ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCE

DEPARTMENT OF ANESTHESIA

EFFECTIVENESS OF PROPHYLACTIC ADMINSTRATION OF INTRAVENOUS PARACETAMOL FOR PREVENTION OF POST SPINAL ANESTHESIA SHIVERING AMONG PARTURIENTS UNDERGOING CESARIAN SECTION AT TIKUR ANBESSA SPECIALIZED HOSPITAL, ADDIS ABABA, ETHIOPIA, 2024/2025, PROSPECTIVE COHORT STUDY

PRINCIPAL INVESTIGATOR

Mussie Gezahegn……. BSc in Anesthesia

A RESEARCH THESIS TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES, DEPARTMENT OF ANESTHESIA FOR PARTIAL FULFILLMENT OF DEGREE OF MASTER OF SCIENCE (MSC) IN ANESTHESIA.

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Topic of the study	Effectiveness of prophylactic administration of intravenous paracetamol for prevention of post spinal anesthesia shivering among parturient undergoing cesarean section at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, 2024/2025
Duration of the study	From January 01 to April 01 2025
Study area	Tikur Anbessa specialized hospital (TASH), Addis Ababa, Ethiopia

Approval by examination board

The undersigned certify that the thesis entitled" Effectiveness of prophylactic administration of intravenous paracetamol for prevention of post spinal anesthesia shivering among parturient undergoing cesarean section at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, 2024/2025" has been done by Mussie Gezahegn undersupervision of Mrs. Meron Abrar (Assistant Professor in Anesthesia) and Mr. Sulaiman Jemal (Assistant Professor in Anesthesia) .

This thesis by Mussie Gezahegn is accepted in its present form by the board of examiners as satisfying thesis requirement for the degree of masters in anesthesia.

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Declaration

I, the undersigned, declare that this thesis entitled, Effectiveness of prophylactic administration of intravenous paracetamol for prevention of post spinal anesthesia shivering among parturient undergoing cesarean section at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia, 2024/2025 is my original work. All sources of materials used for the thesis development have been properly referenced.

This thesis is submitted in partial fulfillment of the requirements for the Master of Science degree in Anesthesia

Principal investigator Name: _____Signature _____Date. _____

Approval of the primary Advisor Name: _____

Signature _____Date. _____

Table of Contents

ACRONYMS

ASA	American Society of Anesthesiology
CS	Cesarean section
TASH	Tikur Anbessa Specialized Hospital
BMI	Body Mass Index
PSAS	Post Spinal Anesthesia Shivering
EMDHS	Ethiopia Mini Demographic Health Survey
GA	General Anesthesia
SA	spinal Anesthesia
BSAS	Bedside Shivering Assessment Score
MAP	Mean arterial pressure

LIST OF FIGURES

LIST OF TABLES

ACKNOWLEDGMENT

I would like to give my warmest gratitude to Addis Ababa University, College of Health Sciences, Department of Anesthesia, for giving me the priceless chance to initiate and complete research thesis. I would like to extend special thank you to Mr. Sulaiman and Mrs. Meron, my advisors, for their unwavering support, direction, and insightful advice throughout the development of this thesis.

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ABSTRACT

Introduction: Spinal anesthesia is known to be a contributing factor to shivering, leading to undesirable complications that have adverse physiological effects. Recent studies suggest that paracetamol may be a promising prophylactic measure. Nevertheless, there is paucity of information on its effect in preventing post-spinal anesthesia shivering in low-income countries like Ethiopia including the study setting.

Objective: The aim of this study is to assess the effectiveness of prophylactic administration of intravenous paracetamol for prevention of post spinal anesthesia shivering among parturient undergoing cesarean section

Methods: Institution based prospective Cohort study was conducted at Tikur Anbessa Specialized hospital, Addis Ababa, Ethiopia from January 01 to April 01 2025. Total of 100 American Society of Anesthesiologists (ASA) Physical Status II mothers who undergo cesarean section under spinal anesthesia was included to the study. Study participants was selected by Systematic random sampling technique. The incidence and severity of shivering, axillary temperature, mean arterial pressure (MAP) and intraoperative adverse effects were assessed at 5 minute after spinal anesthesia, then at 10-minute intervals for 1 hour. The data was analyzed using SPSS version 27 statistical package software. Categorical data was analyzed by using chi square and fisher's exact test. Normality of continuous data was assessed using the Shapiro-Wilk test. Independent sample t-tests was used to compare mean of shivering score between the groups for normally distributed data. Mann-Whitney U tests was applied for non-normally distributed quantitative data.

Result: The incidence of post spinal anesthesia shivering is significantly lower in paracetamol group 15(30%) than non-paracetamol group 27(54%) with p value of 0.015044. In addition, statistically significant difference in grade of shivering was observed (p value=0.035).

Conclusion and recommendation: This study concluded that prophylactic administration of intravenous paracetamol is effective in reducing incidence and severity of shivering following spinal anesthesia. We recommended its use for mothers undergoing cesarean section to reduce post spinal anesthesia shivering incidence and severity.

Key words: Paracetamol, spinal anesthesia, cesarean section, post spinal anesthesia shivering

CHAPTER ONE: INTRODUCTION

1.1. Background of the study

Caesarian section (CS) is the method of delivering the baby through a cut made through the mother's lower abdomen and uterus. It has been indicated for mothers whose labor is not progressing well because of either fetal or maternal problems. Reports on the global CS rate from 1990 to 2018 showed that high-, middle-, and low-income nations continue to see increases in the CS rate. As per the CS statement of the World Health Organization (WHO), the optimum amount of caesarian section was thought to be between the ranges of 10% to 15%(1,2)

The number of Caesarean sections performed worldwide in 2015 was estimated to be 140 million, although rates of delivery vary greatly around the globe. In West and Central Africa, rates range from 4% to over 23% in the United Kingdom, around 32% in the United States and more than 44% of all deliveries in the Latin Americas and the Caribbean(3). According to cross-sectional study that was carried out utilizing Ethiopia Mini Demographic Health Survey (EMDHS) 2019, 5.44% of births were caesarean sections in Ethiopia. The prevalence of caesarian deliveries in Addis Ababa was 38.3%, with certain risk factors, such as maternal education and giving childbirth in a private healthcare facility (1).

Cesarean section may be carried out under general, epidural, or spinal anesthesia (intrathecal). Anesthesia-related maternal mortality in the United Kingdom was halved from 30 to 50 per 100 000 maternities per triennial in the 1970s to 19 per 100 000 maternities in the early 1980s as a result of the transition from general anesthesia (GA) to neuraxial anesthesia (NA). According to recent data, NA appears to be superior to GA in terms of fetal outcomes (Apgar scores and cord pH). Even though NA is better for cesarean delivery (CD), there are occasions in which GA is better, such as emergency cases where NA is not possible in time or where NA is contraindicated. There are several NA methods consisting of combined spinal-epidural (CSE), epidural, and single-shot spinal techniques that share common technical aspects (3,4).

Spinal anesthesia is the most frequently used type of anesthesia for cesarean sections performed on lower segments (LSCS). In contrast to the epidural technique, spinal anesthesia is more rapid and simple to carry out, with a definite end point. It is affordable, simple to use, and, reduced risks of maternal illness and death, newborn depression, minimal risk of regurgitation and aspiration of

gastric contents and a high success rate in contrast to general anesthesia. However it is not without adverse effects like shivering (3,5).

Shivering is referred to as skeletal muscles' involuntary physiological reflex which is capable of efficiently maintaining heat as a reaction of the thermoregulatory system to cold. Vasodilatation, which promotes quick heat loss and a transfer of body heat from the core to peripheral tissue, is the mechanism by which spinal anesthesia causes shivering. This leads to hypothermia and shivering. It is commonly graded utilizing a scale that has been described by Bedside Shivering Assessment Score (BSAS)(5–7). BSAS has sufficient interrater reliability for use among a wide range of practitioners (7).

Paracetamol is a popular, safe and effective analgesic medication possessing antipyretic effects that lowers the hypothalamic temperature set point by centrally mediated prostaglandin inhibition (6,8).After intravenous infusion it has a quick onset of action within fifteen to twenty minutes and diminishes after four hours. According to recent studies, the use of intravenous paracetamol reported to be effective in preventing shivering resulting from spinal anesthesia, thus we aim to evaluate its effectiveness(9).

1.2. Statement of the problem

Shivering has been identified as a common adverse effect in patients having surgery under spinal anesthesia, with incidence of 40–70% (10). The age of the patient, the ambient temperature of the operating room, amount of blood loss, volume of resuscitation fluid and the duration of surgery are typically associated risk factors. Apart from discomfort resulting from post spinal anesthesia shivering, it also results in a rise in the production of carbon dioxide and the utilization of oxygen, leading to hypoxemia and a rise in the lactic acid concentration, delayed wound healing, cardiac ischemia, and increased wound pain(8). Furthermore Shivering may make it challenging to monitor blood pressure, oxygen saturation, and ECG(10–12).Because shivering raises cardiac output and metabolic heat production up to 600% over basal values, mortality and morbidity rates and length of hospital stay of patients who have cardiovascular disease will increase(5).

Thus, preventing post-anesthesia shivering would not only minimize an uncomfortable anesthetic side effect but also avert postoperative problems. Shivering can be prevented and treated with pharmacological and non-pharmacological approaches. Warm fluid administration, wearing warm clothing, using radiant heat, forced air warmers, and raising the operating room's ambient temperature are some examples of non-pharmacological methods (13). However, the main challenge is the limited availability of these devices. Pharmacological treatments including low dose ketamine, dexamethasone, pethidine, tramadol, paracetamol, clonidine, dexmedetomidine, biogenic amines (serotonin 5-HT3 receptor antagonist), and magnesium sulfate are also used (8). Unfortunately, the majority of these medications have unfavorable side effects that make them unsuitable for use as anti-shivering drugs. Pethidine is considered as the gold standard to treat shivering following spinal anesthesia. However, it causes drowsiness, nausea, vomiting, respiratory depression and addiction potential as adverse effects. It is not recommended for breastfeeding mothers, which presents difficult moral and legal issues (9).

Paracetamol, a non-steroidal anti-inflammatory drug, is a commonly used safe and efficient medication for the treatment of mild to moderate pain and shivering (14).In addition, preoperative intravenous paracetamol administration considerably decreased post-cesarean pain within 24-hour (15). At therapeutic levels, the medication often has minimal adverse effects and is well-tolerated. In contrast to opioids, they don't cause side effects including nausea, vomiting, constipation, or

respiratory depression. Since pain has been related to shivering after surgery, treating it also reduces non-thermoregulatory tremors (16).

Even though studies on the effectiveness of intravenous paracetamol for shivering prophylaxis are limited, existing research suggests its potential benefits. The literature on paracetamol's effectiveness in preventing shivering is inconsistent, with some studies showing positive results and others showing no effect (17). To the best of my search, no published studies have investigated the prophylactic use of intravenous paracetamol for prevention of shivering in Ethiopia. Therefore, this study aims to determine its effectiveness in preventing post spinal anesthesia shivering.

1.3. Significance of the Study

One of the most frequent side effects of spinal anesthesia for mothers having cesarean sections is shivering. To prevent or lessen the intensity of shivering, many preventive measures are used. However, those measures are challenging to implement due to availability issues and pharmaceutical adverse effects for pregnant women.

A common approach to managing shivering involves the use of opioids, such as pethidine once it occurs. However, this practice is associated with several potential side effects. Nowadays, intravenous paracetamol is widely accessible and often cost effective option due to its better safety profile. It is safe drug and can be administered for pregnant mother. This makes paracetamol easily applicable to many hospitals. Furthermore, paracetamol aligns with the emerging trend of opioid-free anesthesia, an approach that aims to eliminate perioperative opioid use.

Generalizing findings from other countries may not be entirely applicable to our specific context. Therefore, this study seeks to clarify contradictory findings and will provide valuable insights tailored to our hospital's needs. The results will contribute to improving perioperative anesthetic management strategies, patient care and reducing costs associated to shivering related to complications and prolonged hospital stay at TASH. It will also serve as a resource for future researchers investigating shivering prevention. Additionally, the findings will inform policymakers in implementing effective preventive measures and contribute for improving overall health care service.

CHAPTER TWO. LITRATURE REVIEW

Shivering following spinal anesthesia for cesarean section is a common and distressing complication. While opioids are often used to manage shivering, they carry the risk of adverse effects. Prophylactic intravenous paracetamol has emerged as a promising alternative due to its antipyretic, and analgesic protective properties against shivering. This literature review aims to systematically evaluate the evidence on the efficacy of prophylactic intravenous paracetamol (IV) in preventing or mitigating shivering following spinal anesthesia among mothers undergoing CS.

In a triple-blind, randomized, placebo-controlled study carried out in Japan in the post-anesthesia care unit (PACU), the incidence of severe postoperative shivering was found to be significantly reduced in the paracetamol group (22.2%) compared to the placebo group (73.7%) (Relative risk, 0.302; 95% confidence interval, P =.005). At PACU, the paracetamol group's body temperature was considerably lower (mean [standard deviation {SD}], 37.2°C [0.48°C]) than that of the placebo group (37.9°C [0.63°C]; P <.001) (18).

In contrast, prospective double-blind RCT was done in Thailand on 93 pregnant women, who scheduled for elective caesarean delivery under spinal anesthesia. Following delivery, one group (group P, n=47) received 1000 mg of intravenous paracetamol and the other (group NS, n=46) received 100 ml of normal saline. Shivering was seen in two patients (4.0%) in saline group and three patients (6.0%) in paracetamol group during surgery and was noted in seven patients (15.0%) in group NS and 7 patients (15.0%) in group P at PACU. No significant difference in shivering score reported among the two groups (19).

A double-blind, randomized clinical trial (RCT) conducted at Tabriz's Department of Anesthesiology investigated the efficacy of prophylactic IV paracetamol in mitigating post spinal anesthesia shivering during CS. The study included 100 patients (ASA II) undergoing cesarean sections. The average gestational age was comparable between the paracetamol group (37.94±1.07 weeks) and the control group (37.58±2.07 weeks) (p=0.278). The mean increase in shivering score was significantly lower in the paracetamol group (0.60±0.98) compared to the control group (1.12±1.46) (p=0.041), suggesting that prophylactic paracetamol administration may effectively

reduce the incidence and severity of shivering in patients undergoing cesarean section under spinal anesthesia (20).

In prospective RCT done in Iran on 110 pregnant women, within the paracetamol group (group A), five parturient (9.1%) experienced shivering, while in the saline group (group N), it was observed in 28 parturient (50.9%). The paracetamol group experienced less severe shivering on a scale of 0 to 4 in comparison to the saline group ($P < 0.05$). Age, weight, height, and length of operation did not significantly differ between the two groups ($P > 0.05$). Following the induction of anesthesia, there was a statistically significant ($P > 0.05$) decrease in core temperature in both groups. Incidence of nausea, vomiting, and hypotension did not vary between the two groups ($P > 0.05$)(21).

The mean 4-point shivering score in the paracetamol group was 0.3 ± 0.55, in the ketorolac group was 0.7 ± 0.78, and in the placebo group was 1.4 ± 1.00 (p-value<0.001), according to a prospective comparative study conducted in Pakistan on the pre-empitive effect of IV paracetamol VS IV ketorolac VS placebo on postoperative pain and shivering among patients undergoing septoplasty (22).

The outcome of a clinical trial that involved 64 patients having upper limb surgery under general anesthesia at the Al Zahra and Kashani Hospitals in Isfahan, Iran, shows that the core and peripheral temperatures of patients receiving IV paracetamol were considerably lower ($P < 0.05$). Ten minutes after going into recovery, Shivering was experienced by 2 patients in the intervention group and 10 patients in the control group (31.2% vs. 6.2%). This showed significant differences ($P = 0.02$) (23).

A different comparative observational study on the effects of paracetamol on perioperative shivering for surgeries under spinal anesthesia was carried out in India. At one-hour intra-operative, the paracetamol group (10.5%) showed substantially lower severe shivering scores (≥ 2) than the controlled group (33%) ($p = 0.02$). Within the paracetamol group, no patient had a shivering score more than 2 during the operation. Postoperatively, shivering scores in the paracetamol group measured upon arrival after moving to the PACU and 1-hour post-operative were considerably less than those in the control group with $p=0.040$ and $p=0.044$, respectively. At all times both intra-operative and post-operative heart rate was significantly lower in patients

receiving intravenous paracetamol ($p<0.005$). Axillary body temperature and MAP did not reveal any significant intergroup variations (16).

A RCT done at Ain-Shams University hospital, Egypt, comparing paracetamol and dexamethasone shows, clinically significant post spinal anesthesia shivering (PSAS) was recorded as (15%) in Paracetamol group, (40%) in Dexamethasone group and (77%) in Control group ($P < 0.001$). 90 minutes after spinal anesthesia, core temperatures in all three groups were significantly lower than prespinal values ($P < 0.001$) (10).

In Randomized Controlled Trial done in Egypt assigning 120 patients undergoing liposuction to one of three groups: group P (paracetamol group), group O (ondansetron group), and group S (saline group), Postoperative shivering (POS) was observed to occur less frequently in groups P and O than in group S, with values of 25% and 37.50% vs. 77.50%, respectively, and a P value <0.001. Furthermore, compared to group S, groups P and O had less severe POS ($P<0.001$). The groups did not significantly differ in terms of tympanic temperature and complications (8).

In general, previous studies suggest that prophylactic intravenous paracetamol may effectively reduce the incidence and severity of shivering following spinal anesthesia. Some studies have shown a significant decrease in shivering scores in patients receiving paracetamol compared to controls. However, the existing evidence is not conclusive, and the effectiveness of this approach remains unknown in the Ethiopian context.

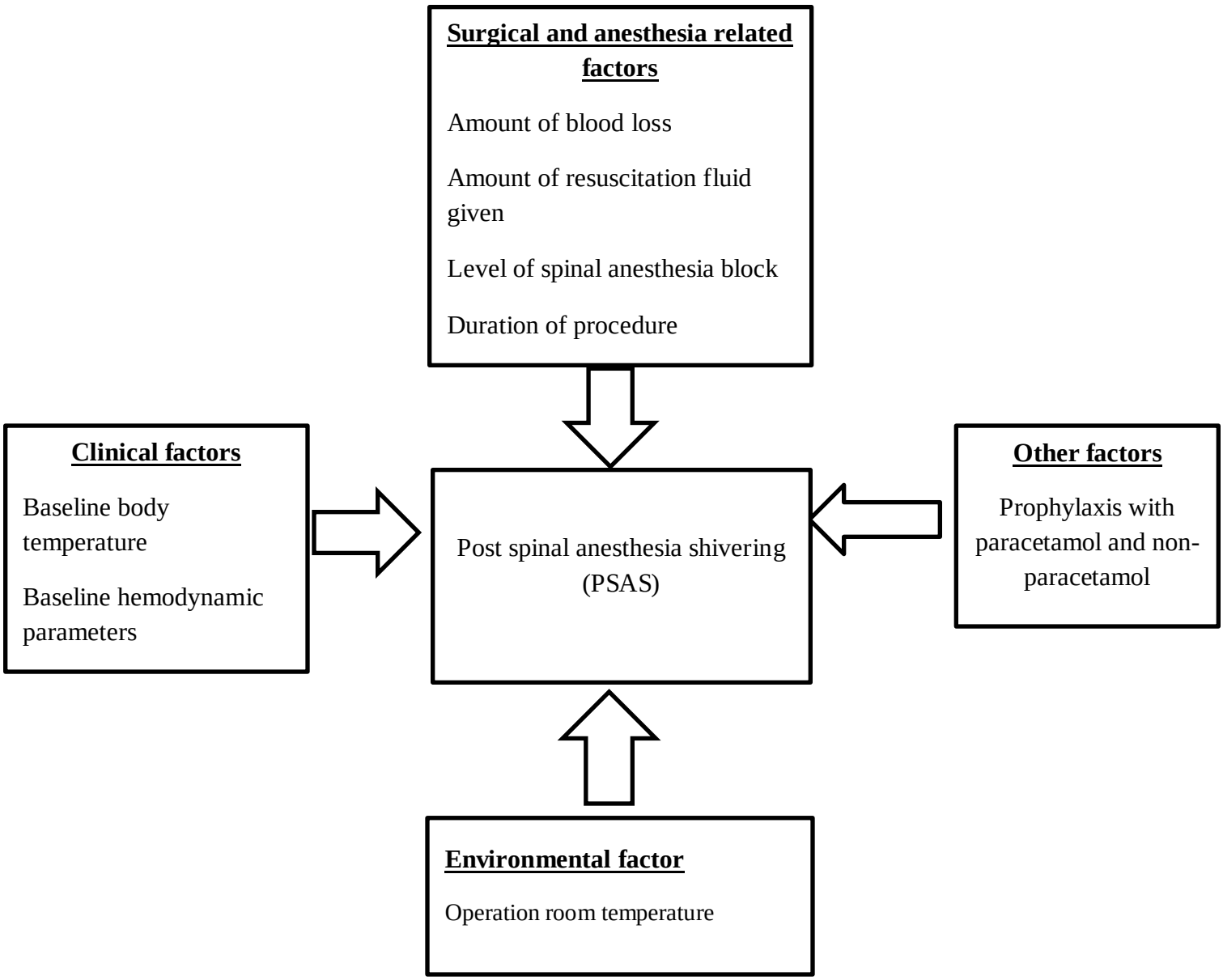

Figure 1: Conceptual frame work showing factors affecting post spinal anesthesia shivering (5,10,24)

Research hypothesis

H0: there is no difference in incidence of post spinal anesthesia shivering between paracetamol group and unexposed groups

HA: there is difference in incidence of shivering between the groups

H0: there is no difference in severity of shivering between paracetamol group and unexposed group

HA: there is difference in severity of shivering between the groups

CHAPTER THREE. OBJECTIVE OF THE STUDY

3.1. General Objective

To assess the effectiveness of prophylactic administration of intravenous paracetamol for prevention of post spinal anesthesia shivering among parturient undergoing cesarean section at TASH, Addis Ababa, Ethiopia, 2025

3.2. Specific Objective

To compare the incidence of post spinal anesthesia shivering between parturient who received paracetamol and those who did not

To compare the severity of post spinal anesthesia shivering between the two groups

CHAPTER FOUR. METHODOLOGY

4.1. Study Area and Period

The study was done at Tikur Anbessa specialized hospital (TASH) from January 01 to April 01 2025. TASH is the largest and one of the oldest multi-specialist tertiary care teaching hospitals in Ethiopia, located in Addis Ababa, the nation's capital. At the moment, TASH offers surgical services in the following departments: obstetrics and gynecology surgery, neurosurgery, cardio-thoracic surgery, pediatric surgery, urological surgery, orthopedic and ENT surgery, and gastrointestinal tract surgery. The hospital serves approximately 500,000 patients annually, including both inpatients and outpatients, and can accommodate around 800 beds. The hospital currently has 17 operating rooms, of which 12 rooms are for elective surgeries and 5 are for emergencies. An average of 180 elective and emergency cesarean sections are performed each month, according to the hospital's monthly report.

4.2. Study design

An institutional based prospective cohort study was conducted from January 01 to April 01, 2025

4.3. Source and Study Population

4.3.1. Source Population

All parturients who come to TASH for undergoing CS.

4.3.2. Study Population

All parturients who was scheduled to give birth by cesarean section under spinal anesthesia at TASH who meet the inclusion criteria during study period.

4.4. Inclusion and Exclusion Criteria

4.4.1. Inclusion Criteria:

All American society of anesthesiologist (ASA) class II mothers who undergo cesarean delivery under spinal anesthesia throughout the study period was incorporated into the study.

4.4.2. Exclusion Criteria:

A parturient was excluded if they have a history of alcohol abuse, hypersensitivity to paracetamol, liver disease, diabetes, hypertension, chronic lung disease, kidney disease (creatinine greater than 1.5), body temperature greater than 38°C or lower than 36°C, or cardiopulmonary disease. Mothers who received labor analgesia with opioids, or had spinal anesthesia with opioid adjuvants such as fentanyl, morphine, pethidine, or dexamethasone, was excluded from the study.

4.5. Sample Size Determination

The sample size for this cohort study was determined using Epi Info version 7.2.6.0. A 1:1 ratio of paracetamol-exposed and control groups was assumed, with a statistically significant p-value of <0.05, a power of 80%, and a 95% confidence interval.

Based on estimates from a previous study done in Iran by Khalili et al., the incidence of shivering was anticipated to be 31.2% in the control group and 6.2% in the paracetamol-exposed group.(23) The minimum sample size calculated by applying the Fleiss method with continuity correction was 90 participants, 45 in each group.

To account for potential missing data:

Final sample size=90+ (10% of 90) =99 ≈100

Thus, total sample size was100 participants (50 in each group).

4.6 Sampling technique and Procedure

A systematic random sampling method was employed to select 100 parturient from the daily schedule of both elective and emergency cesarean sections at TASH. According to situation analysis, the average number of cesarean sections performed per month is 180. In order to include every Kth parturient in the study, K =180×3÷100 ≈5. To ensure a representative sample, the first parturient that meets the inclusion criteria was chosen using simple random sampling, lottery method. Subsequently, every fifth case was included in the study.

4.7. Variables

4.7.1. Dependent Variables

Post spinal anesthesia shivering (Incidence and Severity of shivering)

4.7.2. Independent Variables

Amount of blood loss

Duration of procedure

Baseline body temperature

Operation room temperature

Amount of resuscitation fluid used

Temperature of resuscitation fluid used

Baseline hemodynamic parameters

Prophylaxis with paracetamol and non-paracetamol

4.8. Operational Definitions and definition of terms

Spinal anesthesia: is administration of local anesthetics into the subarachnoid space to provide anesthesia and operative analgesia.

Post spinal anesthesia shivering (PSAS): is abnormal and involuntary contraction of one or more skeletal muscle groups following spinal anesthesia.

Hypothermia: body temperature < 35 Celsius

Grade of shivering;

Shivering will be graded by using the Bedside Shivering Assessment Scale (**BSAS**).

Grade 0: no shivering noted on palpation of the masseter, neck, or chest wall (**None**).

Grade 1: shivering localized to the neck and/or thorax only (**Mild**).

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

Grade 3: shivering involves gross movements of the trunk and upper and lower extremities (**Severe**).

4.9. Data Collection and instruments

Written questionnaires was used to gather the data. Questionnaires was adapted from previously done studies which was developed in English. Data collectors had clear training on how to collect data about severity of shivering, intraoperative hemodynamic parameters and any adverse effects prior to data collection.

Perioperative anesthetic management of mothers undergoing cesarean section in TASH is carried out by anesthesiology residents and BSC anesthesia professionals. Pre-anesthetic evaluation and planning of appropriate anesthetic evaluation is done the day before elective CS. But for emergency cesarean section pre-anesthetic evaluation is done at waiting area immediately before

bringing to operation room. The assigned anesthetist administers antiacids (cimetidine 200-400 mg IV) and prokinetics (metoclopramide 10mg IV).

After the mothers were entered to OR standard anesthesia monitoring (BP, SPO2, RR and ECG) were applied and baseline vital signs were taken. Following this they will be preloaded by 500 to 700ml of normal saline using bilateral IV line and informed for positioning to perform spinal anesthesia. Under strictly aseptic technique SA will be done by using 2.5ml of isotonic bupivacaine at the level of L3 -L4 interspace. Effectiveness of SA will be confirmed by assessing motor, sensory and autonomic blockade. The above activities were routinely done at TASH.

Based on their exposure to prophylactic intravenous paracetamol, as determined by the attending anesthesia provider, participants were prospectively included. Mothers who received 1g of prophylactic intravenous paracetamol 10 minute before spinal anesthesia while on preloading enrolled in the exposed group, while those who did not receive was included in the non-exposed group. Data collectors evaluated shivering after spinal anesthesia among the two groups for one hour.

For both groups, the occurrence of post spinal anesthesia shivering was assessed and graded by using the similar structured questionnaire; by using the Bedside Shivering Assessment Scale (BSAS).

Baseline Hemodynamic parameters (MAP, heart rate, axillary temperature and oxygen saturation respiratory rate) were documented before spinal anesthesia. After SA given, the duration till the shivers starts, degree of shivering and the total amount of anti-shivering medication taken and intraoperative adverse outcomes like nausea and vomiting was all measured and documented. MAP and axillary body temperature was recorded at 5 minutes, then at 10-minute intervals for 1 hour after SA.

Under the supervision of a responsible anesthetist, three BSc anesthesia professionals obtain data at their workplace. Every day, the principal investigator received daily reports from the supervisor regarding each completed questionnaire.

4.10. Data Quality and Control

Following the principal investigator's training of data collectors, the data was gathered and filled on the prepared data abstraction tool. Several steps was taken to ensure data quality. The data

abstraction tool was informally pretested on small number of participants who were not involved in the final sample. The correctness, ease of understanding, consistency, and clarity of the questionnaires was next examined. We made every effort to avoid incompleteness throughout the data collection process. Additionally, the researcher oversee the data collectors and verify each day that the data was complete.

4.11. Data Analysis

After the data obtained, it was analyzed by using SPSS version 27 statistical package software. Descriptive statistics was used to summarize and describe baseline parameters, age and incidence of shivering in paracetamol and unexposed group and was presented as tables and figures. Categorical data like degree of shivering were analyzed by using chi square or fisher's exact test and were presented as frequencies and numbers. Normality of continuous data (age, BMI and duration of surgery) was assessed using the Shapiro-Wilk test and Levene's test was used to assess homogeneity of variance. Independent sample t-tests was used to compare mean of BSAS between the groups for normally distributed data, reported as mean ± standard deviation (SD). Mann-Whitney U tests were applied for non-normally distributed quantitative data and the results are presented as median (interquartile range [IQR]).

4.12. Ethical Considerations

Letter of permission was obtained from Addis Ababa University College of Health sciences, department of Anesthesia Institution review board for ethical approval before data collection and then it was given to TASH administration. Additionally, the study participants gave consent for this thesis to be conducted, and participant confidentiality was maintained.

4.13. Result Dissemination Plan

After the finalization of the study, the result will be submitted to Addis Ababa University, college of health science, Department of Anesthesia and TASH. Publication of the study's results will be tried and they will be sent to scientific journal. The findings of this study will be disseminated through presentations and discussions with the hospital's administrative authorities and will be presented at the annual conference of the Ethiopian Anesthetists Association (EAA).

CHAPTER FIVE.RESULT

5.1. Sociodemographic profiles and baseline hemodynamic parameters

During the study period 100 parturents were involved based on whether received intravenous paracetamol or not. Those who received intravenous paracetamol considered as exposed group and controlled group for those who do not. There were no statistically significant difference in sociodemographic characteristics (age, BMI), baseline heart rate, mean arterial pressure, axillary body temperature, respiratory rate and oxygen saturation among the groups (p value>0.05).

Table 1: sociodemographic profiles (age, BMI) and hemodynamic variables of Paracetamol and non-paracetamol groups in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia from January 01 to April 01 2025

Variables	Paracetamol Group	Non-paracetamol group	p-value
Age (years)	28.54 ± 4.61**	28.82 ± 5.00	0.770
BMI (kg/m²)	24.91 ± 1.86**	24.10 ± 2.71	0.087
Heart rate (beats/min)	92 (11.8)*	90 (15)	0.222
Mean arterial pressure (mmHg)	85.18 ± 3.05**	84.24 ± 4.84	0.249
Axillary temperature (°C)	36.4 (0.4)*	36.3 (0.5)	0.340
Respiratory rate (breaths/min)	18 (2)*	18 (4)	0.249
Oxygen saturation (%)	97 (1)*	97 (1)	0.306

**, Values are presented as mean±SD, independent sample t- test was used; p-value<0.05 considered as statistically significant. *, Tested by Mann-Whitney U test and presented as median (IQR), IQR, interquartile range. P value < 0.05 was taken as significant.

5.2. Comparison of intraoperative MAP and axillary body temperature between paracetamol and non-paracetamol group

There is statistically significant difference in axillary body temperature between paracetamol and no paracetamol group at 5 and 10 min with p value of 0.01755 and 0.044 respectively. There is no statistically significant difference from 20 minutes to 60 minutes (p-values greater than 0.05).

MAP was significantly reduced at 5 and 40 minutes among mothers who took paracetamol (p values of 0.001 and 0.014890, respectively).

Table 2: Comparison of intraoperative axillary body temperature& MAP between Paracetamol and non-paracetamol groups in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia from January 01 to April 01 2025

Axillary body temperature	Paracetamol group	Non paracetamol group	p-value
At 5 min	36.3(0.3)*	36.05(0.7)	0.017550
At 10 min	35.966± 0.35**	35.79± 0.49	0.044
At 20 min	35.7(0.4)*	35.7(0.7)	0.657876
At 30 min	35.55(0.4)*	35.55(0.4)	0.273295
At 40 min	35.4(0.4)*	35.3(0.6)	0.284408
At 50 min	35.4(0.3)*	35.35(0.4)	0.230068
At 60 min	35.4(0.3)*	35.3(0.4)	0.144205
Mean arterial pressure			
At 5 min	74.04± 5.92**	81.24± 7.14	<0.001
At 10 min	72(8)*	72(10)	0.076134
At 20 min	72.72±4.815*	73.88±6.12	0.294781
At 30 min	72.5(7)*	74(8)	0.655765
At 40 min	72.64±4.237**	74.82±4.552	0.014890
At 50 min	73.64±4.805**	75.34±4.801	0.079883
At 60 min	73.86±3.659**	75.06±4.834	0.164769

*, tested by Mann Whitney u test and the values are presented by mean±SD.**,tested by independent sample t test; the values are presented as median(IQR).P<0.05 was taken as significant. SD, standard deviation; IQR, interquartile range

5.3. Comparison of incidence of shivering

The incidence of post spinal anesthesia shivering is significantly lower in paracetamol group 15(30%) than non-paracetamol group 27(54%) with p value of 0.015044. chi-square test was employe and p value <0.05 is considered as statistically significance.

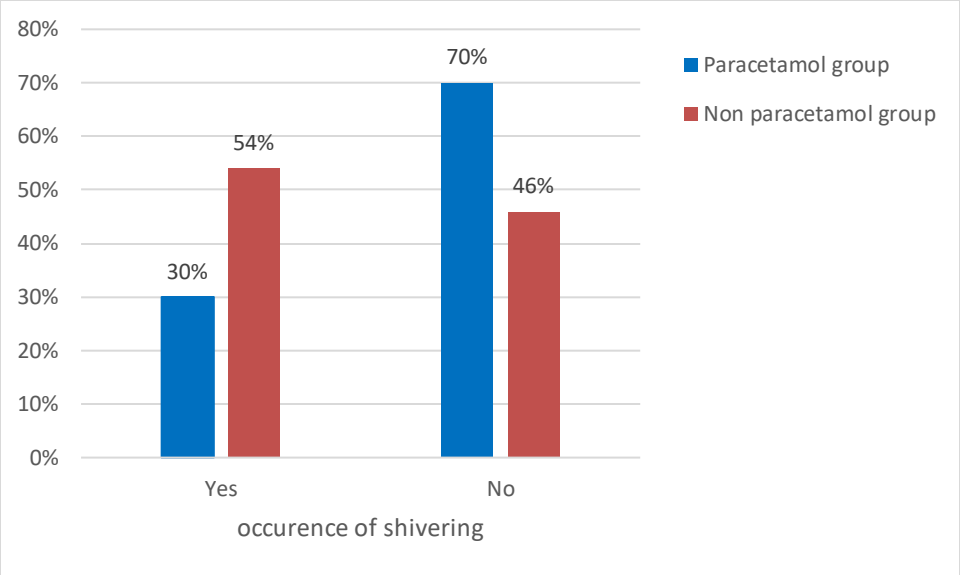

Figure 2: Comparison of incidence of shivering between Paracetamol and non-paracetamol groups in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia from January 01 to April 01 2025

5.4. Comparison of severity of shivering

There was statistically significant different grade of shivering between paracetamol and non-paracetamol groups (p value=0.035). In the Paracetamol group, 12 participants (80%) experienced Grade 1 shivering, 3 (20%) had Grade 2, and none had Grade 3. In contrast, the Non-Paracetamol group had 10 participants (38.5%) with Grade 1, 15 (57.7%) with Grade 2, and 1 (3.8%) with Grade 3. Chi-square test were used and values are presented by numbers and percentages. P value<0.05 considered as statistically significant.

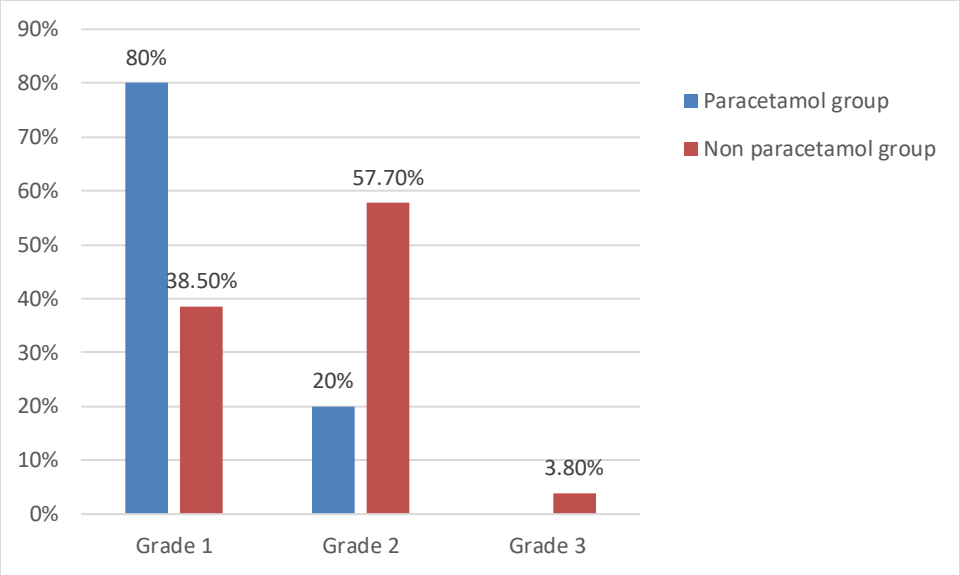

Figure 3: Comparison of severity of shivering between Paracetamol and non-paracetamol groups in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia from January 01 to April 01 2025

5.5. Comparison of nausea and vomiting

There is no significant difference in the incidence of nausea in the paracetamol group (44%) and non-paracetamol group (42%), with a p-value of 0.84. Similarly incidence of vomiting was20% in the paracetamol group compared to 12% in the non-paracetamol group (p- value= 0.28). Chi square test was conducted; the values are presented by number and percentage. P- Value<0.05 taken as significant.

5.6. Comparison of Other intraoperative variables

There was no statistically significant difference between the paracetamol and non-paracetamol groups in terms of time to first onset of shivering (31.27 ± 7.83 vs. 27.56 ± 11.11 min, $p = 0.26$), duration of surgery (39.78 ± 4.71 vs. 39.24 ± 6.32 min, $p = 0.629$), or blood loss (454 ± 79.82 vs. 457.6 ± 120.3 ml, $p = 0.86$). The amount of resuscitation fluid used was lower in the paracetamol group (1314 ± 176.14 vs. 1407 ± 285.36 ml), showing a near-significant difference ($p = 0.053$).

Table 3: Comparison of time to first onset of shivering, duration of surgery, volume of resuscitation fluid and amount of blood loss among Paracetamol and non-paracetamol groups in Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia from January 01 to April 01 2025.

Variable	Paracetamol group	Non paracetamol group	p-value
Time to first onset of shivering in min	31.27± 7.83	27.56± 11.11	0.26
Duration of surgery in min	39.78± 4.71	39.24± 6.32	0.629
Blood loss in ml	454±79.82	457.6±120.3	0.86
Resuscitation fluid used in ml	1314±176.14	1407±285.36	0.053289

Independent sample t test conducted. The values are presented as mean±SD. $P<0.05$ considered as significant. SD, standard deviation

CHAPTER SIX: DISCUSSION

This prospective cohort study evaluated the effectiveness of intravenous paracetamol (IV PCM) for the prevention of post-spinal anesthesia shivering among mothers undergoing cesarean sections. This study demonstrated a significantly lower incidence of shivering in the paracetamol group (30%) compared to the non-paracetamol group (54%), with a p-value of 0.015, indicating statistical significance.

Shivering is a very common complication following induction of anesthesia owing to post anesthesia hypothermia and postoperative pain and causing distress for both patients and clinicians. Additionally, it may affect reading of the monitoring devices. Thus, prevention of shivering is important pharmacologically and non-pharmacologically. Even though several pharmacological agents have been used the best treatment for postanesthesia shivering is still being researched. The result of this study showed that intravenous paracetamol was effective in reducing the incidence and severity of post spinal anesthesia shivering. Paracetamol is a safe, effective and widely used analgesic agent with antipyretic properties that inhibits prostaglandin synthesis to reduce the hypothalamic temperature set point (9,10,25).

The result of current study is consistent with several previous studies that demonstrated the antishivering effect of intravenous paracetamol when given before spinal anesthesia. Shivering has been found to occur 40–70% of patients after anesthesia without any kind of preventative measures.(10) This range comprises the 54% shivering we found in the non-paracetamol group. Our results align with a double-blind randomized controlled trial at Ain-Shams University hospitals that investigated the effectiveness of paracetamol, dexamethasone, and a placebo in preventing post-spinal anesthesia shivering (PSAS) during lower limb and lower abdominal surgeries. In that study, the incidence of post spinal anesthesia shivering was significantly reduced in the paracetamol group (15%) compared to the control group (77%) and the dexamethasone group (40%) ($P < 0.001$).(10) Even though our study included parturents undergoing cesarean section, we also noticed significantly lower incidence of shivering among mothers taking paracetamol compared to mothers who do not. Despite the fact that prophylactic IV paracetamol consistently lowers shivering in both investigations, the incidence of shivering was somewhat higher in our paracetamol group. This may be due to variations in types of surgeries, study populations, timing of paracetamol administration and controlled room temperature in their study.

Furthermore the finding of our study supported by a clinical trial conducted by Khalili G, etal at Al Zahra and Kashani Hospitals in Isfahan on the effect of intravenous infusion of paracetamol before anesthesia induction on the core and peripheral temperature changes and post-operative shivering in patients undergoing general anesthesia. They found 6.2% of patients who received paracetamol had shivering compared to 31.2% in the control group. This difference was statistically significant (P = 0.02) (23). Although the type of anesthesia (general vs spinal) and type of surgery is different from our study, the preventive effect of paracetamol infusion for shivering remains evident in both studies. The higher incidence of shivering in paracetamol group of our study attributed to obstetrics physiological change, spinal anesthesia, temperature of the fluid given, room temperature and different perioperative anesthetic management.

Our results also align with the findings of a prospective, double-blind RCT which was done by Gholami and Hadavi at Besat Nahaja General Hospital in Tehran. They evaluated the prophylactic effect of intravenous paracetamol on post-anesthesia shivering in mothers undergoing elective cesarean section under general anesthesia. Significantly lower incidence of shivering was observed in mothers taking paracetamol (9.1%) as compared to the saline group (50.9%) (P < 0.05) (21). This shows preventive effect of paracetamol for shivering. However the incidence of shivering among the paracetamol group is much lower than the finding of ours. This disparity may be explained by a number of reasons, such as the type of anesthesia (SA vs GA), variations in the study design, and the fact that cold fluid infusion was avoided in their study.

Unlike our study, a randomized controlled trial conducted that was done in Thailand on 93 pregnant women revealed there was not a significant difference between the paracetamol group and control group in the incidence of intraoperative or postoperative shivering. That study found 6% of mothers in the paracetamol group and 4% in the control group shivered intraoperatively, where as 15% in each group experienced shivering in the PACU (19). Variations in sample size, study design, timing of drug administration, and shivering evaluation techniques may be the cause of the inconsistency between the two studies.

In our study, we found that 80% of the mothers in the paracetamol group experienced only Grade 1 (mild) shivering, while the higher proportion from the non-paracetamol group experienced Grade 2 (57.7%) and one case of Grade 3 shivering (3.8%) (P = 0.035). No cases of Grade 3 shivering were observed in the paracetamol group. The paracetamol group did not have any reports of Grade

3 shivering. This shows paracetamol infusion not only reduces the incidence of shivering but also minimizes the severity of PSAS among parturients undergoing cesarean section.

Align with this study, a study done by Wahdan A, etal(8) which shows prophylactic use of paracetamol significantly reduce the incidence and severity of shivering. They studied Paracetamol (P) Versus Ondansetron (O) for Prevention of Postoperative Shivering in Liposuction Surgeries under Combined General Epidural Anesthesia. The incidence of shivering and its severity was found to be reduced in groups P and O compared to saline group with values of 25% and 37.50% vs. 77.50%, respectively. However the study design, study population and timing of paracetamol administration is different from ours.

Moreover our study confirms previous findings of a study done by Esmat M, etal (10) comparing the effectiveness of paracetamol, dexamethasone, and control groups in reducing post-spinal anesthesia shivering. In their study they found clinically significant shivering (defined as Grade ≥2) 15% of patients in the paracetamol group, 40% in the dexamethasone group, and 76% in the control group ($P < 0.001$). These results are comparable to those reported in our study. In our study, we found only 20% of patients in the paracetamol group, compared to 61.5% in the non-paracetamol group experienced clinically significant shivering ($P = 0.035$).

Strength

The sociodemographic characteristics of the study groups and baseline hemodynamic variables affecting the study's outcome are comparable. A comparable type of anesthetic and surgical technique were also employed for comparison between the two groups.

Limitation

Axillary temperature was used to measure body temperature, which may underestimate true core body temperature.

The assessment of shivering was subjective and based on clinical observation, which may be less reliable and consistent compared to objective methods such as electromyography.

Lastly, the follow-up period was only one hour post-spinal anesthesia, which might have missed delayed onset of shivering.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.1 .Conclusion

This study concluded that prophylactic administration of intravenous paracetamol is effective in reducing incidence and severity of shivering following spinal anesthesia among mothers undergoing cesarean section without causing significant hemodynamic instability and side effects like nausea and vomiting.

7.2. Recommendation

We recommended Anesthetists to administer IV paracetamol for mothers undergoing cesarean section before spinal anesthesia to reduce the incidence of occurring and the severity of shivering. In addition we encourage researchers to undergo multicenter study with large sample size to further investigate its effectiveness.

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ANNEXES

Annex 1: Informed consent form English version

Dear Sir /Madam…!

This is _____, graduate student of anesthesia department at Addis Ababa University. We are studying on how to avoid post-spinal anesthesia shivering during cesarean section. We will monitor intraoperative incidents and your vital signs, such as temperature, blood pressure, and shivering, without intervening in your anesthetic or surgical management. Our study is assured to not compromise your anesthetic and surgical management, nor cause any adverse effects on your life. You are allowed to withdraw from the study at any moment if you believe it is negatively impacting you. I want to remind you that the finding of this study will help us to improve our perioperative management of patients like you. Your data will not be disclosed individually because the study's results will be presented in a statistical generalization. If you agree that this study is necessary, kindly sign the following form. No personal information about you will be shared with other people. Thank you for your participation.

Sign_____Date _____

Annex 2: Informed consent form Amharic version

የስምምነት ፎርም

ለ አቶ/ወ/ሮ

_____ እባላለሁ፡፡ በአዲስ አበባ ዩኒበርሲቲ የአንስቴዥያ ት/ት ክፍል ድህረ ምረቃ ተማሪ ነኝ፡፡ በቀዶ ህክምና በሚዎልዱ ጊዜ ከወገብ በታች ማደንዘዣ ከተሰጠ በኋላ ሊኖር የሚችለዉን ማንቀጥቀጥና ብርድ ብርድ ማለት ለመከላከል ጥናት እያደረግን እንገኛለን። በጥናቱ ወቅት በቀዶ ህክምና ጊዜ እንደ የደም ግፊት፥ ሙቀት ፥ማንቀጥቀጥና ሌሎች ተያያዥ ክስተቶች የምንከታተል ሲሆን በርእሰዎ ላይ ምንም አይነት የሚያጎድልብዎት የህክምና አገልግሎት ወይም የሚያመጣበዎት የጎንዮሽ ችግር እንደሌለ አረጋግጥለዎታለሁ፡፡ ጥናቱ የሚያመጣብኝ ችግር ይኖራል ብለው የሚያስቡ ከሆነ በማንኛዉም ሰአት ማቋረጥ የሚችሉ ሲሆን የጥናቱ ዉጤት ግን ወደ ፊት ለሚመጡ እንደርስዎ ላሉ ታካሚዎች የተሻለ የህክምና አገልግሎት እንዲያገኙ የሚያግዝ መሆኑን ልገልጽልዎት እወዳለሁ። የርእሰዎ የግል መረጃ የተጠበቀ መሆኑን እና ምንም አይነት የግል ጉዳዮችዎን የማናስተላልፍ መሆኑን ከወዲሁ ላሳውቀወት እወዳለሁ፡፡ በዚህ ጥናት ለመሳተፍ ፈቃደኛ ከሆኑ ፊርማዎትን ወይም አሻራዎትን ያስቀምጡ፡፡ ለተሳትፎዎ እናመሰግናለን፡፡

ፊርማ _____

Annex 3: Data Collection Tool

Questionnaire: Effectiveness of prophylactic administration of intravenous paracetamol for prevention of post spinal anesthesia shivering among parturient undergoing cesarean section at Tikur Anbessa specialized hospital, Addis Ababa, Ethiopia: 2024/2025

Section 1. Socio demographic and Perioperative Variables

No.	Questions	Response
1	Age	……. years
2.	BMI	……. Kg/m2
3.	Operation room temperature	…… c0
4.	Paracetamol (1g) given preoperatively before 10 minutes of SA	1. yes 2. No

Section 2. Hemodynamic parameters

No	Questions	Response		
4.	Baseline parameters	OR room temperature _____C0 HR _____bpm., MAP _____ mmhg., Axillary body temperature_____C0, RR_____b/m, SPO2 _____%		
5.	Hemodynamic parameters after paracetamol and SA given	Time	To. axillary	MAP
		At 5min	_____c0	_____mmhg
		10min	_____c0	_____mmhg
		20min	_____c0	_____mmhg
		30min	_____c0	_____mmhg
		40min	_____c0	_____mmhg
		50min	_____c0	_____mmhg
		60min	_____c0	_____mmhg

Section 3. Shivering and severity of shivering

No.	Questions	Responses
6.	Is intraoperative shivering occur	1) Yes …. 2) No
7.	If yes, how is the severity of shivering in grade	Grade _____. (0, 1, 2, 3).
8.	Time to 1st onset of shivering	_____min.

Section 4; SA related factors

9.	Site of SA given	Between L3 –L4 other (specify) _____
10.	Types of local anesthetics used for spinal block	Bupivacaine alone, dose _____mg Bupivacaine with adjuvants(specify) with _____dose, _____ mg Others (specify)_____

Section 5. Surgical related factors

11.	Duration of surgery	_____min
12.	Amount of blood loss	_____.ml
13.	Volume of resuscitation fluid used	_____ml.

Section 6. Related side effects

14.	observed side effects	Nausea	Yes	Vomiting	Yes
			No		No

Annex 4: Shivering assessment tool

Bedside Shivering Assessment Scale (**BSAS**).

Grade 0: no shivering noted on palpation of the masseter, neck, or chest wall (**None**).

Grade 1: shivering localized to the neck and/or thorax only (**Mild**).

Grade 2: shivering involves gross movement of the upper extremities in addition to neck and thorax

(**Moderate**).

Grade 3: shivering involves gross movements of the trunk and upper and lower extremities (**Severe**).