

For Clinicians

We advise using ondansetron 8mg IV as an alternative to pethidine for the prevention of postoperative shivering in parturients who will undergo elective cesarean section under spinal anesthesia.

For researchers

By using this study as a reference, other large sample size, multicenter RCT studies for better randomization and control factors were recommended to confirm these findings across different populations and types of anesthesia and to investigate the most appropriate timing of administration and dosage of ondansetron to prevent postoperative shivering.

For policy makers

To give priority for non opoid alternatives for prevention of shivering in obstetric mothers and to include ondansetron in guideline for prevention of postoperative shivering.

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Annexes

Annex I; English version informed consent form.

Dear Participant_____

This is_____.I am a member of the research team the anesthesia department of Addis Ababa University. The purpose of this questionnaire is to gather information on the effectiveness of ondansetron and pethidine for prevention of shivering in patients undergoing cesarean section under spinal anesthesia. I decided to include you in this investigation with the expectation that you would be willing to help me by giving some important information. I ask you some questions that will take 5 minutes of your time. I would like to tell you that our study will not affect your anesthesia and surgical care or will not affect your quality of life in any way. You are allowed to withdraw from the study at any moment if you believe it is badly affecting you. I would like to remind you that the findings of this study will help us to treat patients like you more efficiently. We will maintain the privacy of all the information you provide. We will not include details like your name and address. Only your genuine responses could lead to improvement of our management, and we kindly request that. Please sign in the space below if you agree this study is essential. I would liketo thank you for your participation.

Sign_____date_____

For further information and question ask the investigator

Kassahun445@gmail.com

Annex II: Amharic version of the consent
የስምምነት ፎርም

እኔ----------እባላለሁ፡፡ በአድስ አበባ ዩኒቨርሲቲ የአንስቴዢያ ትምህርት ክፍል የጥናትና ምርምር አባል ነኝ፡፡ የዚህ መጠይቅ አላማ በ ቀዶጥገና ሲወልዱ ከወገብ በታች ማደንዘዣ ከወሰዱ በኃላ ለሚከሰት ብርድ ብርድ ማለት ወይም ማንቀጥቀጥ ለመከላከል የሚሰጡ መድሀኒቶችን ማለትም ኦንዳንሴትሮን እና ፔቲድንን ዉጤታማነት ለማወቅ መረጃዎችን ለመሰብሰብ ነዉ፡፡ እርስዎን ኣንዱ የጥናቱ አካል አድርጌ የመረጥኩት አስፈላጊዉንና ትክክለኛዉን መረጃዎችን እንድሰጡኝ በማሰብ ነዉ፡፡ በጥናቱ ለመሳተፍ ፈቃደኛ ስለሆኑ ከወድሁ ልባዊ ምስጋናየን እያቀረብኩ 5 ደቂቃ እንድሰጡኝ በትህትና እጠይቃለሁ፡፡ በጥናቱ ምክንያት በርስዎ ላይ ምንም አይነት የሚቀነስብዎት የህክምና አገልግሎት ወይም የሚመጣብወት የጎንዮሽ ጉዳት እንደሌለ ላረጋግጥልወት እወዳለሁ፡፡ በማንኛዉም ሰአት ጥያቄዉን አቋርጠው መዉጣት ይችላሉ፡፡ ነገር ግን የርስዎ ምላሽ ለጥናቱ ዉጤታማነት ከፍተኛ አስተዋጽኦ አለዉ፡፡

የርስዎ ምላሽ በሚሰጥር ይጠበቃል፤ለዚህም ሲባል የርስዎ ስምም ሆነ አድራሻ አይገለጽም፡፡ የርስዎ ትክክለኛ መልስ ብቻ ለጥናቱ ስለሚያግዘን ትክክለኛዉን መልስ በመመለስእንድተባበሩንበድጋሜበትህትናአንጠይቃለን፡፡በጥናቱለመሳተፍፍቃደኛከሆኑፊርማዎትን ወይምአሻራዎትንያስቀምጡ፡፡ስለተሳተፉከልብእናመሰግናለን፡፡

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Annex III: Questionnaire

1. Sociodemographic characteristics

No	Questions	Responses
1	Age	Years
2	BMI	Kg/m^2
3	Height	Cm
4	Parity	Primiparous Multiparous
5	History of previous CS	Yes :1,2,3 No
6	Do you experience shivering during previous CS	Yes No
7	Any known drug allergy	Yes, (Specify) ? No
8	Ondansetron 8mg intravenously given	Yes No
9	Pethidine 0.4mg/kg intravenously given	Yes No

2. Baseline hemodynamic parameters

1.Heart rate	
2.Blood pressure	
3.Mean arterial pressure(MAP)	
4.SPO2	
5.Respiratory rate	
6.Temperature	

3. Intraoperative Hemodynamic parameters before administration of study drugs

1.	Heart rate	
2.	Blood pressure	
3.	Mean arterial pressure	
4.	Temperature	
5.	SPO2	
6.	Respiratory rate	
7.	Room temperature	

4. Hemodynamic Parameters after administration of the study drug (ondansetron 8 mg IV/Pethidine0.4mg/kg)

Administered Study drug A. Ondansetron 8mg. B. Pethidine 0.4 mg/kg	Time	Axillary Temperature($\mathbf{C^0}$)	Blood pressure (mmHg)	SPO2	MAP	Heart rate(bpm)	RR
	At 5 min						
	10 min						
	15 min						
	30 min						
	45 min						
	60 min up to PACU						
In PACU	5 min						
	10 min						
	20 min						
	30min						
	40min						
	50min						
	60min						

5. Shivering and severity of shivering after administration of study drug

No	Question	Answers
1	Does the patient shiver	Yes No
2	Onset time first shivering after study drug	_____min
3	Severity of shivering	Grade___(0,1,2,3)
4	Anti-shivering medication used	Medication_____ Dose_____

6. Anesthesia and Surgical related factors

No	Questions	Answer
1	Duration of surgery	
2	Amount of blood loss	
3	Amount of Fluid administered	
4	Site of spinal anesthesia injection	Between L3-L4
		Other specify
5	Dose of Spinal Anesthetics	
6	Level of block for SA	

7. Any observed adverse effect

No	Questions	Answers		
1	Nausea	Yes		Mild_____
				Severe_____
		No		
2	Vomiting	Yes		One episode____
				Two or more episodes of vomiting_____
		No		
3	Anti-emetic given	Yes	Medication	
			Dose	
		No		

8. Does the parturient has any comorbidity

Questions	Answer	
Any comorbidity	Yes	Controlled hypertension
		Controlled Diabetic mellitus
		Controlled asthma
		Other
	No	