
ADDIS ABABAB UNIVERSITY

COLLEGE OF HEALTH SCIENCE

DEPARTMENT OF ANESTHESIA

# EFFECTIVENESS OF PROPHYLACTIC INTRAVENOUS DEXAMETHASONE FOR THE PREVENTION OF INTRAOPERATIVE SHIVERING FOLLOWING SPINAL ANESTHESIA FOR CESAREAN SECTION AT GANDHI MEMORIAL HOSPITAL ADDIS ABABA, ETHIOPIA 2022/2023, PROSPECTIVE COHORT STUDY

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A RESEARCH THESIS TO BE SUBMITTED TO ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE DEPARTMENT OF ANESTHESIA FOR THE PARTIAL FULFILMENT OF THE REQUERIMENT FOR THE MASTERS SCIENCE DEGREE IN ADVANCED CLINICAL ANESTHESIA

JUNE 2023

ADDIS ABEBA, ETHIOPIA

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| Research topic | effectiveness of prophylactic intravenous dexamethasone for the prevention of intraoperative shivering following spinal anesthesia for cesarean section at Gandhi memorial hospital, Addis Ababa. Ethiopia 2022/2023 prospective cohort study |
| Duration of the study | From February 07 to April, 08/2023 |
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## Declaration

The undersigned agrees to accept responsibility for the scientific ethical and technical

Conduct of the research project and for provision of required progress reports as

Per terms and conditions of the Research Publications Office in effect at the time of

Grant is forwarded as the result of this application.

Name of the student: _____Moges Kefale (BSc) _____

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## Acknowledgement

First of all I would like to acknowledge Addis Ababa University College of health science department of Anesthesia to give this chance to do this research thesis.

And I would like to thank my advisors Mrs. Meron Abrar and Mr. Biruk Tesfaye who rescued me from a difficult start, and have been wonderfully encouraging and supportive throughout this thesis development.

Many thanks to Mr. Sileshi Abiy (Ass/prof. in anesthesia) for his constructive comments.

I would like to forward my gratitude to data collectors, parturients participated in this study and Mahatma Gandhi memorial hospital anesthetists.

## Abstract

**Background:** intraoperative shivering is a commonly seen side effect of spinal anesthesia during cesarean section. Different types of medications like; opioids, non opioid agonists, ketamine were for the prevention and treatment of shivering of shivering but it have serious side effects and expensive. Some studies showed dexamethasone had preventive effect with minimal side effects; however there was a limited study about its efficacy in cesarean section.

**Objective:** to assess the effectiveness of prophylactic intravenous dexamethasone for the prevention of intraoperative shivering following spinal anesthesia for cesarean section.

**Methods:** institutional based prospective cohort study was conducted at Gandhi memorial hospital from February 07 to April 08/2023. Ninety eight ASA II parturients undergoing cesarean section under spinal anesthesia were involved in the study. Systematic random sampling technique was used to select study participants from scheduled for cesarean section. Parturients premedicated with 0.1mg/kg dexamethasone before 10 minutes of spinal anesthesia and non dexamethasone groups were followed for 50minutes intraoperatively. The incidence of intraoperative shivering was compared between groups. The data was entered into Epi data v4.6 and analyzed using SPSS version 26 software. Continuous data was checked for normality distribution and analyzed using independent samples t-test. Non-normally distributed data was analyzed using Mann Whitney U test. Chi square and fisher's exact test were used to analyze categorical data. Descriptive data were displayed using tables and figures. P value < 0.05 was considered as statistically significant.

**Result:** the incidence of intraoperative shivering was 32.1% in dexamethasone group and 67.8% in non dexamethasone group (p value =.000084). There was statistically significant difference in grade of shivering (p value=.044); the result showed; 48.1% had grade 1, 19.2% had grade 2, 0% had grade 3 shivering in dexamethasone group. Whereas, 15.8% had grade 1, 80.7% had grade 2, 1% had grade 3 shivering in non dexamethasone group.

**Conclusion and recommendation:** this study concluded that prophylaxis intravenous dexamethasone 0.1 mg /kg before 10minutes of spinal anesthesia had effective prevention of intraoperative shivering during cesarean section. We recommend premedication of prophylaxis intravenous dexamethasone (0.1mg/kg) to prevent intraoperative shivering during cesarean section under spinal anesthesia.

Key words: cesarean section, dexamethasone, shivering, spinal anesthesia

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## Acronym/abbreviations

| | |
|---|---|
| ASA | American Society of Anesthesiologists |
| BMI | Body mass index |
| BP | Blood pressure |
| BSc | Bachelor science |
| C/S | Cesarean Section |
| DVT | Deep Venous Thrombosis |
| ECG | Electrocardiogram |
| IV | Intravenous |
| L3-L4 | Lumbar 3- lumbar 4 |
| MAP | Mean Arterial Pressure |
| MSc | Masters Science |
| OR | Operation Room |
| PSA | Post Spinal Anesthesia |
| RCT | Randomized control trial |
| RR | Respiratory Rate |
| SA | Spinal anesthesia |
| SPO2 | Oxygen Saturation |
| SPSS | Statistical Package for the Social Sciences |
| TO | Temperature |
| VS | Versus |

# Chapter one

## 1. Introduction

### 1.1. Background

Shivering is autonomic or physiologic mechanism of generating of heat to the body by skeletal muscle shaking or contraction. The causes of shivering is still not clear, it is suggested to be the contribution of different mechanisms, includes change in thermoregulatory center threshold, re-distribution of body heat (usually decreases the core body temperature by 0.5 $C^0$- 1.0 $C^0$ during neuraxial anesthesia), decreased core body temperature and the cooling effect of fluids administered into the subarachnoid space near to neuronal axis. The occurrence of shivering more than 55% and ranged from 10% to 85% in most studies after spinal anesthesia (1-3).

Spinal anesthesia is introduction of local anesthetics into the subarachnoid space results in operative analgesia and anesthesia. Its advantages are; early ambulation and decrease risk of DVT, awake mother and see when the fetus is delivered and increase mother and fetal bond, it avoid general anesthesia related complications, avoid polypharmacy. However it has many side effects; like hypotension, high and total spinal, nausea, vomiting, and shivering is seen frequently after spinal anesthesia (1, 2, 4).

Spinal anesthesia decreased sympathetic activities, uncontrolled spinal reflexes, adrenal suppression, and release of pyrogenic materials and then disorganizes body thermoregulation by inhibiting tonic vasoconstriction and leads to redistribution of blood and core body heat to the peripheral tissues. The consequence of these finally exposes the parturient to become hypothermic and develops shivering. Post spinal anesthesia shivering is stated as the sixth intraoperative complication with incidence of 55-56.7% (5, 6).

During pregnancy there is high circulating progesterone hormone which decreases shivering threshold, on the other hand in the central nervous system there is increased sweating threshold and decreased vasoconstriction, in addition to these sympathetic blockage of spinal anesthesia impairs thermoregulation of the body and causes peripheral vasodilatation and transfer of core heat to the peripheral tissue and heat lost through skin (7).

Dexamethasone is grouped under steroid drugs. It acts as an immune and anti-inflammatory suppressant. Its anti-inflammatory effects, restriction of the dissemination of vasoconstrictors and pyrogenic cytokines, and control of immunological response serve as its primary prevention mechanisms for post-spinal anesthesia shivering (8).

## 1.2. Statement of the problem

Shivering is a protective reflex that increase production of body heat through vigorous involuntary skeletal muscle activity, to compensate for the decreased core body temperature. Intraoperative shivering interfere with electrocardiogram, blood pressure monitoring which is very challenging that post spinal anesthesia hypotension is inevitable and hypotension causes nausea vomiting and desaturation unless early monitored and managed immediately, and prominently increase oxygen consumption and carbon dioxide production which can be detrimental for parturients with low cardiopulmonary reserves, and causes the parturients stressed, anxious, discomfort and dissatisfied (1, 5, 6, 8-11). Therefore, effective prevention should be done on intraoperative shivering following spinal anesthesia during cesarean section and complications associated with it. And it is essential to keep the parturient normothermic in the intraoperative period.

Shivering can be prevented using a variety of pharmaceutical and non-pharmacological techniques. The prevention and treatment of shivering after spinal anesthesia for cesarean section employed drugs such opioids, ondansetron, clonidine, anticholinergics, and ketamine. In contrast, non-pharmacological techniques like radiant heating, raising the room's temperature, using blankets, and warming fluids were employed. However, sedation, hypertension, respiratory depression, nausea, and vomiting are typical adverse effects of both opioid and non opioid medications (5, 6, 9-11).

The highest incidence and degree of shivering were occurred after skin disinfection, before the delivery of the fetus (3).

Regarding non-pharmacological methods they are not available and functional all the time in our resource limited set up.

Another rationale, of choosing dexamethasone is that it provides a prevention of nausea and vomiting, prompts appetite, suppresses inflammation and acts as a good analgesic agents (12-14). Some studies showed that dexamethasone has preventive effect of shivering; however there is a limited and not well studied about its efficacy in cesarean section.

This study was observed whether prophylactic intravenous dexamethasone prevented intraoperative shivering during cesarean section under spinal anesthesia.

## 1.1. Significance of the study

Intraoperative shivering following spinal anesthesia is commonly seen during cesarean section. But its prevention is still trouble during cesarean section under spinal anesthesia. Even though there are various preventive modalities they are not easily accessible, applicable and the side effect of medications to the parturients.

Dexamethasone can be easily afforded, cost effective and routinely used drug as well as minimal side effects than other shivering preventive medications. This indicates the result of this research can be easily practiced at any hospital. Studies on effectiveness of prophylactic intravenous dexamethasone for prevention of shivering after spinal anesthesia for cesarean section were limited. According to our search, no published study was discovered in Ethiopia. Additionally, we did this thesis since it was challenging to generalize study findings from other nations due to different management modes due to the economic and technological gaps in our resource limited set up.

The findings of this study will also serve as a guide for program designers as they seek out efficient preventative approaches, select the best alternative route, and assess the efficacy of implemented preventive interventions aimed at shivering. The outcome of the study will contribute to Mahatma Gandhi memorial hospital anesthesia management strategies and it will be an input for future research and Addis Ababa University College of health science school of medicine department of anesthesia. It will contribute to science in future opioid free anesthesia protocol.

# Chapter Two

## 2. Literature Review

Incidence of shivering after spinal anesthesia for cesarean section varies from 10% - 85% in different studies (1-3, 5, 6).

Dexamethasone is grouped under steroid drugs it has anti-inflammatory and immune depressant action. Its preventive mechanism of post spinal anesthesia is by controlling of immune response and lowering temperature difference between dermal and core body temperature through its anti-inflammatory effect and inhibition of the spread of vasoconstrictors and pyrogenic cytokines (8).

A study done in Indonesia on the effect of dexamethasone and pethidine in lowering the incidence of shivering in cesarean section patients under spinal Anesthesia showed; grade 0 shivering was the most common type of shivering in all study groups. the incidence and severity of shivering were 25.9%, grade 0= 74.1% in pethidine group, 37%, grade 0=63% in dexamethasone group, and 59.3%, grade 0=40.7% in control group ($p<0.05$) (9).

A single center randomized controlled study conducted in Malaysia on evaluating effect of prophylactic intravenous dexamethasone in post spinal shivering: showed; the occurrence of shivering was observed in both groups as early as 5 minutes after spinal anesthesia. Highest grade of shivering in dexamethasone group were grade 2 and only two participants in the saline group experienced grade 3 shivering and required a single dosage of pethidine. No patients in either group experienced grade 4 shivering. Incidence of grade 3 and 4 shivering ($p=0.49$) and pethidine use ($p=0.49$) did not significantly differ between the two groups (15).

A double blind RCT study conducted in Iran to assess effectiveness of dexamethasone in comparison with pethidine for the prevention of post spinal shivering showed that; in relation to the skin temperature in all three groups, the control group had a greater reduction in temperature than the other two groups (P 0.05). In the dexamethasone group, 10% of patients experienced postoperative shivering, compared to 47.5% of patients in the control group, and 37.5% in the pethidine group shows a significant difference ($P = 0.001$). Only three patients in the pethidine and control groups, one patient in the dexamethasone group were experienced postoperative nausea, which did not differ statistically from one another ($P = 0.54$) (16).

Another randomized double blind placebo controlled trial study conducted in India to assess the effectiveness of intravenous dexamethasone versus tramadol for prevention of shivering after general anesthesia showed: the incidence and severity of shivering among groups were 51% patients, 49% had grade 0, 21% had grade 1, 30% had grade 2, and 0% had grade 3 shivering in control group; whereas 9% patients , 91% had grade 0, 4% had grade 1, 4% had grade 2, 1% had grade 3 in tramadol group, and 23% patients, 78% had grade 0, 18% had grade 1, 2% had grade 2, 2% had grade 3 shivering in dexamethasone group (p value < 0.001) (17).

A comparative study conducted in Iran to evaluate the prophylactic effects of ketamine, dexamethasone, and pethidine in preventing postoperative shivering showed; post-operative shivering were observed in 37.8% of ketamine group, 31.1% of dexamethasone group, and 11.1% of pethidine group ( p =0.012). No hallucination, delirium, nausea, vomiting, hypertension, tachycardia, or other complications were seen in any of the patients (18).

Another study conducted in Iran on comparing the efficacy of prophylactic intravenous dexamethasone and pethidine on postoperative shivering in elective cesarean section under spinal anesthesia showed; in comparison to the control group, shivering was less common and less severe in the pethidine and dexamethasone groups (P 0.05). The means of the shivering scores were 0.03 for the pethidine group, 0.15 for the dexamethasone group, and 0.27 for the control group. Pethidine and dexamethasone groups substantially consumed less pethidine to reduce postoperative shivering than the control group (P 0.05) (19).

A research conducted in Iran on comparison of the effect of dexamethasone, midazolam, and ondansetron injection alone, or in combination, and placebo on the severity of shivering during and after spinal anesthesia in orthopedic operations of the lower limb; showed that; when comparing the central and peripheral temperatures between the groups before the anesthesia and at 5, 10, 15, 20, 25, and 30 minutes after it, there was no significant difference (P > 0.050). The severity of shivering varied significantly between the groups throughout the first, second, third, and fourth minutes up to fifteen minutes, the placebo group experienced more severe shivering (P 0.001) (20).

A study conducted in India on efficacy and potency of dexamethasone in comparison with ketamine and tramadol in the prevention of post-operative shivering showed the incidence of severe postoperative shivering; in the dexamethasone group, 73.3% had grade 0 shivering, 10.0% had grade 1, 6.7% had grade 2, and 10.0% had degree 3 whereas, 50.096% had grade 0, 16.7% had

grade 1, 6.79% had grade 2, 16.7% had grade 3 shivering in ketamine group, and 75.9% had grade 0, 6.9% had Grade 1, 10.3% had grade 2, 6.9% had grade 3 shivering in tramadol group (21).

A prospective double blind study done in India on prophylactic intravenous dexamethasone versus dexmedetomidine for post spinal shivering during lower segment cesarean section showed the incidence of shivering was 13.75% in dexmedetomidine group, and 31.25% in dexamethasone group. shivering was persisted for longer duration and incidence of sedation was statistically high in dexmedetomidine group than dexamethasone group (P = 0.0022) (22).

A research done in Bangladesh on dexamethasone for prevention of postoperative shivering; showed, incidence and severity of shivering were 15% in the dexamethasone group, 4 patients had grade 1, 2 patients had grade 2, and none had grade 3 shivering, whereas 55%, in the placebo group, 12 patients had grade 1, 7 patients had grade 2, and 3 patients had grade 3 shivering ($P<0.05$). There was no grade 4 shivering in either groups (23).

Another study conducted in Iran to asses on comparison between dexamethasone and pethidine for prevention of shivering following spinal anesthesia during cesarean section showed; the incidence of shivering, nausea and headache; shivering was present in 50% of the parturients in the normal saline group, 72.7% of the dexamethasone group, and 45.5% of the pethidine group. Additionally, 45.5% of those who received dexamethasone, 40.9% of those who received pethidine, and 50% of those who received normal saline experienced nausea. Indifferent dexamethasone had a positive action on post spinal anesthesia headache for cesarean section (9).

A research done in Morang, Nepal on effectiveness of dexamethasone for prevention of intraoperative shivering in caesarean delivery under subarachnoid block showed; the incidence and severity of shivering were 36.4%, grade 0=63.6%, grade 1=13.6%, grade 2=18.2%, grade 3=2.3%, grade 4=2.3% in control group, whereas 9.1%, grade 0=90.9%, grade 1=2.3%, grade 2=0.0%, grade 3=4.5%, grade 4=2.3% in dexamethasone group (p=0.002) (6).

A study conducted in Egypt on efficacy of dexamethasone on prevention of post-operative spinal shivering in comparison with intravenous ketamine plus midazolam during elective cesarean section showed; the incidence of shivering among ketamine plus midazolam were 10% whereas 33.3% in the dexamethasone and 40% in the Placebo groups. The incidence of sedation was higher in the ketamine plus midazolam than dexamethasone and placebo groups (11).

Another study done in Egypt on comparative study between dexamethasone and ondansetron for prevention of shivering during spinal anesthesia showed; Shivering was 30% in dexamethasone

group, 40% in ondansetron group, and 66.7%) in control group (P< 0.05). In the control group, the average times before shivering began were 22.3 17.96 whereas, 19.55 ± 17.08 in the dexamethasone, and 22.2 ± 22.29 in the ondansetron group. Shivering intensity was significantly reduced in the groups receiving dexamethasone and ondansetron compared to the control group (P < 0.05) (24).

In addition another study done in Cairo, Egypt on prevention of post spinal anesthesia shivering in gynecological surgeries between mirtazapine vs. dexamethasone showed that; the incidence of shivering and the mean dose of pethidine consumption were higher in the control group, whereas the onset of shivering and the response rate after single dose of pethidine were lower than the mirtazapine and dexamethasone groups. Occurrence of pruritus, nausea, vomiting, were higher in control group than the dexamethasone and mirtazapine groups. Sedation was higher in mirtazapine group than dexamethasone and control groups (25).

Another research done in Egypt on post spinal anesthesia shivering in lower abdominal and lower limb surgeries a comparison between paracetamol and dexamethasone showed; the occurrence of shivering in the control group was significantly higher, while the onset of shivering was significantly lower than in the paracetamol and dexamethasone groups. Clinically significant shivering (shivering grade≥2) was 15.0% in paracetamol group, 40.0% in dexamethasone group and 76.0% in control group. The need for meperidine treatment was 15.0% in the paracetamol group, 40.0% in the dexamethasone group and the most common in the control group (77.0%) (1).

A research done in Ethiopia on 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 showed; the incidence and intensity of shivering was 21.9%, 12.5% had grade 2 shivering, and 9.4% had grade 3 shivering of patients in the pethidine group and in the dexamethasone group, 12.5% experienced grade 1 shivering and 18.8% had grade 3 shivering. The dexamethasone group experienced much less shivering, however it was not statistically significant. The mean time for the first onset of shivering was 65 minutes in the dexamethasone group and 81 minutes in the pethidine group. The median amount of anti-shivering medication consumed was 54.2 mg in the dexamethasone group and 68.8 mg in the pethidine group (8).

## 2.1. Conceptual frame work

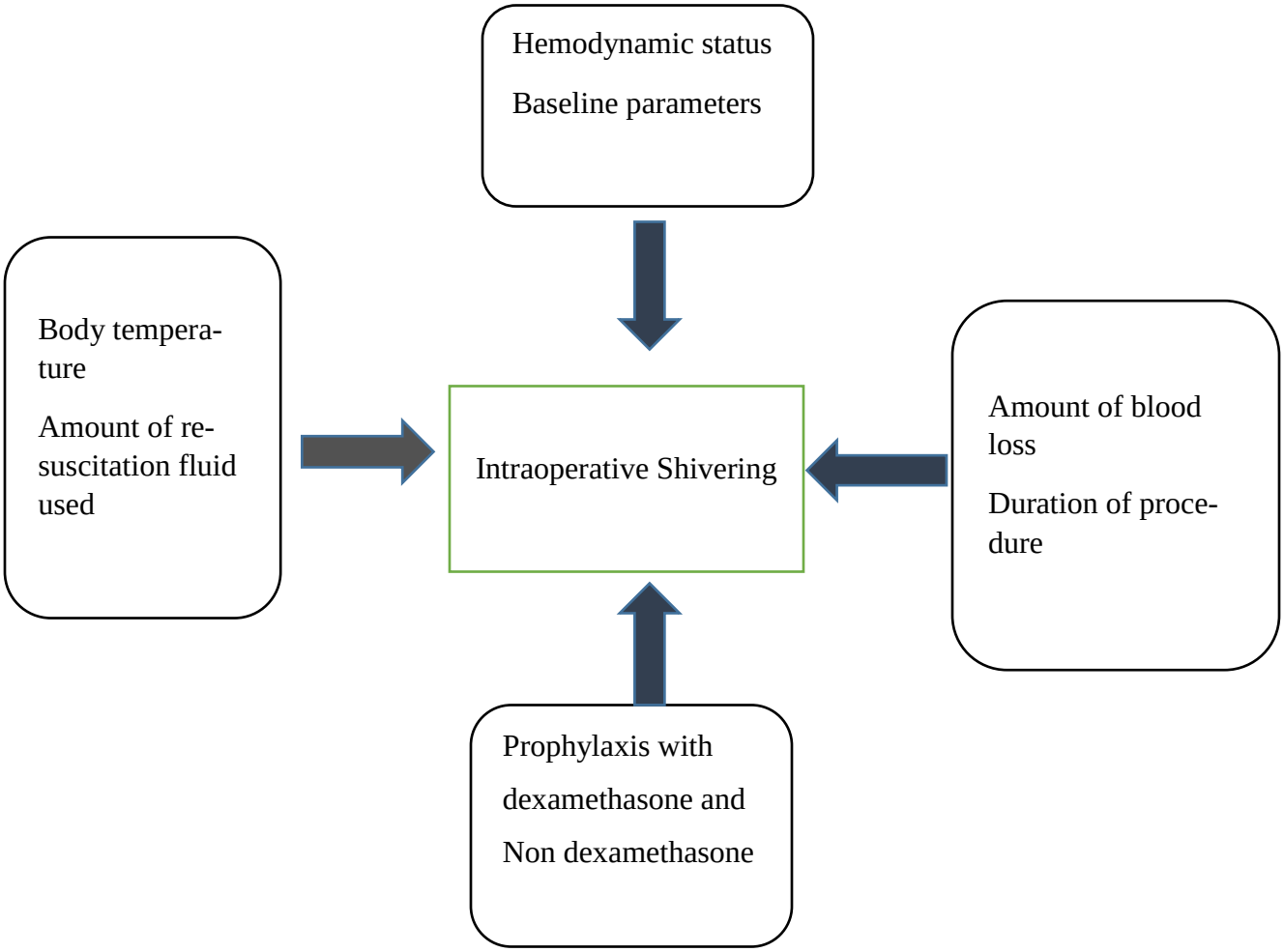


Figure 1: factors affecting intraoperative shivering following spinal anesthesia: (1-3, 5, 6).

## 2.1. Research hypothesis

1. H0: there is no significant difference in incidence of intraoperative shivering between dexamethasone and non-dexamethasone groups

2. HA: there is statistically significant difference in incidence of shivering between the two groups

1. H0: there is no significant difference in severity of shivering between the two groups

2. HA: there is statistically significant difference in severity of shivering between groups

# Chapter three

## 3. Objectives

### 3.1. General objectives

- To assess the effectiveness of prophylactic intravenous dexamethasone for the prevention of intraoperative shivering following spinal anesthesia for cesarean section at Gandhi memorial hospital, Addis Ababa. Ethiopia 2023

### 3.2. Specific objectives

- ✓ To compare the incidence of intraoperative shivering between dexamethasone and non dexamethasone groups
- ✓ To compare the severity of intraoperative shivering between the two groups

# Chapter four

## 4. Methods and materials

### 4.1. Study design and period

An institutional based prospective cohort study design was conducted from February 07 to April 08/2023.

### 4.2. Study area

The Mahatma Gandhi Memorial Hospital in Addis Ababa was the site of the study. Since in 1951 E.C, it has been the only governmental maternity service hospital in Ethiopia. It was given that name in honor of Mahatma Gandhi. It is one of Addis Ababa's thirteen public hospitals, which are run by the Addis Ababa health bureau. The hospital primarily provides gynecological, obstetric, and reproductive health care for women and children. The hospital has four operating rooms and 100 beds, and on average, 280 cesarean sections are performed there each month.

### 4.3. Source population

All parturients who were coming at Gandhi memorial hospital to give birth.

#### 4.3.1. Study population

All parturients who were scheduled for giving birth by cesarean section under spinal anesthesia at Gandhi memorial hospital who fulfil the inclusion criteria during study period.

## 4.4. Variables

#### 4.4.1. Dependent variable

- Intraoperative shivering

#### 4.4.2. Independent variables

Axillary body temperature

Baseline parameters

Hemodynamic status

Amount of resuscitation fluid used

Duration of the procedure

Amount of blood loss

Prophylaxis with dexamethasone and non-dexamethasone

## 4.5. Eligibility criteria

### 4.5.1. Inclusion criteria

American society of anesthesiologist's class II parturients

All partureints who give birth by cesarean section under spinal anesthesia during study period were included in the study.

### 4.5.2. Exclusion criteria

Parturients who had known hypersensitivity for dexamethasone, parturient who took opioid and steroid medication for labor analgesia, failed spinal, uncooperative patient, parturients with hypo/hyperthyroidism, patients with cognitive disorder, psychological disorders, having neuro-muscular and neurogenic disorder, baseline axillary body temperature <36.0 and >37.5 degree centigrade were excluded from the study.

## 4.6. Sample size

The sample size was calculated by using Epi info 7 for independent cohort and taking into account one to one ratio of the dexamethasone exposed and non exposed groups with the assumption of a p value <0.05 as statistically significant and a power of 80%, the sample size was calculated to be 88(44 parturients each group). After accounting 10% of lost follow up the total sample size was 98(49 parturients each group). The sample size was established based on a prior study conducted in Morang, Nepal, which revealed that the incidence of shivering in dexamethasone exposed and non exposed were 9.1% and 36.4% respectively (6).

### 4.6.1. Sampling procedures

Using a systematic random sampling technique, 98 parturients were participated in the study from daily scheduled for both elective and emergency cesarean section. From situational analysis Mahatma Gandhi memorial hospital had provided 280 cesarean section delivery services under spinal anesthesia within a month. Thus, to enroll every $K^{th}$ parturient into the study, $K = 280 \div 98 \approx 3$. Therefore, every third case that meets the inclusion criteria for the study was chosen from consecutively scheduled for cesarean section parturients. The first participant was chosen by lottery method from the first three cases to serve as a starting point for the sample. The initial chosen number was three and served as the random process started. Following that, each subsequent parturient from the randomly selected starting number was included in the study until the target sample size was reached.

## 4.7. Data collection procedures

Data was collected through written questionnaire. Questionnaires were adopted and prepared in English first and translated to local language Amharic and back to English to check for consistency, and in order to obtain relevant quality data. Data collectors were well trained about what he/she would conducting clearly first.

In Mahatma Gandhi memorial hospital perioperative anesthesia management for cesarean section were performed by BSc and MSc anesthesia professionals.

Preoperative evaluation, planning for appropriate anesthesia type and management after deciding to proceed with the surgery informed consent were signed. Parturients came for surgery assigned anesthetists administered the mother with anti-acids (cimetidine 200-400mg or ranitidine 50mg IV), prokinetics (metoclopramide 10mg IV) as a premedication. Some anesthetists added 0.1mg/kg IV dexamethasone as a premedication others not.

The above premedication drugs were given depending on their onset of action to get the desired effect during waiting list or after entered in to the OR before 10 minutes of spinal anesthesia given as the anesthetist's preference.

The parturient entered in to the OR table, standard anesthesia monitoring (BP, ECG, RR and SPO2) were attached and baseline v/s were recorded and orally informed for digital axillary thermometer probe placement. After baseline v/s measured and recorded double IV line placement was assured and oriented for positioned to inject spinal anesthesia.

Then after, with strictly aseptic technique SA was done with 0.5% of 3ml bupivacaine alone at L3-L4 interspace for all parturients and normal saline or lactated ringer's fluid were co-load intraoperatively.

Operative analgesia and anesthesia block were confirmed by assessing autonomic, sensory and motor block. This all activities were the routinely practiced anesthesia management protocols in Gandhi memorial hospital. Data collectors separated patients who received 0.1 mg/kg IV dexamethasone as a premedication into a dexamethasone group and those who were not into a non-dexamethasone group.

We were only observed for intraoperative shivering between groups those parturients classed under ASA II on daily practiced basis there in Mahatma Gandhi memorial hospital not administered new drugs.

In both groups, the occurrence of intraoperative shivering was evaluated and graded using the same structured questionnaire; by using the Bedside Shivering Assessment Scale (BSAS.

Grade 0: no shivering 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**).

Based on situational analysis made in Mahatma Gandhi memorial hospital most c/s procedures took 50minutes. So, parturients were followed for 50 minutes intraoperatively.

The time to first onset of shivering and other anti-shivering drug total dose used were recorded. At the time of assessment hemodynamic parameter (MAP), axillary temperature (after SA at 5 minutes then after 10 minutes interval for 50 minutes) and intraoperative adverse outcomes for nausea and vomiting were also assessed.

Data was collected by four BSc anesthesia professionals at work place, supervised by one responsible senior anesthetist, who are familiar to recording perioperative data. Each questionnaire was reviewed daily by the supervisor and reported to the primary investigator every day.

## 4.8. Operational definition

Shivering: is abnormal and involuntary contraction of one or more skeletal muscle groups.

Grade of shivering;

Shivering was 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**).

Hypothermia: temperature < 35 $C^0$

Intraoperative: the time period when the patient entered into the operation room up to end of surgery.

## 4.9. Data analysis procedures

The collected data was carefully reviewed for accuracy before being entered into Epi data version 4.6 and exported to SPSS version 26 for analysis. Descriptive statistics was used to summarize data, tables and figures. The normality distribution of data were tested using Shapiro-Wilk test and homogeneity of variance were tested using Levine's test for continuous data. Independent sample t- test was used to analyze normally distributed data and presented as mean ±SD. For non-normally distributed quantitative data, Mann-Whitney U test was used and presented as median (IQR). Categorical data were analyzed using chi square and fisher's exact test and presented as numbers and frequencies (percentages). P value < 0.05 was considered as statistically significant.

### 4.9.1. Data quality management

After training given by the principal investigator for data collectors, data was collected and properly filled on the prepared format. Then the questionnaires were checked for its accuracy, clarity, and consistency. If there was any ambiguous or incompleteness, it was avoided during data collection period. As well as the researcher was supervise the data collectors and check for the completeness of the data daily.

### 4.9.2. Ethical consideration

Ethical clearance and approval were obtained from institutional ethical committee (REF. NO. 9329/227), college of health science, Addis Ababa University. And permission to conduct this thesis was obtained from the study participants and confidentiality of each participant information was secured.

### 4.9.3. Dissemination of the results

This result will be presented to anesthesia department as part of a partial fulfilment of master's science degree in anesthesia, and to Gandhi memorial hospital. Further effort should be made to publish the findings on national and international peer reviewed journals.

# Chapter 5. Results

A total of 98 ASA class II parturients (49 parturients each group) were included with full response rate. There were no significant difference in demographic profiles (age, BMI) distribution between dexamethasone and non dexamethasone groups. (Table 1)

## 5.1. Sociodemographic profiles

***Table 1*: demographic profiles (age, BMI) between dexamethasone and non-dexamethasone groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| variables | Dexamethasone group | Non dexamethasone group | p-value |
|---|---|---|---|
| Age | 27.76±3.31 | 27.90±3.88 | .845 |
| BMI | 27.01±2.94 | 26.44±2.91 | .306 |

Age and body mass index presented as mean ± SD, tested by independent sample t-test; p value < 0.05 was taken as statistically significant. SD, standard deviation

## 5.2. Comparison of baseline parameters of study groups

Normality distribution of baseline parameters were tested using Shapiro Wilk's test (p value>0.05) and there was no significant difference between the two groups. (Table 2)

***Table 2:* baseline hemodynamic parameters of dexamethasone and non-dexamethasone groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| Baseline hemody-namic Variables | Dexamethasone group | Non dexamethasone group | P value |
|---|---|---|---|
| Axillary body temper-ature | 36.45±.021 | 36.44±.24 | .793 |
| Heart rate | 87.10±6.91 | 87±6.33 | .650 |
| Mean arterial pressure | 74.53±5.35 | 74.24±5.6 | .797 |
| Oxygen saturation | 96.00±.79 | 96.02±.80 | .899 |
| Respiratory rate | 21.55±1.5 | 21.41±1.45 | .634 |

Baseline hemodynamic parameters axillary body temperature, heart rate, mean arterial pressure, oxygen saturation and respiratory rate presented as mean ±SD. Tested by using independent t-test; p value <0.05 was taken as statistically significant.

### 5.3. Comparison of intraoperative axillary body temperature& MAP between dexamethasone and non-dexamethasone group

There was no significant difference between groups in terms of MAP and axillary body temperature at 30 minute (p value=.265) and at 40 minute of recording (p value = .316). But there was statistically significant difference in recording of axillary body temperature at 5 minute, 10 minute, 20 minute and 50 minute of measurement. (Table 3)

***Table 3:*** **Comparison of intraoperative axillary body temperature& MAP between groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| intraoperative axillary body temperature | Dexamethasone group | Non dexamethasone group | P value |
|---|---|---|---|
| At 5 minutes** | 35.61(.23) | 35.21(.24) | .0000096 |
| At 10 minutes** | 35.61(.36) | 35.19(.30) | .0000085 |
| At 20 minutes** | 35.64±.27 | 35.34±.35 | .000011 |
| At 30 minutes* | 35.35(.24) | 35.31(.47) | .265 |
| At 40 minutes* | 35.64±.302 | 35.70±.305 | .316 |
| At 50 minutes** | 35.66±.201 | 35.88±.198 | .000086 |
| Intraoperative mean arterial pressure | | | |
| At 5 minutes** | 71.47±5.54 | 68.90±4.99 | .018 |
| At 10 minutes* | 65.04±5.62 | 64.02±5.97 | .386 |
| At 20 minutes* | 63.41±5.69 | 62.49±5.39 | .414 |
| At 30 minutes** | 62.92±5.29 | 60.41±6.55 | .040 |
| At 40 minutes* | 61.29±3.98 | 60.87±4.01 | .643 |
| At 50 minutes* | 61.78±3.26 | 60.71±2.22 | .212 |

***,** tested by Independent t-test and presented as mean ±SD. **, tested by using Mann -Whitney U test and presented as median (IQR). IQR, interquartile range; SD, standard deviation. P value < 0.05 was considered as significant.

## 5.4. Other intraoperative variables

There was statistically significant difference in mean time to first onset of shivering (p value = .0000028) and median total dose of tramadol consumption (p value = .007). However, median duration of surgery time in minutes, amount of blood loss and amount of fluids used were comparable between groups. (Table 4)

***Table 4:*** **Other intraoperative variables (amount of blood loss, amount of fluids used) in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| variables | Dexamethasone group | Non dexamethasone group | P value |
|---|---|---|---|
| First onset of shivering in minutes | 23.17±2.93 | 15.95±4.26 | .0000028 |
| Amount of intraoperative surgical blood loss in ml* | 794.69±81.65 | 801.84±89.59 | .681 |
| Amount of intraoperative fluid taken in ml* | 2463.27±243.84 | 2475.51±226.87 | .797 |
| Total tramadol consumption dose in mg | 50.00(25) | 50.00(0) | .007 |
| Duration of surgery in minutes** | 40(13) | 42.25(6) | .514 |

***,** tested by Independent t-test and presented as mean ±SD. **, tested by Mann-Whitney U test and presented as median (IQR). IQR, interquartile range; SD, standard deviation. P value < 0.05 was considered as significant.

## 5.5. Incidence of intraoperative shivering

There was statistically significant difference between dexamethasone and non dexamethasone groups (p value = .000084). The incidence of intraoperative shivering was 32.1% in dexamethasone group and 67.8% in non dexamethasone group. Tested by using chi square test and fisher's exact test, presented as percentages by using pie chart. P value < 0.05 was considered as statistically significant.

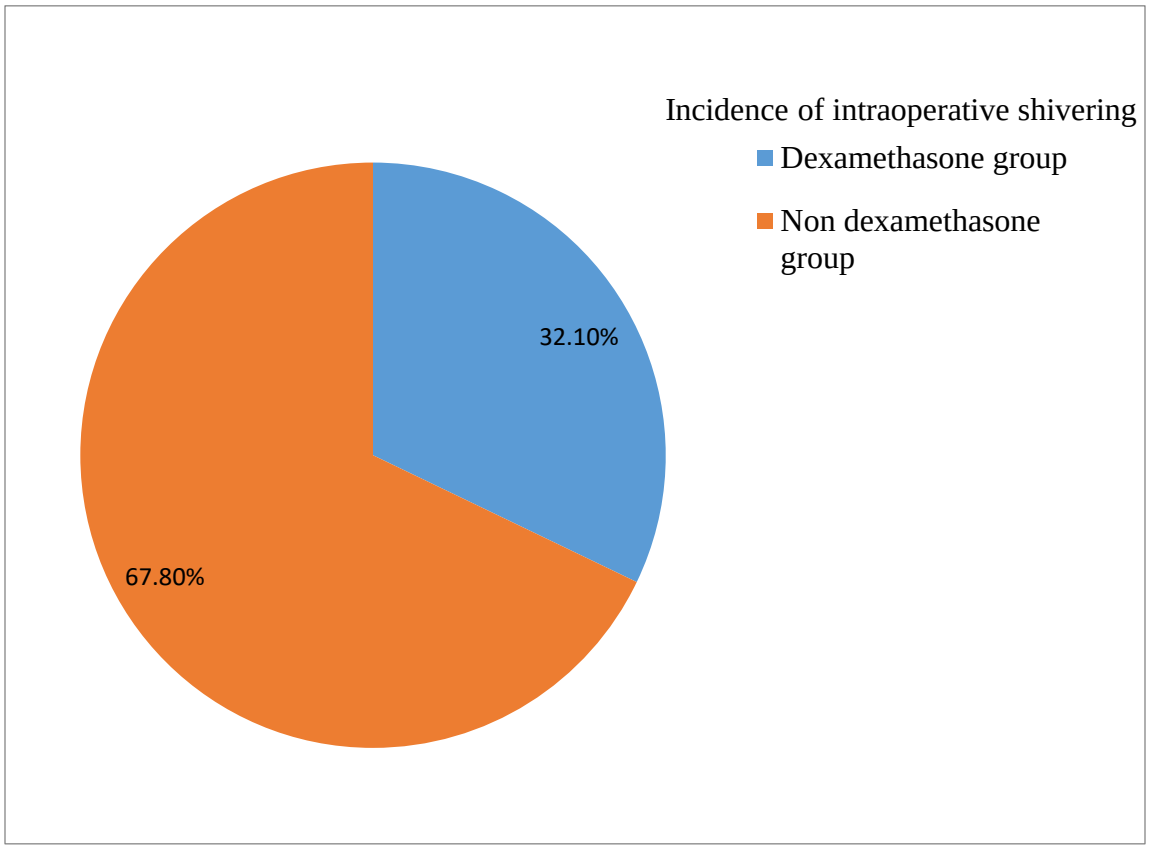


**Figure 2: pie chart showed incidence of intraoperative shivering between groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

## 5.6. Severity of shivering in grade between groups

There was statistically significant different grade of shivering between dexamethasone and non-dexamethasone groups (p value=.044). The highest score of shivering was grade 2 (which was 80.7%) in non-dexamethasone group and there was no grade 3 (which was 0%) in dexamethasone group. Tested by using chi square test and fisher's exact test, presented as percentages by using bar graph. P value < 0.05 was taken as statistically significant.

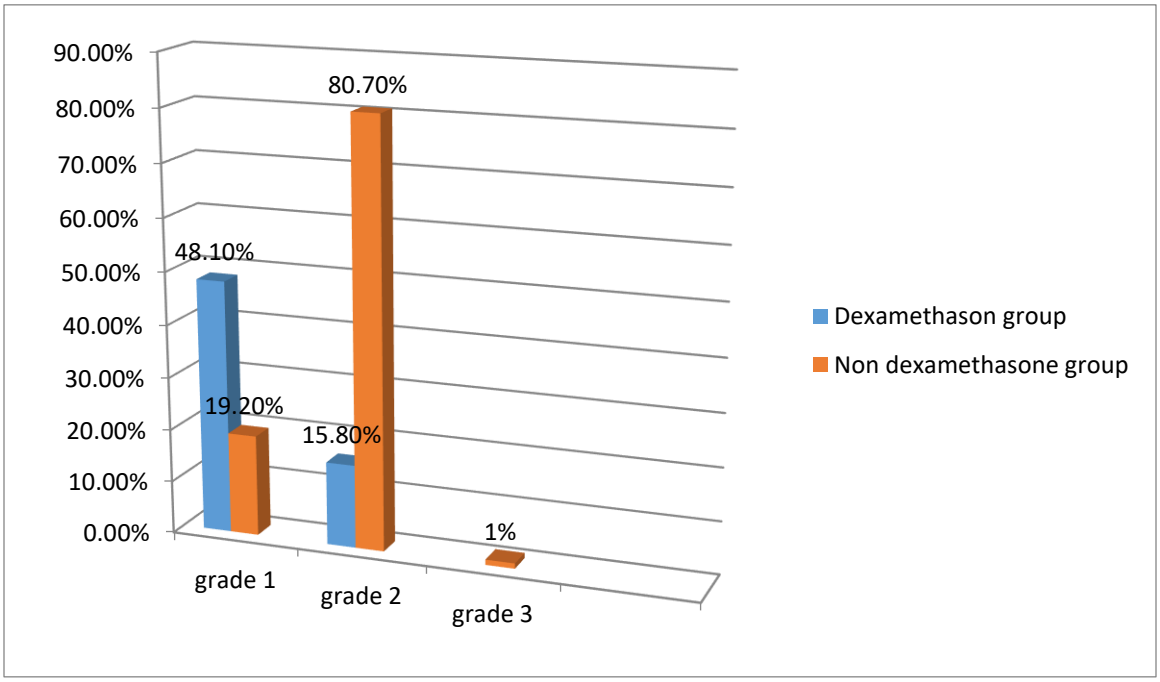


**Figure 3: Bar graph showed grade of shivering between the two groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

## 5.7. Comparison of nausea and vomiting between groups

There was statistically significance difference of nausea and vomiting incidence between dexamethasone and non-dexamethasone groups. The incidence was 27.8% had nausea in the dexamethasone and 82.7% had nausea in non-dexamethasone group (p value =.001) and 17.2% had vomiting in dexamethasone and 82.7% had vomiting in non-dexamethasone group (p value=.000043). Tested by using chi square test and fisher's exact test, presented as numbers and percentages. P value < 0.05 was taken as significant. (Table 7)

# Chapter 6: Discussion

In this study dexamethasone was found effective preventive prophylaxis for intraoperative shivering following spinal anesthesia for cesarean section. The incidence, severity, consumption of median total dose of tramadol, nausea and vomiting reduction was observed in dexamethasone group as compared with non-dexamethasone group.

In the current study exposure variables like, baseline parameters, amount of resuscitation fluid used, amount of intraoperative blood loss and median duration of surgery time in minutes were comparable between dexamethasone and non-dexamethasone groups.

And also, there was no significant difference between groups during intraoperative recording of mean arterial pressure and axillary body temperature at 30 minutes and 40 minutes of recording (p value =.265 and .316 respectively). However, there was statistically significance difference in axillary body temperature at 5min, 10min, 20min, and 50minutes of recording in mean and median axillary body temperature during intraoperative period (p value < 0.05). This could be due to usage of other anti-shivering medication (tramadol) during intraoperative shivering, premedication/not premedication of dexamethasone, lack of controlled room temperature and fluid temperature.

The mechanism of dexamethasone for the prevention of post spinal anesthesia shivering is by controlling immune response and lowering dermal and core body temperature difference through its anti-inflammatory effect and inhibition of the spread vasoconstrictors and pyrogenic cytokines (8).

The present study showed; the incidence of intraoperative shivering was 32.1% in dexamethasone group and 67.8% in non dexamethasone group (p value =.000084).

Similar RCT study was done in Morang, Nepal on effectiveness of dexamethasone for prevention of intraoperative shivering in caesarean delivery under subarachnoid block showed; the incidence of shivering was 9.1% in dexamethasone group and 36.4% in control group. This variation may be due to difference in method of study, intraoperative anesthetic management, controlled room temperature, and non-pharmacological prevention of shivering were used so far in their study (6).

In line with the current study a research done in Indonesia on the effectiveness of dexamethasone and pethidine in lowering the incidence of shivering was 37% in dexamethasone group and 59.3% in control group (p value < 0.05) (9). This could be due to equal dose of dexamethasone (0.1mg/kg) used for premedication.

In contrast with this study, a research conducted in Iran on the efficacy of prophylactic intravenous dexamethasone and pethidine on postoperative shivering in elective cesarean section under spinal anesthesia showed; the incidence of shivering was reduced in dexamethasone group (0.15) compared to controlled group (0.27)( p value <0.05) (19). Which is lower than the values in this study, this may be due to sample size used (99) compared to the current study more than by one sample (98), dose of dexamethasone (0.15mg/kg) used higher than in this study (0.1mg/kg) and time of dexamethasone administration after delivery of the fetus in their study and before 10minutes of spinal anesthesia given in the current study.

In contrast to the present study another study was conducted in Iran to assess on comparison between dexamethasone and pethidine for prevention of shivering following spinal anesthesia cesarean section showed; the incidence of shivering was 72.7% in the dexamethasone group and 50% parturients in the normal saline group( p value =0.149) (9). Which is higher than this study, this may be due to different in number of sample size 66 samples were used in their study and 98 samples in this study were used.

In line with this study a research was done in Egypt on efficacy of dexamethasone on prevention of postoperative spinal shivering in comparison with intravenous ketamine plus midazolam during elective cesarean section showed; the incidence of shivering was 33.3% in the dexamethasone group and 40% in the placebo group (11). This value is closer with incidence of shivering with dexamethasone group of current study (32.1%). This could be due to same dexamethasone dose used (0.1mg/kg) for premedication and different anesthesia management.

The current study showed; there was statistically significant difference in grade of shivering between dexamethasone and non dexamethasone groups (p value = .044). The severity of shivering in grade were 48.1% had grade 1, 19.2% had grade 2, 0% had grade 3 shivering in dexamethasone group and 15.8% had grade 1, 80.7% had grade 2, 1% had grade 3 shivering in non dexamethasone group. In contrast with this RCT research done in Morang, Nepal showed; the severity of shivering were grade 0 = 63.6%, grade 1 = 13.6%, grade 2 = 18.2%, grade 3 = 2.3%, grade 4 = 2.3% in control group. Whereas, grade 0 = 90.9%, grade 1 = 13.6% grade 2 = 0.0%, grade 3 = 4.5%, grade 4 = 2.3% in dexamethasone group( p = 0.002) (6). This variation could be due to controlled room temperature and fluid temperature in their study and different anesthesia management.

In the present study grade 2 (80.7%) shivering in the non dexamethasone group and grade 1 (48.1%) shivering in the dexamethasone group were the commonest observed grade of shivering. Which is in contrast with study done in Indonesia showed; grade 0 shivering was the common type of shivering in both dexamethasone (63%) and control (40.7%) groups. This may be due to different study design, intraoperative anesthesia management.

This study showed the consumption of median total dose of tramadol was 50.00(25) mg in dexamethasone group and 50.00(0) mg in non dexamethasone group (p value = .007). In line with this, a study done in Iran showed the consumption of pethidine to control shivering after surgery was significantly lower in dexamethasone group compared to control group ( p value < 0.05). This indicates premedication with dexamethasone reduces opioid consumption.

In the current study 27.8% in the dexamethasone and 82.7% in the non dexamethasone groups were experienced nausea (p value = .001). Whereas, 17.2% in dexamethasone group and 82.7% in non dexamethasone group had vomiting (p value = .000043). In contrast to this, a study conducted in Iran showed; 45.5% in the dexamethasone group and 50% in the normal saline group experienced nausea. This indicates prophylaxis with dexamethasone reduces risk of intraoperative nausea. But there was no difference between groups in a study done in Morang, Nepal showed; nausea and vomiting was 6.8% in control group and 4.5% in dexamethasone group (p value = 0.645).

## 6.1. Strength of the study

Baseline variables such as demographic and pre-operative characteristics were homogeneous.

## 6.2. Limitation of the study

Due to lack of  room temperature thermometer, OR room and IV fluid temperature were not controlled, confounding variables still possible due to lack of randomization and control

# Chapter 7: Conclusion and recommendation

## 7.1. Conclusion

Based on the result of current study we concluded that prophylaxis intravenous dexamethasone had effective prevention of intraoperative shivering following spinal anesthesia for cesarean section in terms of incidence, severity, total dose of tramadol consumption, nausea and vomiting.

## 7.2. Recommendation

**For anesthesia professionals**

We recommended to provide premedication with prophylaxis of intravenous dexamethasone (0.1mg/kg) before 10minutes of spinal anesthesia for effective prevention of intraoperative shivering during cesarean section.

**For researchers**

By considering the present study as a baseline further RCT study for better randomization and control factors was recommended.

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## Annex I

Informed consent form

Dear Sir /Madam…!

This is _____. I am a member of a research team of anesthesia department at Addis Ababa University. We are studying on how to prevent intraoperative shivering during cesarean section under spinal anesthesia. We will not intervene on any of your anesthetic or surgical management. We just follow your vital signs and intraoperative incidents like temperature, blood pressure, shivering… during the intraoperative period. I confidently can assure you that our study will not compromise your anesthetic and surgical management nor it will cause any adverse effects on your life. If you feel that this study affects you negatively, feel free to stop your participation in the study at any time. I would like to remind you that the results of this study will hopefully improve our clinical management of patients like you. So, don't you feel that you are saving life of others with no harm and hazard happening on you? The results of the study will be announced in statistical generalization that means the data from you will not be reported individually. If you feel that this study is essential, please put your signature on the space below. Since the date is secured with code none of your personal data will be disclosed to anybody. You are not supposed to write your name, just put your own signature below. Thank you for your cooperation.

Sign_____Date _____

የስምምነት ፎርም

_____ እባላለሁ። በአዲስ አበባ ዩኒበርሲቲ የአንስቴሽያ ት/ት ክፍል የጥናትና ምርምር አባል ነኝ። በቀዶ ህክምና ሲወልዱ ከወገብ በታች ማደንዘዣ ከተወሰደ በኋላ የሚከሰት ብርድ ብርድ ማለት እና ማንቀትከት እንደት መከላከል እንደሚቻል እያጠናን እንገኛለን። በጥናቱ ምክንያት በርእሰዎ ላይ ምንም አይነት የሚቀነስበዎት የህክምና አገልግሎት ወይም የሚያመጣበዎት ተጓዳኝ ችግር እንደሌለ አረጋግጥለዎታለሁ። የርእሰዎ የግል ምስጢር የተጠበቀ መሆኑን እና ምንም አይነት የግል መረጃዎትን የማናስተላልፍ መሆኑን ከወዲሁ ላሳውቀወት እወዳለሁ። በጥናቱ ለመሳተፍ ፈቃደኛ ከሆኑ የግል ፊርማዎትን ወይም አሻራዎትን ያስቀምጡ። ለተሳትፎዎ እናመሰግናለን። ፊርማ

_____

## Annex II

Questionnaire: Effectiveness of prophylactic intravenous dexamethasone (0.1mg/kg) for prevention of intraoperative shivering during cesarean section under spinal anesthesia at Gandhi memorial hospital, 2022/2023

Section 1. Socio demographic characteristics

| No. | Questions | Response |
|---|---|---|
| 101 | Age | years |
| 102 | BMI | $Kg/m^2$ |
| 103 | Dexamethasone (0.1 mg/kg) given preoperatively before 10 minutes of SA | 1. yes<br>2. no |

Section 2. Hemodynamic parameters

| No. | Questions | Response | | |
|---|---|---|---|---|
| 201 | Baseline parameters | OR room temperature _____$C^0$<br>HR _____bpm., MAP _____ mmhg., Axillary body temperature_____C0,<br>RR_____b/m, SPO2 _____% | | |
| 202 | Hemodynamic parameters after dexamethasone and SA given | Time | To. axillary | MAP |
| | | At 5min | _____$c^0$ | _____mmhg |
| | | 10min | _____$c^0$ | _____mmhg |
| | | 20min | _____$c^0$ | _____mmhg |
| | | 30min | _____$c^0$ | _____mmhg |
| | | 40min | _____$c^0$ | _____mmhg |
| | | 50min | _____$c^0$ | _____mmhg |

Section 3. Shivering and severity of shivering

| No. | Questions | Responses |
|---|---|---|
| 301 | Is intraoperative shivering occur | 1) Yes ….<br>2) No |
| 302 | If yes, how is the severity of shivering in grade | Grade _____. (0, 1, 2, 3). |
| 303 | Time to 1st onset of shivering | _____min. |
| 304 | Is other anti-shivering medication used | 1) Yes (If yes what medication were used and its dose…) |

| | | |
|---|---|---|
| | | Pethidine, dose_____ mg<br>Tramadol, dose_____ mg<br>Ketamine, dose_____ mg<br>Other(specify)____<br>dose_____ mg<br>2) No |

Section 4; SA related factors

| | | |
|---|---|---|
| 401 | Site of SA given | Between L3 –L4 other (specify) _____ |
| 402 | Types of local anesthetics used for spinal block | Bupivacaine alone ,dose _____mg<br>Bupivacaine with adjuvants(specify) with _____dose, _____ mg<br>Others (specify)_____ |

Section 5. Surgical related factors

| | | |
|---|---|---|
| 501 | Duration of surgery | _____min |
| 502 | Amount of blood loss | _____.ml |
| 503 | Amount of resuscitation fluid used | _____ml. |

Section 6. Associated side effects

| | | | | | |
|---|---|---|---|---|---|
| 601 | Any observed side effects | Nausea | Yes | Vomiting | Yes |
| | | | No | | No |

## Annex III

Shivering was 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**).

***Table 5:*** **Incidence of intraoperative shivering between groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| Incidence of shivering | Dexamethasone group | Non dexamethasone group | P value |
|---|---|---|---|
| Yes | 18(32.1%) | 38(67.8%) | .000084 |
| No | 31(73.8%) | 11(26.2%) | |

Tested by using chi square test and fisher's exact test, presented as numbers and percentages. P value < 0.05 was taken as statistically significant.

***Table 6:*** **Comparison of severity of shivering between the two groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| **severity of shivering in grade between groups** | | | | |
|---|---|---|---|---|
| Severity | grade 1 | grade 2 | grade 3 | p value |
| Dexamethasone group | 13(48.1%) | 5(19.2%) | 0(0%) | .044 |
| Non dexame-thasone group | 14(15.8%) | 21(80.7%) | 3(1%) | |

Tested by using chi square test and fisher's exact test, presented as numbers and percentages. P value < 0.05 was taken as statistically significant.

***Table 7:*** **Comparison of incidence of nausea and vomiting between groups in Gandhi memorial hospital Addis Ababa, Ethiopia from February 07 to April 08/2023.**

| | Dexamethasone group | Non dexamethasone group | p-value |
|---|---|---|---|
| Nausea | | | |
| yes | 10(27.8%) | 26(82.7%) | .001 |
| no | 39(62.9%) | 23(37.1%) | |
| Vomiting | | | |
| Yes | 5(17.2%) | 24(82.7%) | .000043 |
| no | 44(63.7%) | 25(36.2%) | |

Tested by chi square test and fisher's exact test, presented as numbers and percentages. P value < 0.05 was taken as statistically significant.