ADDIS ABABA UNIVERSITY

COLLEGE of HEALTH SCIENCE

DEPARTMENT OF ANESTHESIA

EFFECT OF LOW DOSE INTRATHECAL PETHIDINE ADDED TO BUPIVACAINE ON PREVENTION OF INTRAOPERATIVE SHIVERING AMONG GERIATRIC PATIENTS UNDERGOING ELECTIVE SURGERY UNDER SPINAL ANESTHESIA AT PETER SPECIALIZED HOSPITAL: PROSPECTIVE COHORT STUDY FROM JANUARY 1/23-APRIL 30/23.

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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.

Assurance of principal investigator Name: _____Signature _____Date. _____

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List of acronym and abbreviation

AAU: Addis Ababa University

ASA: America society of anesthesiologist

BMI: Body mass index

C/S: Caesarean section

HCL: Hydrochloride

HR.: Heart rate

IT: Intrathecal pethidine

KG: Kilo gram

MAP: mean arterial pressure

MG: Milligram.

MIN: minutes

ML.mil liters

NSAID: Non steroid anti-inflammatory drug

OR: operation room

RCT: Random control trial

SAB: Sub arachnid block

SPO2: oxygen saturation

TO: axillaries temperature

TURP: Transurethral resection of the prostate

WHO: World health organization

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Abstract

Background: Shivering is one of the most common unpleasant problems associated with spinal anesthesia, causing dissatisfaction and undesirable complications in patients undergoing elective surgery under spinal anesthesia. However, the prevention of shivering has not been thoroughly investigated. This study aims to assess the effect of low-dose intrathecal pethidine on the prevention of intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia.

Objective : The objective of this study is to compare the effect of low-dose intrathecal pethidine (0.2mg/kg) added to bupivacaine and bupivacaine alone on the prevention of intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia at St Peter Specialized Hospital from January 1/23 to April 30/23.

Methods: A Prospective cohort study was conducted. The study participants were allocated into two groups: those given low-dose (0.2mg/kg) intrathecal pethidine with bupivacaine and those given bupivacaine alone, based on the medication administered by the responsible anesthetist. The data were analyzed using student's t-test or Mann–Whitney U test, based on the normality of distribution, and the results were presented as mean ± SD. The categorical data were analyzed using the chi-square test, and the results were presented as frequency and percentage. A p-value of less than 0.05 was considered statistically significant.

Results: The incidence of shivering was observed to be 72.4% in the non-exposed group and 24.14% in the exposed group, which is statistically significant with a p-value <0.05 (0.0000…). Additionally, there was a stastiscally significant difference the intensity of shivering between the two groups, with p- value of <0.05 (0.003).

Conclusion: Administering a low dose (0.2mg/kg) of intrathecal pethidine with bupivacaine is effective in reducing the incidence and intensity of intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia, although it may cause mild pruritus.

Keywords: Shivering, low dose intrathecal pethidine, bupivacaine, geriatrics, elective surgery, spinal anesthesia.

Chapter One: Introduction

1.1. Background:

Shivering is defined as spontaneous, rhythmic, oscillatory, tremor-like muscular hyperactivity that occurs as a physiological stress response to core hypothermia in an attempt to raise metabolic heat production. It is unpleasant and undesirable complication that occurs after subarachnoid block (SAB) and is primarily caused by sympathetic blockade-induced vasodilatation. Mainly occurs in hypothermic patients but may also occur in normothermic individuals (1).

Shivering is an uncomfortable and distressing complication after surgery, ranging from mild symptoms such as skin eruptions to severe forms with generalized continuous skeletal muscle contractions. It interferes with the monitoring of electrocardiograms (ECG), blood pressure (BP), and oxygen saturation. It also increases oxygen consumption, lactic acidosis, and carbon dioxide production, and decreases patient satisfaction while increasing discomfort (2).

Most elderly patients undergoing surgery are likely to have cardiovascular and pulmonary disorders (30% to 60%). Therefore, they are vulnerable to shivering complications, including increased oxygen consumption and carbon dioxide production. This can be dangerous for patients with limited ventilator and cardiac reserve (3). Furthermore, shivering can lead to surgical difficulties, dislodging clots, and increasing postoperative bleeding (4).

The shivering scale developed by Crosley and Mahajan classifies shivering during surgery into five categories based on the level of muscular activity: zero (no apparent symptoms of shivering), one (piloerection or peripheral vasoconstriction without apparent shivering), two (where only one muscle is active), three (widespread shivering involving a few muscle groups), and four (total body shaking) (5).

Pethidine, an opioid with substantial kappa agonism and a phenylpiperidine derivative, has a molecular structure similar to local anesthetics. It has been used as a sole intrathecal anesthetic for surgery due to its ability to stabilize membranes and provide surgical pain relief with comparatively low side effects. Limited motor blockade caused by intrathecal pethidine may allow for earlier postoperative movement (5). Meperidine HCl, another name for pethidine, has a

history of use for shivering, a relatively frequent complication associated with spinal and general anesthesia that can be distressing to patients and occasionally result in deleterious consequences (6).

Spinal anesthesia-induced sympathetic blocking and vasodilatation redistribute heat and alter the thermoregulatory system in the hypothalamus, leading to hypothermia. Shivering increases metabolic activity and oxygen consumption by up to 200-500%. It causes arterial hypoxia and has been shown to correlate with an increased risk of myocardial ischemia. It also increases intraocular and intracranial pressure and has other effects such as increased cardiac output, peripheral vascular resistance, carbon dioxide production, prolonged coagulation, stress response, and lactic acidosis. Additionally, shivering interferes with ECG monitoring and pulse oximetry due to motion artifacts (7).

Elderly individuals are more prone to hypothermia due to their decreased ability to regulate body temperature through vasoconstriction, shivering, and loss of muscle, fat, and subcutaneous tissues. Furthermore, their reduced physiological reserves increase the risk of hypothermia-related adverse events. Therefore, the prevention of inadvertent hypothermia should be mandatory for elderly patients undergoing elective surgery (8).

Shivering during neuraxial anesthesia may interfere with the monitoring of blood pressure, electrical diagrams, and pulse oximetry, in addition to reducing patient comfort and satisfaction (9).

1.2. Statement of the problem

The range of post-anesthesia incidence of shivering is from 5% to 65% after general anesthesia and 55% after spinal anesthesia, making it one of the most frequent and unwelcome complications that cause discomfort and dissatisfaction in patients (10).

Post-anesthetic shivering and significantly reduced thermal comfort is common negative effects during the initial postoperative period (11).

During and after subarachnoid anesthesia, the threshold for shivering may decrease as hypothermia due to vasodilatation, leading to heat loss and peripheral redistribution of heat. Although it is usually not fatal, it can have serious consequences for patients with a history of cardiac or pulmonary problems, such as increased oxygen consumption (12).

Elderly patients undergoing spinal anesthesia are more likely to have respiratory and cardiovascular problems (30% to 60%), making them more susceptible to shivering and its side effects, including increased oxygen demand and carbon dioxide production. This necessitates an increase in cardiac output and minute ventilation, which can be harmful in individuals with low cardiac and ventilator reserve (13).

Shivering can have detrimental cardiovascular effects and also complicate surgery, displace clots, and increase postoperative bleeding (4).

HYPOTHESIS

1. HO,.Adding low dose intrathecal pethidine has no effect on intraoperative shivering
2. HA, Adding low dose intrathecal pethidine has effect on intraoperative shivering

1.3. Significance of the study

Elderly patients undergoing neuraxial anesthesia are more susceptible to hypothermia and shivering, which can increase oxygen consumption, ventilation, and cardiac output (14). Regional anesthetics cause vasodilatation in the skin's blood vessels, leading to an inability to maintain homeostasis, especially in elderly surgical patients, as it increases blood flow to the skin and heat loss. According to a study, older individuals who are prone to shivering-related oxygen consumption, metabolic demands, and cardiovascular morbidities benefit the most from the preventive effect of adjuvant low-dose intrathecal Meperidine to bupivacaine against shivering (15). The findings of this study will serve as input for future researchers. It will increase the knowledge of healthcare providers regarding the incidence of shivering after neuraxial block and support evidence-based, high-quality care. Furthermore, it will help bridge information gaps by exploring the combination of low-dose intrathecal pethidine with bupivacaine to prevent intraoperative shivering, particularly in elderly patients undergoing elective surgery under spinal anesthesia who have insufficient compensatory responses to shivering. This study can serve as a starting point for future research on this topic of interest.

Chapter Two: Literature review

A prospective trial conducted in Ludhiana, India, in 2014 defined shivering as morbid and uncomfortable for patients. It can make monitoring of ECG, blood pressure, and pulse oxygen saturation difficult. Shivering also increases oxygen use, lactic acidosis, and carbon dioxide production, putting patients at risk for damage if they have a low cardiopulmonary reserve (16).

An observational prospective study conducted in hospitals in the sub-Saharan area in 2016 found that post-surgical shivering presents in various categories, ranging from a minor form that causes skin eruptions to a severe form that causes persistent shaking of 50-80% intensity (17).

In a randomized controlled trial conducted in Iran in 2007, 80 patients scheduled for TURP under spinal anesthesia were divided into case and control groups to examine the effectiveness of adding low-dose intrathecal pethidine to bupivacaine. In the case group, spinal anesthesia was administered using 75 mg of hyperbaric lidocaine 5% in addition to 15 mg of Meperidine. Shivering episodes were observed throughout the procedure and in the recovery area.

Measurements of systolic blood pressure, heart rate, arterial oxygen saturation, and body temperature were taken before the induction of anesthesia, as well as 5, 15, and 30 minutes after the induction, and in the recovery room. The incidence of shivering was 0% in the Meperidine group, while it was 27.5% in the control group (4).

In quasi-experimental research conducted in Indonesia in 2019, it was found that the elderly are more prone to hypothermia compared to adults. The study's findings showed that patients between the ages of 41 and 65 accounted for 46.7% of those who had hypothermia, while the incidence rate for patients between the ages of 18 and 25 was 13.3%. Spinal anesthesia delayed shivering compensations and resulted in hypothermia in the elderly compared to adults (18).

The efficacy of intrathecal lipophilic opioids in decreasing the incidence of shivering in women undergoing cesarean delivery under spinal anesthesia was systematically examined in 21 studies involving 1433 patients at Western University. Intraoperative shivering was much less common in the intrathecal Meperidine group compared to the control group (2.7% vs. 13.6%). However, nausea and vomiting were significantly more common in the intrathecal Meperidine group compared to the control group (19).

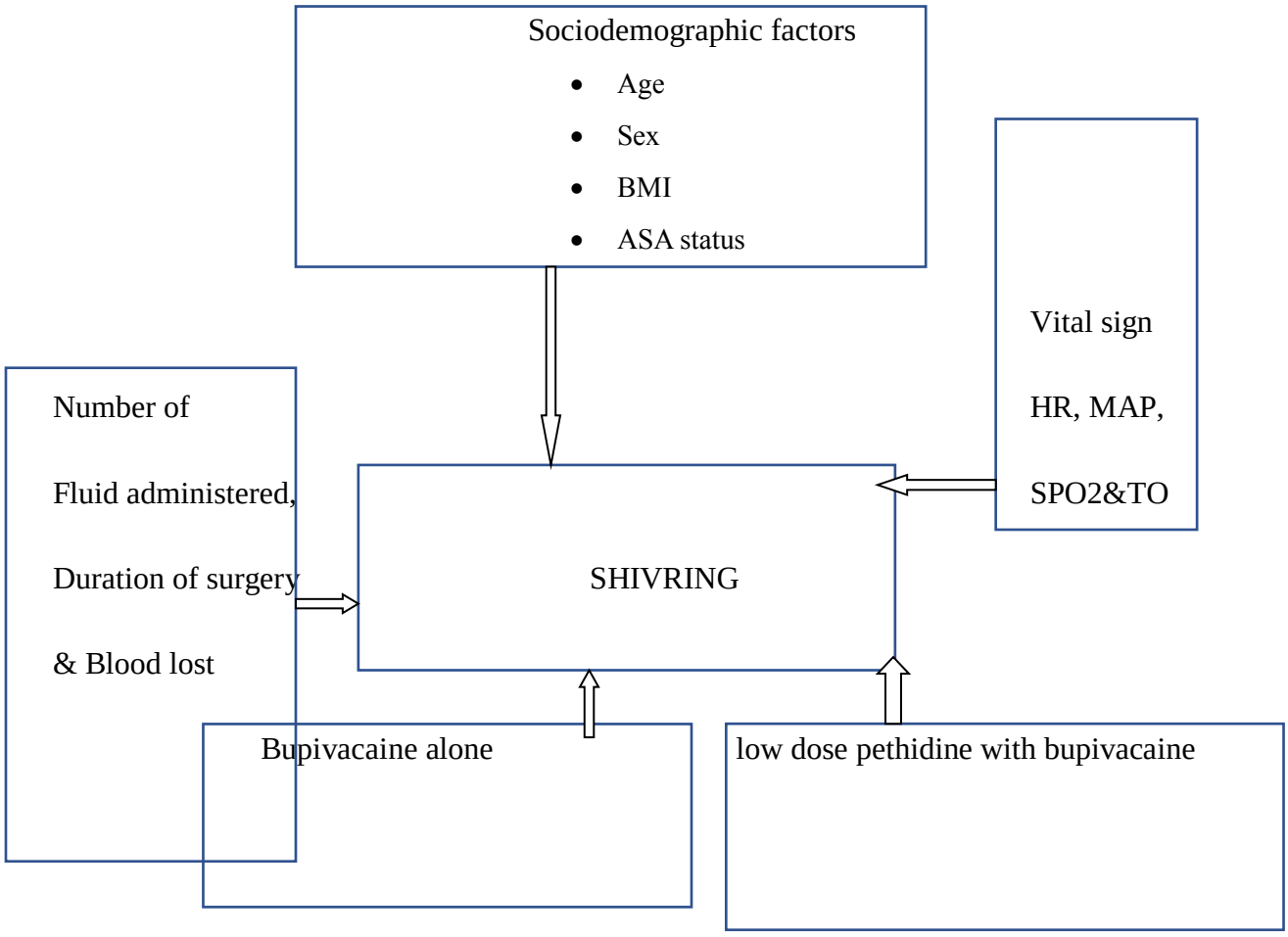
A study conducted in South Korea in 2010 investigated whether intrathecal Meperidine (0.2 mg/kg) reduces the frequency and severity of shivering following spinal anesthesia for transurethral procedures. Fifty patients scheduled for elective transurethral resection surgeries under spinal anesthesia were randomly divided into two groups. The Meperidine group received Meperidine (0.2 mg/kg) and 0.5% hyperbaric bupivacaine (8 mg), while the saline group received normal saline. The Meperidine group had significantly fewer cases of shivering compared to the saline group (4% vs. 32%, respectively) (20).

In another study, a randomized trial included 150 pregnant women without an urgent need for a C-section who were randomly assigned to three groups. In the standard group (S group), spinal anesthesia was administered using 0.5% hyperbaric bupivacaine (12.5 mg) along with 0.5 mL of 0.9% saline. The P5 group received the same amount of bupivacaine along with 5 mg of pethidine, and the P10 group received 10 mg of pethidine. When compared to the S group, both the P5 and P10 groups showed significantly lower incidence and severity of shivering (21).

In an Iranian double-blind randomized controlled trial, the effectiveness of intrathecal Meperidine was compared with intravenous ketamine in preventing shivering during spinal anesthesia for lower limb orthopedic surgeries. Patients in the control group exhibited more intense shivering than the other groups at all examination time points (20, 60, 80, 100, and 120 minutes following spinal anesthesia). The incidence of shivering at 20 and 60 minutes after the start of spinal anesthesia was 2.855% and 1.775% in the ketamine and Meperidine groups, respectively, while it was 4.62% in the control group. However, there were no significant differences in the frequency of nausea, vomiting, or pruritus between the three groups (22).

Conceptual frame work

This conceptual framework was created by studying various preoperative shivering-related literatures to show different factors affecting shivering.



Chapter Three: Objective of the study

3.1. General objective

- ✓ To assess the effect of adding low dose intrathecal pethidine (0.2mg/kg) with bupivacaine on prevention of intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia at St Peter Specialized Hospital from Juanuary01/23 to April 30/23.

3.2 .specific objective

- ✓ To compare the incidence of intraoperative shivering between groups
- ✓ To compare the intensity of intraoperative shivering between groups

Chapter Four: study methods and materials

4.1 study area and period

The study was conducted at St Peter specialized Hospital from January 01/23 to April 30/23. St Peter Specialized Hospital is located in Addis Ababa, Ethiopia. It was established in 1953 EC. The Hospital is the country's first TB specialized referral Hospital. Currently it provides surgical services for more than 500 patients per month. It has six operation rooms and three ICU room with a total of 12 beds. It provides surgical service for Orthopedic, urologic, Maxilla-facial, neurologic, C/S, Gynecologic, Pediatric, plastic, and emergency procedures.

4.2 Study design

Observational prospective cohort study was conducted using a two-arm model, one model was low dose (0.2mg/kg) intrathecal pethidine with bupivacaine and the other model was bupivacaine alone groups. The incidence and severity of shivering is assessed based on shivering scale measurement.

4.3 population

4.3.1 Source of population

All patients admitted for elective surgery under spinal anesthesia at St Peter Specialize Hospital from Juanuary1/2023 to April 30/2023..

4.3.2 Study population

All geriatrics patients admitted for elective surgery under spinal anesthesia fulfill inclusion criteria at St Peter Specialize Hospital from Juanuary1/2023 to April 30/2023.

4.4. Eligibility

4.4.1 Inclusion criteria

All geriatrics patient aged >65 and admitted for elective surgery under spinal anesthesia at St Peter Specialize Hospital from Juanuary1/2023 to April 30 2023will be included in the study.

4.4.2. Exclusion criteria

- Patients unable to understand oral or written information
- Patient taking opioids and NSAIDs
- Premedicated with dexamethasone
- Premedicated with paracetamol
- Allergy to narcotics
- Patient who takes MO inhibiters
- Patients preloaded with warm fluid
- Patients who received other than pethidine with bupivacaine and bupivacaine alone for spinal anesthesia

4.5. Sampling technique and sample size determination

4.5.1. Sample size determination

Sample size for the study was calculated using double population proportion formula for comparison of two proportion with equal sample size Sample size for the study was calculated using double population proportion formula for comparison of two proportions with equal sampling size based on the following assumption significance level 5% (α= 0.05), power of study (1-β) of 80%.

Incidence of shivering which was done in South Korea for exposed groups low dose (0.2mg/kg) pethidine with bupivacaine was (4%) non-exposed group was (32%) respectively: based oon double population proportion formula sample size =n

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

=27 per each group

n = Sample size in each group

α =significance level (1.96)

1-β=power of study at 80% (0.84)

q1= 1-p1

q2=1-p2

P1= low dose intrathecal pethidine with bupivacaine exposed group

P2= bupivacaine alone in non-exposed group

By considering a contingency of 5%, the sample size becomes 29 individuals per each group. Thus, the total sample for both groups was 29x2= 58. Therefore 58 participants were involved in the study.

4.5.2. Sampling technique

We planned to use a systematic sampling technique to get the required sampling size during the study period. According to situational analysis of logbook in last 3 months, approximately 80 elective geriatrics patients underwent elective surgery under spinal anesthesia for different surgical procedure. Therefore, we included every patient who fulfilled the inclusion criteria to the study until the required sample size was fulfilled in each group. Study participants assigned to bupivacaine and Pethidine (Group BP) or bupivacaine alone (Group B) based on the type of medication they received by the responsible anesthetist managing the case. In St Petro's hospital, most anesthetists use either Pethidine with bupivacaine or bupivacaine alone to administer spinal anesthesia (SA).

4.5.3. Data Collection

Data was collected using structured questionnaire once data collectors have received one day training. BSc and MSc anesthetist were assigned to collect data.

When the patients brought to the operating room, they were assessed by data collectors on the waiting room if they fulfilled the inclusion criteria. The premedication history, drug history and the sociodemographic variables were checked and baseline vital signs recorded before they receive SA.

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4.6. Variable

4.6.1. Dependent variable

- Intraoperative shivering

4.6.2. Independent variable

- Sociodemographic characteristics (age, sex, weight, height, BMI, ASA)
- Type of procedure
- Base line vital sign
- Duration of surgery
- Blood loss
- Fluid intake
- Type of medication received for SA
- Intraoperative hemodynamic changes
- Intraoperative complications

4.7. Data quality assurance

Pretest of the questionnaire was done on 5% of the sample size before actual data collection. Data collectors and supervisors were given half day training about the objective of the study and each component of the questionnaire.

During data collection, regular supervision and follow up was made. The principal investigator cross checked the filled questionnaire for completeness.

4.8 Operational Definitions

Geriatrics: means according to WHO definition patients with age>65 years-old

Elective surgery: procedures which is done on schedule.

Hypothermia- a core body temperature less than 35 ^{0}C.

Post spinal Intra operative shivering: shivering occurring after spinal anesthesia was administered

Tachycardia: heart rate greater than 100

ASA status: - American society of anesthesiologist validated surgical risk stratification
ASA 1- patients without any co morbidity except the cause for the surgery

ASA2- patient with mild or controlled systemic disease

ASA3- patient with uncontrolled or severe systemic disease

ASA4 –patient with a severe systemic disease that is a constant threat to life.

The severity of shivering is classified into 5 groups based on muscular activities:

The shivering scale developed by crossly and Mahajan classifies shivering during surgery into five categories based on the level of muscular activity (5).

Zero (no apparent symptoms of shivering).

One (piloerection or peripheral vasoconstriction without apparent shivering).

Two (where only one muscle is active).

Three (widespread shivering involving a few muscle groups).

Four (total body shaking)

4.9. Data processing and analyzing

After data collection, Data was checked manually for completeness and then coded and entered into the SPSS version 26 software for analysis.

Normality test was done using histogram Shapiro Wilk& plot as well as homogeneity of variance was checked using Levine's test. The Checked data were not normally distributed (age, weight, height, vital sign, amount of fluid, amount blood lost and duration of surgery). Therefore, non-parametric tests were used to analyze the data. The continuous data (age, weight, height, vital sign, and amount of fluid, amount blood lost and duration of surgery) were analyzed using Mann– Whitney U test.

The categorical data were analyzed using chi-square test. The result was presented in frequency & percent. P-value of less than 0.05 was considered statistically significant.

4.10. Ethical considerations

Ethical approval was obtained from the ethical review board of college of medicine and health sciences, AAU before the start of data collection. Then, permission letter was submitted to St Peter Hospital administration office explaining the objective and purpose of the research with a copy of the ethical approval letter. Data collectors took informed consent from each study participant before data collection. The privacy of study participants were kept at every stage of data collection.

4.11. Dissemination plan

The study result will be submitted to Addis Ababa University, college of medicine and health sciences, department of anesthesia. It will be presented on anesthesia research conference. The finding will also be published in reputable journals to reach the vast scientific community around the world.

Chapter Five: Results

During the study period, a total of 58 ASA (II) and ASA (III) patients were included in the final analysis based on they received a low dose (0.2mg/kg) of intrathecal pethidine with bupivacaine or bupivacaine alone during spinal anesthesia.

The findings of this study indicated that there was no statistically significant difference in sociodemographic variables between the two groups, with a p-value > 0.05.

The incidence of shivering showed a statistically significant difference between the two groups, with 24% and 72% for bupivacaine with pethidine and bupivacaine alone groups, respectively (Table 3). The intensity of shivering was lower in the exposed compared to the non-exposed group, with a p –value of 0.003.

Among the intraoperative complications, eight out of nine patients in the exposed group developed pruritus, accounting for 27.5%, while only one patient in the non-exposed group developed pruritus, accounting for 3.4%. This demonstrated a significant difference in the incidence of pruritus between groups, with a p-value < 0.05 (0.011). However, none of the patients required treatment for pruritus.

Regarding intraoperative nausea and vomiting, three patients (10.3%) in the exposed group and four patients (13.7%) in the non-exposed group developed these symptoms. There is no statistically significant difference between the two groups in terms of nausea and vomiting, with a p-value of 0.687.

5.1. Sociodemographic characteristics

The distribute of sociodemographic characteristics including age, height, weight, ASA classification, and gender was compared between the groups.

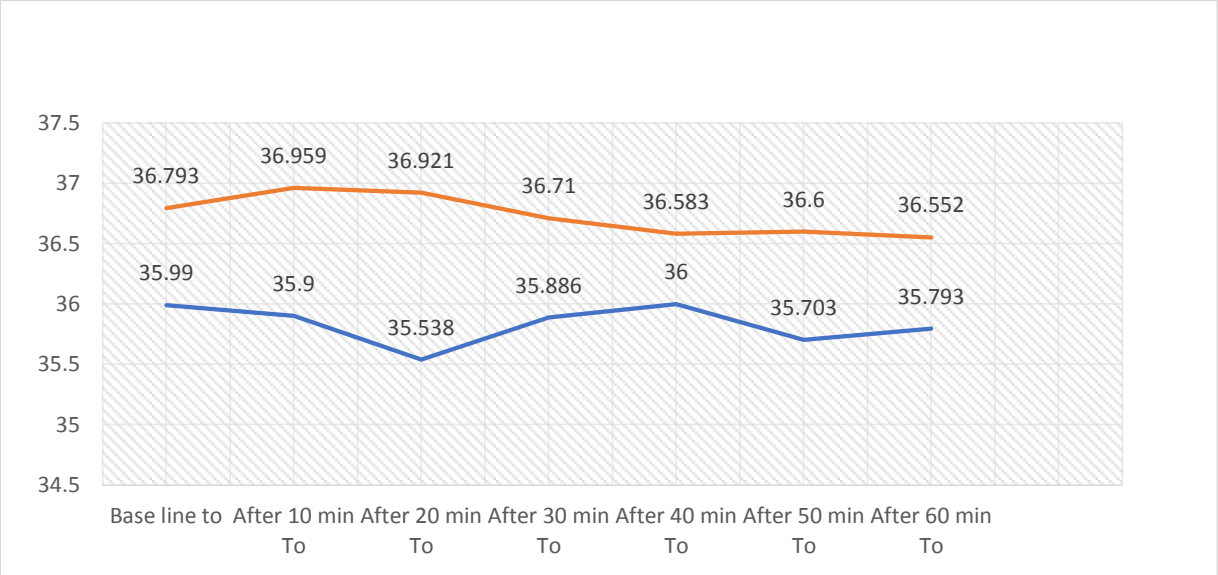
The results showed no significant difference between the two groups.

Table I: Demographic Characteristics of geriatric patients undergoing elective surgery under spinal anesthesia at St. Peter Specialized Hospital, Addis Ababa, Ethiopia, from January 1 to April 30, 2023.

Variable	Exposed group	Non exposed group	P value
Age	69.1±4.83	68.897±3.9582	0.78
Height	161.6217. ±3747	158.172±6.0773	0.211
Weight	63.345±7.6171	61.103±7.2867	0.819
Gender M/F	16/13	9/20	0.060
ASA 2/3	25/4	25/4	0.647

5.2. Intraoperative Hemodynamic measurement

Saturation Heart rate, temperature& Mean Arterial Pressure were measured and recorded every 10 minutes, there was no statistically significant difference between groups in vital sign except axillary temperature which is significant with p _value <0.05 .



Key. Non exposed groups exposed groups

Figure (I): Represents mean temperature difference between groups.

5.3. Intra operative condition

Table II: Type of surgery, fluid intake duration surgery and amount of blood lost among geriatrics patients undergoing elective surgery under spinal anesthesia at ST Peter Specialized Hospital, Addis Ababa Ethiopia, from January 0123 to April 3023.

Variable Surgery type	Exposed group	Non expose group	P value
Proctectomy	5	4	0.67
Herniorrhaphy	10	2	
Vein ligation	2	3	
Hemorrhoidectomy	2	6	
Orthopedics	1	5	
other procedure	9	9	
Duration	102.758±29.0193	100.690±24.1914	0.911
Fluid take	1065.517±609.6110	1103.448±8888.2096	0.938
Blood lost	258.276±115.51	260±130.9580	0.752

Table II: intrar operative value between groups showed no significant difference with a p- value> (0.05)

5.4. Incidence and Intensity

Incidence and intensity of shivering among geriatrics patients undergoing elective surgery under spinal anesthesia in ST Peter Specialized Hospital, Addis Ababa Ethiopia, from January 0123 to April 3023.

Table III: Incidence of shivering between groups showed significant difference with a p- value < (0.001)

Variable		Exposure group	Non exposure group	P value
Shivering	Yes	7(24.14%)	21(72.4%)	0.00000….
	no	22(75.86%)	8(27.6%)	

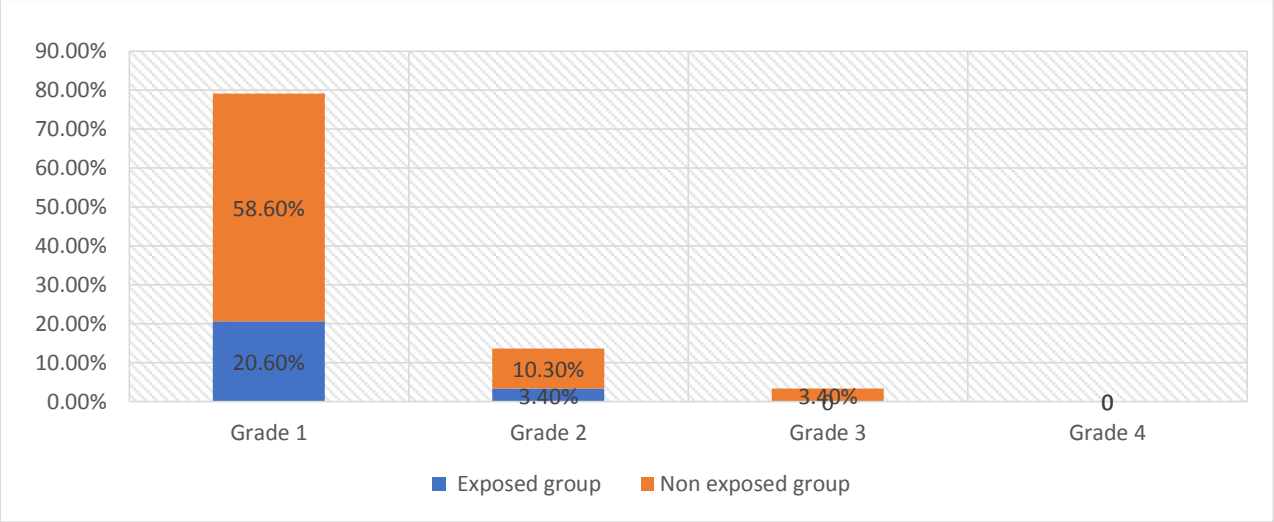


Figure (II): severity of intra operative shivering showed significant difference between the groups with p -value less than 0.05

5.5. Intra operative complication

The comparison of intraoperative complications between the exposed group and non-exposed group showed that there was no significant difference in the incidence of nausea and vomiting, with a p-value greater than 0.05 (0.687). However, A significant difference in the incidence of pruritus, with a p-value less than 0.05 (0.01). The exposed group had a higher incidence of pruritus (27.5%) compared to the non-exposed group (3.4%).

Table 4: Intraoperative Complications in Geriatric Patients Undergoing Elective Surgery under Spinal Anesthesia at St. Peter Specialized Hospital, Addis Ababa, Ethiopia, from January 0123 to April 3023

Variable		Exposed group	Non exposed group	P value
complication	pruritus	8(27.5%)	1(3.4%)	0.01
	Nausea and vomiting	3(10.3%)	4(13.7%)	0.687

Chapter Six: Discussion

Shivering is a troublesome side effect of spinal anesthesia (SA).Meperidine HCl has been historically used to manage shivering (6).

This study demonstrated that the administration of 0.2mg/kg of intrathecal pethidine with bupivacaine effectively reduces the incidence and intensity of shivering during surgery.

This finding revealed a significant difference in the incidence and severity of intraoperative shivering between the groups, with p-values < 0.05. However, there were no significant differences between the groups in terms of sociodemographic factors, intraoperative values, intraoperative vital signs (except temperature), and nausea and vomiting ($p=0.687$).

This study results are consistent with a study conducted in South Korea by Chun D-H, Kill H, Kim H-J, Park C, and Chung K-H. In their study, "Intrathecal Meperidine reduces intraoperative shivering during transurethral prostatectomy in elderly patients," they found a significant difference in the incidence and intensity of intraoperative shivering between the groups, with a p-value < 0.05. The incidence of intraoperative shivering was 32% in the non-exposed group and 4% in the exposed group.

However, their study did not find significant differences in sociodemographic factors, intraoperative vital signs (except body axillary temperature), intraoperative complications of nausea and vomiting & pruritus between the groups (21).

Furthermore, our findings align with an RCT study conducted in Iran in 2007. In this study, 80 patients scheduled for transurethral resection of the prostate (TURP) under spinal anesthesia were divided into case and control groups to investigate the effectiveness of adding low-dose intrathecal pethidine to bupivacaine on prevention of intraoperative shivering

This studies by Davoudi M, Mousavi-Bahari SH, and Farhan chi Demonstrated a significant difference in the incidence and severity of intraoperative shivering between the groups, with a p-value < 0.05. The incidence of intraoperative shivering was 27.5% in the non-exposed group and 0% in the exposed group. Similar to this study, their study did not find significant differences in sociodemographic factors, intraoperative vital signs , intraoperative complications between the groups (4).

In line to our findings, a study conducted in South Korea by Chun D-H, Kill H, Kim H-J, and Park C revealed a significant difference in the incidence and severity of intraoperative shivering between the groups, with a p-value of less than 0.05. However, there were no significant differences between the groups in terms of sociodemographic factors, intraoperative vital signs, and intraoperative complications (21).

This study also observed a mild incidental effect of pruritus in the exposed groups compared to the non-exposed groups, which contrary to a study conducted in Iran on patients undergoing transurethral resection of the prostate (TURP) (4) and also a study conducted in South Korea on TURP patients did not find any incidental effects of pruritus between the groups (21).

In terms of intraoperative complications, our study found that the occurrence of nausea and vomiting was comparable between the groups. However, in a randomized controlled trial (RCT) conducted in Iran in 2007, involving eighteen patients scheduled for TURP under spinal anesthesia, there was a mild increase incident of nausea and vomiting among the pethidine groups(4).

One possible explanation for our study's findings is that the addition of low-dose intrathecal pethidine with bupivacaine reduces the incidence and severity of intraoperative shivering.

This effect may be attributed to the molecular structure of pethidine, an opioid with substantial kappa agonism and a derivative of phenylpiperidine. The molecular structure of pethidine is comparable to that of local anesthetics, allowing it to stabilize membranes. Furthermore, pethidine provides effective surgical pain relief with relatively low side effects. The limited motor blockage caused by intrathecal pethidine may also facilitate earlier postoperative movement (5).

6.1. Strength

- We took measures to minimize bias and control for confounding factors during the data collection period.
- This study is a new for throughout the country.

6.2 Limitations

- The study was not conducted across multiple centers, and the selection of procedures was not specific due to the short duration of the study. Additionally, financial constraints limited our ability to follow patients for more than one hour.

Chapter Seven: Conclusion and Recommendation

7.1. Conclusion

Administering a low dose (0.2 mg/kg) of intrathecal pethidine with bupivacaine is effective in reducing the incidence and intensity of intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia. However, it should be noted that there is a mild incidence of pruritus associated with this intervention.

7.2. Recommendations

We recommend that clinicians consider using a low dose (0.2 mg/kg) of intrathecal pethidine with bupivacaine to prevent intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia.

Furthermore, we encourage researchers to conduct multicenter studies with larger sample sizes, focusing on specific procedures, to further investigate the effectiveness of adding a low dose of intrathecal pethidine with bupivacaine in preventing intraoperative shivering among geriatric patients undergoing elective surgery under spinal anesthesia.

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Reference

1. Kharbuja K. Comparison of Pethidine and Tramadol for the Control of Shivering in Patients undergoing Elective Surgery under Spinal Anesthesia. Comp Pethidine Tramadol Control Shivering Patients undergoing Elect Surg under Spinal Anesth. 2016;4(2):64–7.

2. Destaw B, Melese E, Jemal S. International Journal of Surgery Open Effects of prophylactic intravenous dexamethasone versus pethidine for prevention of post-spinal anesthesia shivering for patients who underwent transurethral resection of the prostate under spinal anesthesia : Prospe. Int J Surg Open [Internet]. 2020;26:137–44. Available from: https://doi.org/10.1016/j.ijso.2020.08.015

3. Shivering. R Coll Anesth Southampt. 2017;

4. Davoudi M, Mousavi-Bahar SH, Farhanchi A. Intrathecal meperidine for prevention of shivering during transurethral resection of prostate. Urol J. 2007;4(4):212–6.

5. Sia ATH, Chow MYH, Koay CK, Chong JL. Intrathecal Pethidine : An Alternative Anaesthetic for Transurethral Resection of Prostate ? Dep Anaesth ,Toa payoh Hosp ,singapore. 1997;25:650–4.

6. Stephanie L, Laura L, Kathena D, Melissa V, Ashlee N. Meperidine hydrochloride : Summary Report Summary Report Meperidine hydrochloride. Univ Maryl Cent Excell Regul Sci Innov Univ Maryl Sch Pharm. 2022;

7. Between C, Low P, Ketamine D, For O, Of P, During S, et al. SPINAL ANAESTHESIA ; COMPARISON BETWEEN PROPHYLACTIC LOW DOSE KETAMINE AND ONDANSETRON FOR PREVENTION OF SHIVERING DURING SPINAL ANAESTHESIA IN PATIENTS UNDERGOING LOWER ABDOMINAL. Yousuf M, Haider SA, Aziz MM, Waris S Spinal anaesthesia; 2015;22(8):1029–33.

8. Cho S, Yoon S, Lee S, Jee Y, Cho C, Sung T. Clinical efficacy of short-term prewarming in elderly and adult patients : A prospective observational study. Int J Med Sci. 2022;19:1548-1556. doi:

9. Crowley LJ, Buggy DJ. Shivering and Neuraxial Anesthesia. Schwartz's Princ Surg.

2008;33(3):241–52.

10. Ferede YA, Aytolign HA, Mersha AT. “ The magnitude and associated factors of intraoperative shivering after cesarean section delivery under Spinal anesthesia ” : A cross sectional study. Ann Med Surg [Internet]. 2021;72(October):103022. Available from: https://doi.org/10.1016/j.amsu.2021.103022

11. Papahatzi A, Souleles P. Effects of hypothermia and shivering on standard PACU monitoring of patients. Panagiotis Kiekkas, RN, MSc Maria PoPanagiotis Kiekkas, RN, MSc Maria Poulopoulou, RN Argiri Papahatzi, RN Panagiotis Souleles, RN Patras, Greeceulopoulou, RN Argiri Papahatzi, RN Panagiotis Souleles, RN Patras, Greece. 2005;73(1):47–53.

12. Hamdy S. Prevention of Post-Spinal Anesthesia Shivering : Low Dose Ketamine vs Tramadol. Dep Anesth Intensive care, Fac Med Al-Azhar Univ Cairo, Egypt Discl. 2020;108–15.

13. Davoudi M, Mousavi-bahar SH, Farhanchi A. Intrathecal Meperidine for Prevention of Shivering During Transurethral Resection of Prostate. Endourol Stone Dis Intrathecal. 2007;4(4):212–6.

14. Sivevski AG, Karadjova D, Ivanov E, Kartalov A. Neuraxial anesthesia in the geriatric patient. Front Med. 2018;5(SEP):3–6.

15. Lin Y, Chen C, Liao Y, Liao AH, Lin P. Preventing shivering with adjuvant low dose intrathecal meperidine : A meta-analysis of randomized controlled trials with trial sequential analysis. Sci Rep [Internet]. 2017;(June):1–14. Available from: http://dx.doi.org/10.1038/s41598-017-14917-5

16. Tewari A, Dhawan I. Use of oral tramadol to prevent perianesthetic shivering in patients undergoing transurethral resection of prostate under subarachnoid blockade. Dep Anesthesiol Dayanand Med Coll Ludhiana, India Address. 2014;8(1).

17. Luggya TS, Kabuye RN, Mijumbi C, Tindimwebwa JB, Kintu A. Prevalence , associated factors and treatment of post spinal shivering in a Sub-Saharan tertiary hospital : a prospective observational study. BMC Anesthesiol [Internet]. 2016;1–5. Available from:

http://dx.doi.org/10.1186/s12871-016-0268-0

18. Qona A, Rosuliana NE, Bratasena IMA, Cahyono W. Management of Shivering in Post-Spinal Anesthesia Using Warming Blankets and Warm Fluid Therapy. 1Faculty Nursing, Univ Airlangga, Surabaya, Indones 2Sekolah Tinggi Ilmu Kesehat Mataram, Mataram, Indones Abstr. 2019;14(3).

19. Subramani Y. Effect of Intrathecal Lipophilic Opioids on the Incidence of Shivering in Women Undergoing Cesarean Delivery after Spinal Anesthesia : A Systematic Review and Bayesian Network Meta- analysis of Randomized Controlled Trials . :1–23.

20. Chun D-H, Kil H, Kim H-J, Park C, Chung K-H. Intrathecal meperidine reduces intraoperative shivering during transurethral prostatectomy in elderly patients. Korean J Anesthesiol. 2010 Dec 1;59:389–93.

21. Press D. Effect of low dose of intrathecal pethidine on the incidence and intensity of shivering during cesarean section under spinal anesthesia : a randomized , placebo-controlled , double-blind clinical trial. Karim nasseri Dep Anesth intensive Care, Soc Determ Heal Res Center, Fac Med Kurdistan Univ Med Sci pasdaran Street, 6617713446, Sanandaj, iran. 2016;3005–12.

22. Gholinataj A, Baradari AG, Najafi S, Kiabi FH. Comparison of Intravenous Ketamine with Intrathecal Meperidine in Prevention of Post-anesthetic Shivering after Spinal Anesthesia for Lower Limb Orthopedic Surgeries : A Double-blind Randomized Clinical Trial. 1Department Anesthesiol Fac Med Maz Univ Med Sci Sari, Iran *Email. 2021;6.

ከ ቃለ ጣቢይቅበ ፊትፈ ቃደኝነ ትጣየ ቂያ ቅጽ፡

ሰላም ታጤናይስጥላኝ

እኔ _____እባላለሁ።በአዲስአበባዩንቨርስቲአንስትዚያት/ቤትየጥናትቡድንአባልነኝ።
የጥናቱዋናአላማ በሆስፒታለውስጥከወገብበታቺወይም ግማ ሽ አንስትዚያ/ሰመመንወስደዉቀዶህክም ናየሚሰራ
ላቸዉንታካሚ ውቺም ንአዬነትግማ ሽ አንስትዚያ/ሰመመንእንደተሰጣቸዉለም ሳሊቡቢቫኪንየሚ ባልብቻወዬም
ቡቢቫኪንእናፒቲዲንየሚ ባልአንስትዚያ/ሰመመንበመጠንዬሰጣልእናአፕሪሽ ንበሚ ደረግላቸዉስአትየሚ ሰማ ቸ
ዉስሚ ትካለለም ሳሊ ብርድብርድማ ለትወይም በብርድየሚ መጣየመንቀጥቀጥስሚ ትየሚ ሰማ ቸዉከሆነያለዉን
መጠንሁነታእናየትኛዉንአዬነትአንስትዚያ/ሰመመንየተሰጣቸዉእንደተሰማ ቸዉማ ጥናትስለፈ ለኩነው።
ይህንንበተመለከተተሳትፎዎትሙለበሙለበዕርሶፈ ቃደኝ ነትላይየተመሰረተነው።
በዚህጥናትመሳተፉም ሆነአለመሳተፉበሆስፒታለውስጥበም ታገገኝ ው/በም ታገኘ ውአገልግሎትላይም ንም አይነ
ትለው ጥአያመጣም ።የተመረጡበዚህሆስፒታልህክም ናስለተደረገለወትብቻነው።
ው ጤቶቹም በሚ ስጥርየሚ ጠበቁሲሆንየስም ወይንም ማ ንኛ ውም መረጃአይገለጽ ም ።
እንዲ ሁም የሚ ሰጡትም ላሽ ከርሰወጢናማ ንነት ጋርበማ ንኛ ውም መልኩአይያያዝም ።
በጥናቱእንዲ ካተቱፈ ቃደኛኖት?
1. ፈ ቃደኛሆኛለሁ2.ፈ ቃደኛአይደለሁም

Annex 1: Informed Consent

My name is ——— I am here on behalf of Abraham Addis A student of postgraduate at Addis Ababa University College of health science department of anesthesia. He is conducting research for the partial fulfillment of the degree of Master of anesthesia on the incidence and severity of post spinal intra operative shivering in Ethiopia. 'He received Ethical clearance from Addis Ababa university college of health science department of anesthesia ethical committee.

Being part of this study will not affect in any way the service you are getting in this hospital.

.The data will get be kept strictly confidential and will not disclose to anyone other than member of our survey team. I respect any of your decision. The findings of this study will provide information about the incidence and severity of post spinal intra operative shivering which helps for responsible stakeholders to develop strategies and take appropriate measures to solve the Gaps and ensure the welfare of patient's management in intra operative shivering. This study will not harm any study participants.

Do you agree to participate in the study?

1. Yes 2. No (if no, stop)

Data collector _____ Signature _____

If you have any concerns, you can contact the principal investigator through:

0974131404/0989814740

addisabrham335@gmail .com

Annex2: Questionnaire

Section one: socio-demographic and operative characteristics of the patient

Q. code	Variable	measurement	Response circle no and write measurement number
101	Age	……years	
102	Sex	1. Male 2. female	1, 2,
103	Weight	……kg	
104	Height	……cm	
104	Type of Procedure	Procedure name	

Section two:

Section three: vital signs of the patient

Q. code	Time interval	HR	SPO2	MAP	TO
201	Baseline vital sign				
202	Vital sign after 10 min of SA				
203	Vital sign after 20 min of SA				
204	Vital sign after 30 min of SA				
205	Vital sign after 40 min of SA				
206	Vital sign after 50 min of SA				
207	Vital sign after 60 min of SA				

SA……. Spinal Anesthesia

HR ……. hear rate

SPO2 ……Oxygen saturation

MAP…means arterial blood pressure

To…. axillary body temperature

Min…. time in minutes

Section three: patient characteristics and intraoperative complications

Q. code	Variable	measurement	Response circle no for Q. CODE 300 and write amount and measurement for others.
300	Medication taken for spinal anesthesia	1. Bupivacaine alone 2. Bupivacaine with adjuvant…….	1, 2,
301	Fluid take	ml	
302	Duration of operation	min	
303	Blood lost	ml	
304	Nausea and vomiting	1, yes 2, no	1, 2,
305	pruritus'	1, yes 2, no	1, 2,

ml….mil liters

Section four: incidence and severity of shivering

code Variable		measurement	Response circle no
shivering		1, yes 2, no	1, 2,

code	variable	measurement	Response circle no
400	shivering	1, yes 2, no	1, 2,
If yes code no 400 goes Q401		measurement	
401, Grade of shivering	Grade of shivering	0, no shivering 1, piloerection or peripheral vasoconstriction but no visible shivering 2, muscular activity in only one muscle group 3, muscular activity in more	0, 1, 2, 3,

		than one muscle group but not generalized shivering; 4, shivering involving the whole body	4,

No……. number

Q……question