



ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE
SCHOOL OF MEDICINE DEPARTEMENT OF ANESTHESIOLOGY
CRITICAL CARE AND PAIN MEDICINE RESEARCH

Intravenous Dexamethasone versus meperidine in the prevention of post-spinal shivering in urological surgery patients a randomized control trial at Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia, 2024 G.C.

Final thesis to be submitted to the Department of Anesthesiology, Critical care and Pain medicine in Partial Fulfillment of the Requirement for Specialty Program in Anesthesiology.

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Addis Ababa, Ethiopia May 2024

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DECLARATION OF THE PRINCIPAL INVESTIGATOR

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 Department and College, in effect at the time of grant is forwarded as the result of this application. Name of the student: Dr Elisabeth Temesgen in partial fulfilment for completion of specialty of anesthesiology and critical care.

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Signature _____ APPROVAL OF THE FIRST ADVISOR

Name of the first advisor: _____ Date.

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APPROVAL OF THE SECOND ADVISOR Name of the second advisor:

_____ Date. _____ Signature

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ABSTRACT

Background: Shivering is defined as an involuntary, oscillatory skeletal muscular action that increases oxygen consumption (200%–500%) and carbon dioxide production, resulting in arterial hypoxemia, lactic acidosis, and a rise in intraocular and intracranial pressure. It's one of the complications that decrease patient satisfaction. There are both preventive and management measures for shivering; meperidine (pethidine) is the first line agent; and there are also other classes of drugs that have proven to be effective, such as alpha-2 agonists, tramadol, dexamethasone, ketamine, and ondansetron. In this study, dexamethasone will be compared with pethidine.

Objective; was to compare the efficacy of dexamethasone versus pethidine in the prevention of post-spinal shivering at the Black Lion Hospital in Addis, Ethiopia.

Method; institutional based single blinded randomized control trial, the study was conducted at Addis Ababa University School of health science which is found in Addis Ababa. The source population will be all elective patients undergoing surgery under neuraxial anesthesia. The final sample size for this study is 56. The data will be collected intraoperatively using a pretested questioner by trained data collectors. Data will be checked for completeness and entered using Epi-info software and cleaned then imported to SPSS 27 software for analysis. Descriptive analysis will be done for the Socio-demographic and clinical characteristics of the participants. independent t test for comparison of continuous variable and chi square test for categorical variables used for analysis. The association considered significant when a p value is less than 5% at 95% confidence interval

Result - Total incidence of shivering is 28% and dexamethasone group has 36%, pethidine group has 20% with p value (0.18). From intraoperative variables systolic blood pressure has significant reduction in pethidine group p value (0.001). Moderate to severe shivering was seen in 6 (19%) patients in dexamethasone group while 2 (6.7%) patients in pethidine group had moderate shivering. 2 patients from dexamethasone group required rescue management. Nausea is seen in 5 patients from pethidine group and 2 patients from dexamethasone group. None of the patients had vomiting or hypotension.

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Conclusion – Intravenous 0.1 mg dexamethasone is as effective as intravenous pethidine for prevention of visible muscular shivering with reduced incidence of complication.

1. INTRODUCTION

1.1 Background

Shivering is defined as an involuntary, oscillatory skeletal muscular action that happens as a physiological response to increase metabolic heat production. It is common in up to 30%-60% of individuals undergoing central neuraxial anesthesia and 5%-65% of patients undergoing general anesthesia. (1)

Shivering is frequent in hypothermic patients, but it can also be noticed in normothermic individuals throughout the perioperative phase. Shivering is a physiological response to cold, while peripheral vasoconstriction is the major attempt to save heat. The most common cause of post-anesthetic shivering is perioperative hypothermia, which occurs due to spinal reflex impairment; shivering also occurs in normothermic patients, most likely due to spinal reflex blockage, decreased sympathetic activity, adrenal gland suppression, and pyrogen release. (2)

Various investigations on the prevalence of post-spinal shivering in Uganda have revealed an 8.15% prevalence of shivering occurring predominantly at 20 minutes, with hypotension and hypothermia as linked factors. Shivering was efficiently addressed with Pethidine 25 mg. (3) The same study done on an obstetric patient in Addis Ababa showed an overall incidence of intraoperative shivering following cesarean section under spinal anesthesia of 51.8%. (4) Hypothermia, hypotension, and surgery length were found to be the most related factors in studies.

Prevention is the critical step in the management of shivering. Most studies advocate several non-pharmacological and pharmacological strategies to avoid and manage this condition.

The first step in preventing preoperative hypothermia is to prevent internal redistribution can be avoided by covering the patient for 30 minutes with a forced-air warmer prior to anesthesia administration. (5)

The most effective and extensively used and had remarkable finding medicine to treat post-spinal shivering is intravenous (IV) meperidine (pethidine).

Pethidine is thought to reduce post-spinal shivering by acting as an agonist on mu and kappa receptors, resulting in a decrease in shivering threshold temperatures. meperidine

has a substantial anti-shivering effect, as it reduces the shivering by double that of cutaneous vasoconstriction at an equal dose which makes the drug more effective in thermoregulation rather of analgesics when compared with other opioids. (6) however, adverse effects such as respiratory depression, drowsiness, nausea, vomiting, pruritus, and urine retention limit the ideal dose of pethidine in avoiding shivering. (7)

DEXAMETHASONE Since the mechanism causing shivering in general anesthesia is almost identical to that in spinal anesthesia. Dexamethasone is a popular medication for preventing nausea and vomiting in addition to being a potent analgesic and anti-inflammatory. (8) discovered that IV dexamethasone 0.1 mg/kg in combination with pethidine 0.2 mg/kg is more effective than pethidine alone in preventing post-spinal shivering, but it has opioid adverse effects.

Dexamethasone is thought to reduce the activation of inflammatory mediators, obstruct the transmission of nociceptive C-fibers, and decrease ectopic neural discharge to reduce inflammation and pain. (9) Therefore, its primary inhibitory action on the thermoregulatory center and prevention of the production of inflammatory mediators may help explain its function in reducing post-spinal shivering. (8)

1.2 Statement of problem

One of the most frequent issues following surgery is post-anesthesia shivering, which can result in a number of consequences including hypoxemia, lactic acidosis, and catecholamine release.

Studies in recent years have shown that even mild hypothermia (10C – 20C) can triple the incidence of adverse cardiac outcomes (11) an increase in surgical blood loss and increase in need for blood transfusion by 20% is also noted.

Shivering mechanism is complicated, many different medications have been tried, and more drugs can still be researched. Pethidine has been regarded by various authors and the ASA review as a common and generally efficient anti-shivering drug, but since it is a potent opioid, it is not without adverse effects. which forces us to look for an alternative medication.

As a result, post-spinal shivering is a significant burden. It requires us to exhaust all preventive measures, especially given the scarcity of non-pharmacologic equipment.

Because many studies show the administration of preventative measures, those pharmacologic measures that are easily available, inexpensive, and have the fewest adverse effects should be employed as preventive measures.

There is limited study comparing dexamethasone to the conventional anti-shivering pethidine, despite its being a widely used and inexpensive medication to reduce shivering.

The findings could pave the way for future studies into post-spinal shivering prevention techniques in resource-constrained situations like ours.

1.3 Significance of the study

Maintaining operating room temperature is a common difficulty following surgery in underdeveloped countries with a lack of means to maintain normothermia, such as external heating such as the use of blankets, forced air warmers, and warmed fluids. The inconsistency in pharmacologic drug supply will make it difficult to implement pharmacologic preventive or corrective treatments. Currently, research evaluating the efficacy and side effects of various pharmacologic therapies for shivering is being published in this field of study. As a result, in a system like ours, it is critical to conduct research in this field, particularly for pharmaceuticals that are widely available, inexpensive, and have low side effect profiles.

2. LITRATURE REVIEW

2.1 Overview

post-anesthesia shivering size and associated factors in Tikur Anbesa specialized hospital, 2019. A pre-tested institutional-based cross-sectional study was conducted. The overall incidence of post-anesthesia shivering was 46.9% of patients, with most patients (52.2%) experiencing grade 3 shivering. In the analysis being female and having a body temperature less than 36°C were all considered risk factors for PAS. Finally, there was a significant overall incidence of shivering (46.9), necessitating strict intraoperative temperature monitoring and the implementation of active warming. (12)

2.2 prevention and management of post spinal shivering

Radiant heat systems used in the recovery room are effective methods of preventing or quickly suppressing postanesthetic shivering. The use of a recovery room can minimize the frequency and duration of post anesthetic shivering in all patients. Raising the skin temperature improves thermal comfort in all patients and independent of the method used. (15)

Tramadol decreased thresholds for shivering and vasoconstriction, which is consistent with the drug's effect on ant shivering. Tramadol concentrations had a linear effect on lowering cold sensitivity thresholds, however the differences were negligible (about 0.6–0.9°C). (16)

The frequency of postanesthetic shivering is greatly reduced with clonidine 1.5 or 3 g/kg given at the conclusion of the procedure. The frequency of postanesthetic shivering appears to be reduced much more when doses are increased above this value. The use of 200 to 300 g of clonidine as a premedication and during surgery decreased the incidence of postanesthetic shivering in patients having heart surgery by a factor of 3.5.

a study in India, the purpose of the study was to examine the effectiveness of pethidine, tramadol, and ketamine in preventing shivering brought on by spinal anesthesia as well as their adverse effects. 90 adults were divided and given intravenous doses of pethidine (0.4 mg kg⁻¹), tramadol (1.0 mg kg⁻¹), and ketamine (0.5 mg kg⁻¹). Shivering occurrences were higher in Group T than in Group P and Group K after 30 minutes of

spinal anesthesia ($P = 0.05$), but similar after that. Patients in the ketamine and pethidine groups scored more sedation than those in the tramadol group. The ketamine group experienced fewer cases of nausea, vomiting, and pruritus than the other two groups ($p = 0.001$). (17)

Comparative study of pethidine and tramadol, intravenous dexmedetomidine. 102 individuals undergoing spinal or combination spinal and epidural anesthesia for elective surgery were enrolled in a prospective, randomized, double-blinded trial. Following an intrathecal injection of 15 mg of 0.5% hyperbaric bupivacaine, sixty of them began to shiver. They were given 0.5 g/kg of dexmedetomidine, 0.5 mg/kg of pethidine, or 0.5 mg/kg of tramadol intravenously. The dexmedetomidine group had the highest response rate to treatment. (19)

A study comparing the effectiveness of tramadol and pethidine in reducing postoperative shivering after sub-arachnoid block and contrasting their negative effects. At 10, 15, 20, and 30 minutes, Group Pethidine's shivering score was much lower than Group Tramadol. Similar to how Group Pethidine had lower scores for nausea/vomiting and dizziness but greater scores for sedation. (20)

In Dila, Ethiopia, research on the effectiveness of prophylactic intrathecal pethidine for preventing post-spinal anesthesia was undertaken (A total of 86 pregnant women participated in a randomized controlled experiment that was double-blinded and single-centered. Shivering frequency and intensity, as well as side effects, were noted. In the control and treatment groups, shivering was seen in 53.5 and 20.9% of people, respectively. This was statistically significant, with $p = 0.002$. (21)

There are potentially effective medications that can be used in addition to pethidine, according to several comparative studies on the effectiveness of various pharmaceuticals versus pethidine.

A double-blind randomized controlled trial on intravenous dexamethasone was conducted to reduce the occurrence, severity, and requirement for treatment for post-spinal shivering in 72 patients who needed spinal anesthesia and randomly assigned them to either dexamethasone 0.1 mg/kg (maximum of 8 mg) or normal saline. The dexamethasone group experienced considerably less obvious muscular shaking (grades 2 to 4) than the placebo group ($p = 0.003$). The maximum levels of shivering recorded

in the dexamethasone and saline groups were 2 and 3, respectively. Dexamethasone can attenuate the drop in core body temperature, particularly 15 minutes after spinal anesthesia, with substantially less muscular shivering (31)

Prophylactic administration of dexamethasone has proved a positive effect in numerous studies, particularly in general anesthesia, but requires additional validation.

2.3 Dexamethasone versus pethidine

In Iran, 66 pregnant women participated in a double-blind, randomized clinical trial in 2012 for elective cesarean sections. All patients with ASA I-II were divided into three groups. Despite the statistical lack of a difference in shivering reduction across. There were 11 (72.5%) trembling cases in Normal Saline group, 6 cases (27.3%) in Dexamethasone group, and 12 cases (54.5%) in Pethidine group also there were more side effects with pethidine. (23)

A study was done in Addis Ababa, Ethiopia at Dagmawi Menelik second hospital in 2020 a prospective cohort study to examine the effectiveness of prophylactic dose of dexamethasone and pethidine. 64 patients who met the inclusion criteria and underwent TURP were the subjects of an institution-based prospective cohort study. there was no significant difference in the frequency or intensity of shivering between the pethidine and dexamethasone groups ($p > 0.05$). Dexamethasone (4 mg) and pethidine (25 mg) are both excellent anti shivering medications. (25)

3.OBJECTIVES

3.1. General objective

To compare the efficacy of dexamethasone with pethidine in the prevention of post-spinal shivering in urologic surgery patient at the Black Lion Hospital in Addis Ababa, Ethiopia.

3.2. Specific objective

Assessment of the incidence of shivering following the administration of a prophylactic agent, comparison of the incidence of shivering between the groups receiving dexamethasone and pethidine, evaluation of the severity of shivering and comparison between the two groups, comparison of intraoperative variables (systolic blood pressure, axillary temperature and heart rate) between the two groups, and evaluation of the incidence of complications between the two groups

4. RESEARCH METHODS AND MATERIALS

4.1. Study area and period

The study conducted at TASH in Addis Ababa, the capital city of Ethiopia. It is one of the biggest hospitals in the country and serves people coming from four corners of the country. Currently TASH gives surgical services in the following departments: Neurosurgery, Cardio-Thoracic surgery, Pediatric surgery, Urological surgery, ENT and orthopedic surgery, gastrointestinal tract surgery, Obstetrics and Gynecology surgery. Anesthesia services are provided by the department of Anesthesiology Critical care and Pain medicine, and anesthesia department.

The study was conducted from May 2023- May 30, 2024G.C.

4.2 Study design

Institutional based single blinded prospective randomized control trial was conducted.

4.4 Population

4.4.1 Source population

All adult patient who undergoes surgery under spinal anesthesia in Tikur Anbessa hospital.

4.4.2 Study population

All selected adult patient undergo surgery under spinal anesthesia for urological procedure in the specified period

4.5 Eligibility criteria

4.5.1. Inclusion criteria

All adult patients above 18 years of age, ASA I and ASA II, urology surgery patient

4.5.2. Exclusion criteria

- Patient with hemodynamic instability
- Septic patient

- patient who was on steroid
- Having neuromuscular disease or neurologic disturbance
- Baseline body temperature <36.5 and >38 degree centigrade
- Having uncontrolled diabetes mellitus other endocrine abnormalities.
- Patients who need blood transfusion
- a known history of alcohol or substance abuse, or receiving vasodilators and medications likely to alter thermoregulation were excluded from the study.
- Duration of surgery less than 30 minute

4.6 Sample size determination

The sample size estimated using the primary outcome data from a previous study, that compare pethidine, ketamine and dexamethasone effect on the prevention of post spinal shivering, utilizing the Mean values of central temperature for the two drugs at the 40th minute. (26)The mean temperature for dexamethasone, pethidine 36.47 and 36.1 with standard deviation of 0.47,0.53 respectively. OpenEpi, Version 3, open source calculator was used for calculation. 10% was added for lost to follow up, total sample is 56, 28 allocated for each group.

TABLE 1 SAMPLE SIZE DETERMINATION

Input Data		
Confidence Interval (2-sided)	95%	
Power	80%	
Ratio of sample size (Group 2/Group 1)	1	
	Group 1	Group 2Difference*
Mean		0.4
Standard deviation	0.47	0.53
Variance	0.2209	0.2809

Sample size of Group 1	25
Sample size of Group 2	25
Total sample size	50

4.7 Sampling technique

Simple randomization technique

4.8 Data collection

Before collecting data, data collectors received training that included a quick lecture on the degree of shivering. all patients who scheduled for elective spinal surgery undergoing urologic procedure, met the inclusion criteria, and volunteered to participate. written informed consent was taken and extensively evaluated before surgery by history taking. chart review and complete blood count as baseline investigation for all of them

At the day of operation standard monitoring applied including the attachment of baseline axillary temperatures, pulse oximetry, ECG, and standard monitoring of NIB P. All the patients covered by a single layer of surgical drapes, exposing only the surgical site. All patient has 18G IV cannula attached with room temperature fluid and putted on 3litter of intranasal oxygen. patients blinded and randomly allocated by the investigator and given prophylactic IV pethidine (group P) 25 mg, dexamethasone (group D) 0.1 mg/kg max dose of 8mg. given before administration of spinal anesthesia by the anesthesia provider, 15mg of heavy bupivacaine with 100µg of morphine as additive administered via a 22- or 23-gauge spinal needle at the L4 and L5 levels in sitting position patients then placed back in the supine position immediately after administration and the degree of sensory block evaluated and tested using cold sensation. and severity of shivering assessed by using (22) classification of severity of shivering as

Grading of shivering ((27)

Grade

Grade

Grade 0	No shivering
Grade 1	Visible muscle activity confined to one muscle group
Grade 2	Visible muscle activity in more than one muscle group
Grade 3	Gross muscle activity involving the whole body

TABLE 2 SEVERITY OF SHIVERING

five-point scale used for assessment of sedation(28)

1: Fully awake and oriented;

2: Drowsy;

3: Eyes closed, but rousable to command;

4: Eyes closed, but rousable to mild physical stimulation

5: Eyes closed but unarousable to mild physical stimulation

The axillary temperature, hemodynamic parameters and any postoperative adverse events such as nausea, vomiting recorded. monitored for a period of 60 minutes after administration of spinal anesthesia.

4.9 Study variables

4.9.1 Dependent variable

- Incidence of shivering
- Severity of shivering
- Incidence of complication
- Hemodynamic variables after anesthesia

4.9.2 Independent variable

- Body temperature
- Prophylactic medication used
- Hemodynamic parameters like RR, T°, MAP and SPO2 before administration of spinal anesthesia
- Duration of the procedure
- Intra operative fluid used
- Intra operative bleeding

4.10 Operational definition

Shivering; is the abnormal and uncontrolled movement of one or a group of muscles that occurred within 60 minutes of administration of preventive drug

Moderate shivering – grade II shivering

Severe shivering – grade III shivering that require administration rescue medication.

Grades of Shivering grade using a four-point scale method(27)

- Grade 0: no shivering
- Grade 1: muscular activity in only one muscle group;
- Grade 2: muscular activity in more than one muscle group but generalized
- grade 3: generalized one.

Sedation; is a state in which responsiveness decreases to the point of becoming unresponsive due to the administration of a drug for prophylactic post spinal shivering.

Nausea; sense of illness with a want to vomit

Hypotension; a more than 20% reduction in blood pressure in relation to a baseline pressure.

4.11 Data quality assurance

Data quality assured through carefully designed structured questionnaire. Appropriate modification taken before the actual data collection. also, the quality of data ensured through training of data collectors, close supervision, and prompt feedback, and reviewing each of the completed questionnaires daily.

4.12 Data entry and analysis

After the data collected and completeness confirmed, it entered to the SPSS version 27. Data cleaning was performed to check for outliers, missed values and any inconsistencies before the data analyzed using the software. Independent t test for continuous variable and chi square test for categorical variables used for analyzing the data. Descriptive statistics like frequency tables, charts and descriptive summaries used to describe the independent variables. The association considered significant when a p value is less than 5% at 95% confidence interval.

4.13 Ethical issue

The department of anesthesiology, critical care, and pain medicine granted the study ethical clearance and provided a letter of support.

4.14 Work dissemination plan

The study's findings submitted to Addis Abeba University's School of Medicine, where presented to the health science community and communicated to those involved, as well as published in peer-reviewed scientific journals.

5. RESULT

5. 1 demographic results and patient related factors

A total of 60 patients were enrolled, from which 30 patient as exposed group given dexamethasone and others given pethidine as control group.

patient's demographic and perioperative factors were comparable between the two groups variables from each group were compared for significance using independent sample t test for continuous variables and chi square test for categorical variables. There is no significant difference between the groups demographically.

TABLE 3 DEMOGRAPHIC AND PATIENT RELATED FACTORS

	dexamethasone	pethidine	P - value
Age	46.38 ± 16.96	39 ±17.9	0.817
female	13 %	13%	1.000
Male	36 %	36%	0.876
ASA I	21 %	38 %	1.333
ASA II	28 %	11 %	0.008
Duration of surgery			
< 1hour	24	23	0.754
	6	7	0.654

5. 2 Comparison of baseline perioperative hemodynamic variables

baseline systolic blood pressure diastolic blood pressure, baseline heart rate, baseline axillary temperature was taken from both groups expressed as mean with standard deviation. Normal distribution of baseline variables was assessed by Shapiro wilks test. Variables were assessed with independent sample t test with no statistical difference between them.

TABLE 4 BASELINE HEMODYNAMIC VARIABLES

SYSTOLIC BP	131 ± 13.345	127 ± 12.543	0.193
DIASTOLIC BP	80 ± 8.3	73.8 ± 8.7	0.006

BASELINE	83 ± 9.9	82 ± 8.8	0.943
HEART RATE			
SPO2	95 ± 1.6	95 ± 1.6	0.06
BASELINE	36.3 ± 3.28	36.32 ± 2.69	0.864
AXILLARY T			

Surgical related factors were expressed as number statistical significance was analyzed using cross tabs and chi square analysis.

TABLE 5 SURGICAL RELATED FACTORS

	DEXAMETHASONE		PETHIDINE	P -VALUE
DURATION OF SURGERY	< 1hr	24	23	0.754
	1 – 2hr	6	7	
IRRIGATING FLUID USED >500 ML		30	30	0.554
BLOOD LOSS < 500ML		30	30	

5.3 comparison of intraoperative variables (systolic blood pressure and axillary temperature)

These variables are expressed as mean plus standard deviation. Significance was assessed with independent sample t-test.

Table 6 Systolic blood change intraoperatively

		dexamehasone	pethidine	P value
Systolic BP before		129.87 ±12.38	124 ± 12.7	0.084

anesthetic administration			
10 th minute	123.5 ±12.4	112.5 ±8.9	< 0.01
systolic BP			
20 th minute	128 ± 15.7	118 ±9.2	< 0.01
30 th minute	130 ±12.4	119 ±10.5	< 0.01
40 th minute	132 ±12.2	121 ±11.5	< 0.01
50 th minute	127 ±14.5	123 ±12.4	< 0.001

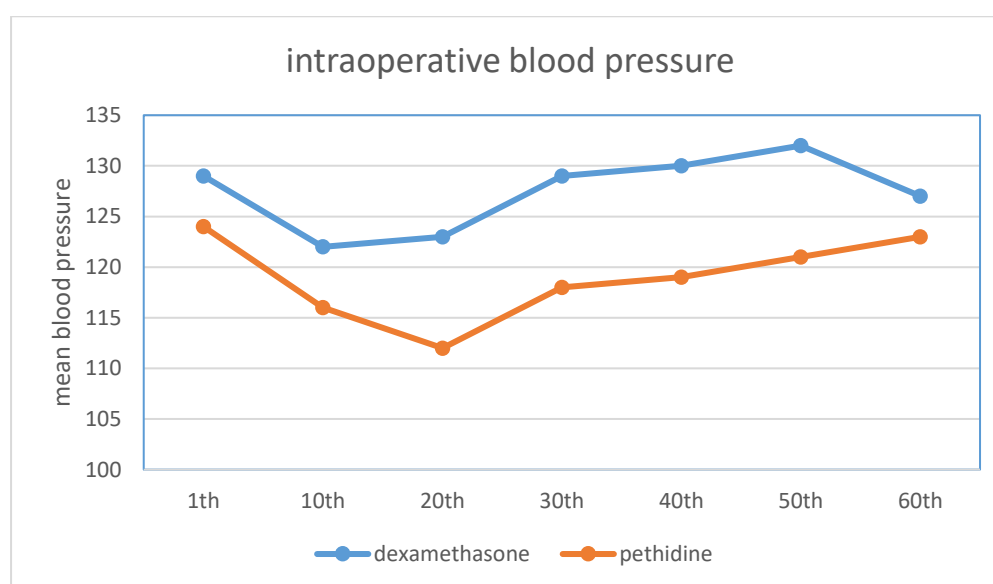


FIGURE 1 LINE GRAPH OF INTRAOPERATIVE SYSTOLIC BP CHANGE

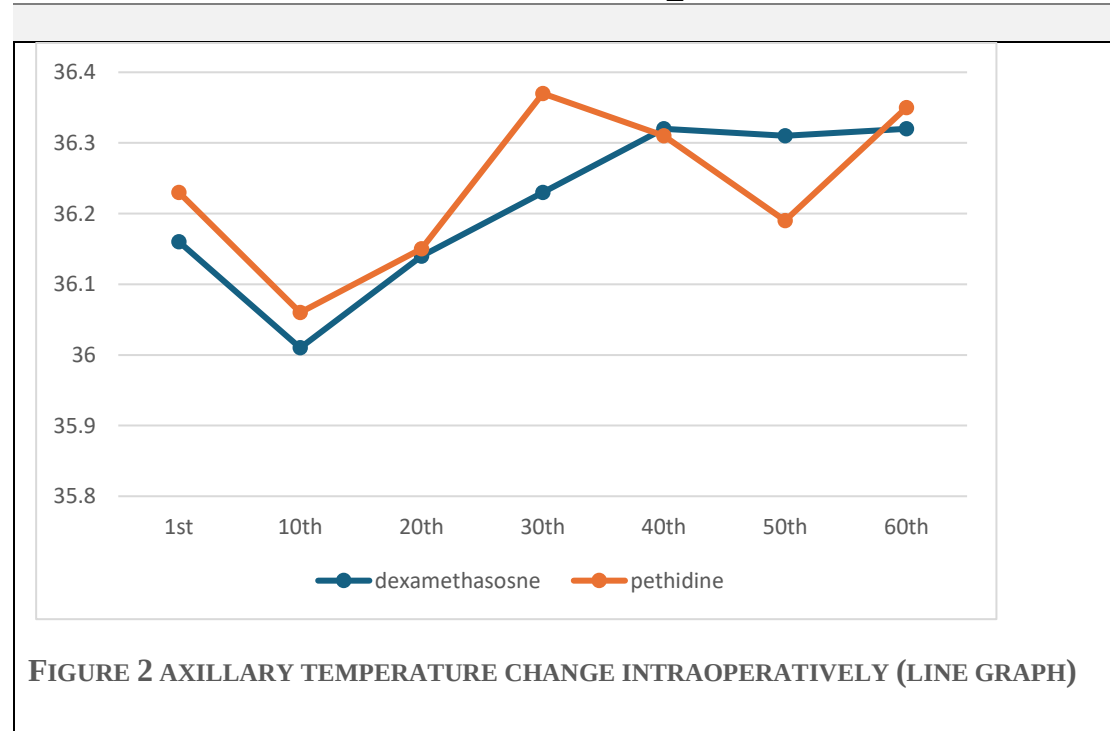
The intraoperative systolic blood pressure between the two groups before to the administration of anesthesia was not statistically significant.

Subsequent tests revealed a statistically significant decrease in mean systolic blood pressure among the pethidine groups p value (<0.001). Intraoperatively within each group systolic blood pressure was assessed between the baseline and 10 minutes after the administration of anesthetics, none of the patients has hypotension that required administration of vasopressor.

Axillary temperature comparison between dexamethasone and pethidine groups expressed as mean and standard deviation.

TABLE 7 AXILLARY TEMPERATURE CHANGE

	dexamethasone	pethidine	P - value
Axillary temperature before anesthesia	36.16 $\pm$ 0.28	36.23 $\pm$ 0.29	0.33
10th minute	36.01 $\pm$ 0.33	36.06 $\pm$ 0.35	0.45
20th minute	36.14 $\pm$ 0.32	36.15 $\pm$ 0.27	0.96
30th minute	36.23 $\pm$ 0.31	36.37 $\pm$ 0.23	0.74
40th minute	36.32 $\pm$ 0.325	36.31 $\pm$ 0.25	0.83
50th minute	36.31 $\pm$ 0.34	36.19 $\pm$ 0.37	0.12



Axillary temperature comparison between the two groups intraoperatively has no significance.

Intraoperative heart rate change between pethidine and dexamethasone group

TABLE 8 HEART RATE CHANGE INTRAOPERATIVELY

dexamethasone	pethidine	P - value
---------------	-----------	-----------

Heart rate before	84.7 ± 8.591	87.2 ± 10.66	0.263
10 th	84.7 ± 9.655	84.87 ± 9.698	0.662
20 th	82.77 ± 9.19	84.13 ± 9.63	0.402
30 th	82.83 ± 9.17	84.13 ± 9.37	0.650
40 th	81.93 ± 8.866	80.53 ± 10.03	0.607
50 th	81.07 ± 8.956	81.17 ± 8.956	0.704

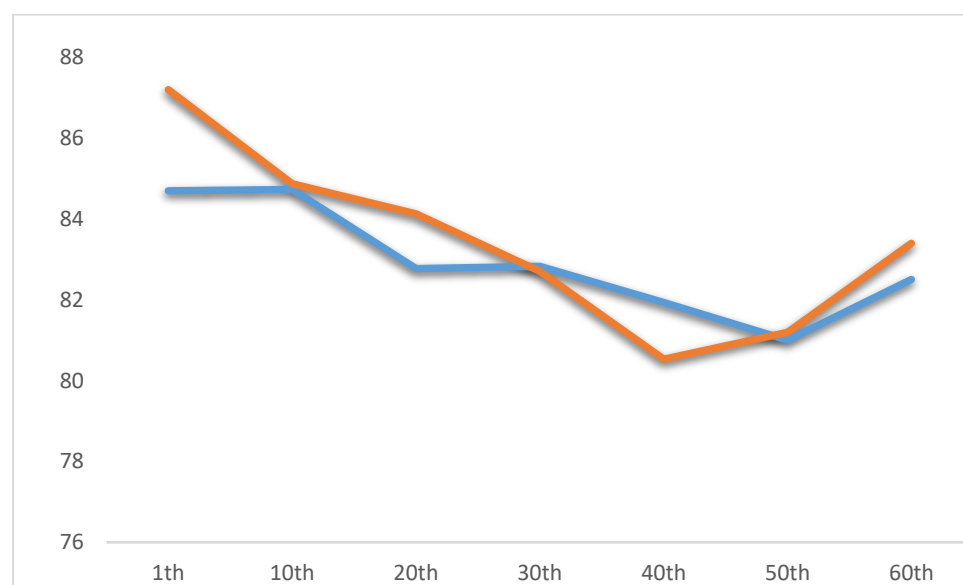


FIGURE 3 INTRAOPERATIVE CHANGE IN HEART RATE (LINE GRAPH)

5. 4 Incidence of shivering

Incidence of shivering was identified with percentage over all incidence of shivering 28 %, 36 % for dexamethasone group and 20 % for pethidine group. p-0.18)

TABLE 9 INCIDENCE OF SHIVERING

	DEXAMETHASONE	PETHIDINE	TOTAL	P VALUE
INCIDENCE OF SHIVERING	36% (11)	20% (6)	28% (17)	0.18

5.5 Severity of shivering

TABLE 10 SEVERITY OF SHIVERING

	Dexamethasone group	Pethidine group	P - value
Grade 1	5 (16%)	4(13%)	0.263%
Grade 2	4 (13%)	2(6.7%)	
Grade 3	2 (6%)		

Grade of shivering in dexamethasone groups in grade 1 is 5 (16%), grade 2 is 4 (13%) and grade 3 is 2 (6.6%). Whereas in pethidine for grade 1 is 4(13%), grade 2 is 2 (6.7%). Tested using the Fisher Exact Test and Chi Square Test, and the results were displayed as a percentage on a bar graph with a p-value of 0.263.

As rescue management for grade 3(severe shivering) only 2 patients require pethidine 25 mg in the dexamethasone group, but none required rescue therapy in the pethidine group.

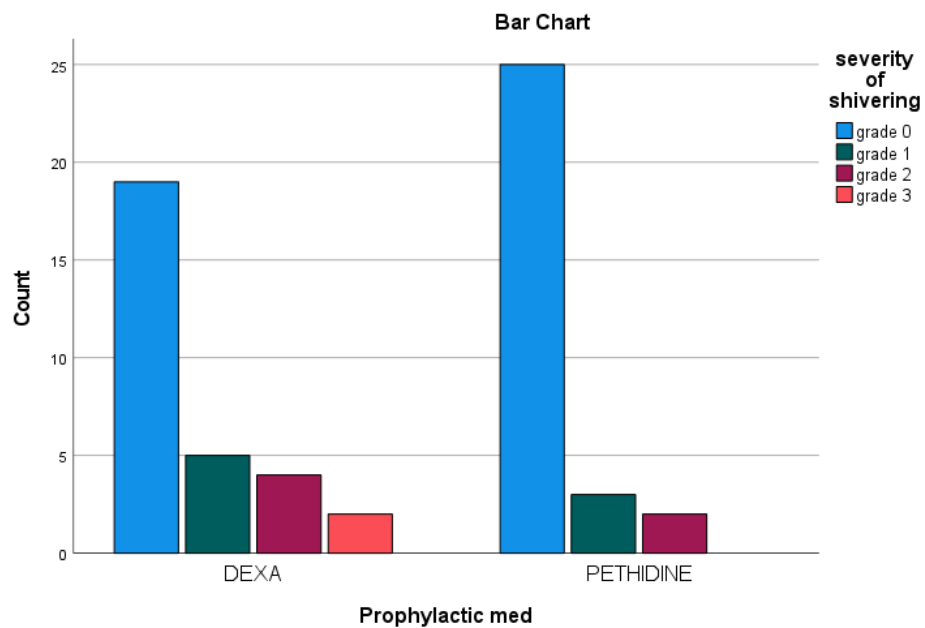


Figure 4 bar graph shows severity of shivering

5.6 Incidence complication

Five patients in the group receiving pethidine and three patients in the group receiving dexamethasone had nausea: none of the patients in either group experienced vomiting. None of the patient has experienced sedation.

6.DISCUSSION

This research aims to evaluate the effectiveness of prophylactic intravenous dexamethasone against pethidine as a preventive measure against post-spinal shivering in patients undergoing urologic surgery.

It is unclear how pethidine works on preventing PAS although it most likely affects the thermoregulatory center directly or through opioid receptors. (37) The proposed effect of preventing post anesthesia shivering is by its anti-inflammatory effect, minimizing the difference between the core and peripheral temperature by its anti-pyrogenic effect this has been proven by different study. (8,29, 30)

Shivering is present in 28% (17/60) of the participants in this study. Pethidine group is (6) 20% and dexamethasone's group is (11) 36%, with a p-value (0.18). There has been a 40% decrease in the total incidence of shivering as compared to a prior study conducted at Tikur Anbessa Hospital. (14)

In line with this study done by Belete et al on 2018 Menelik II hospital in Addis Ababa comparing dexamethasone and pethidine intravenous prophylactic effect, incidence of shivering 43%, 21 % for dexamethasone and meperidine groups respectively with p value of 0.11. This study has the same groups of patients demographically as well type of surgery like our study. (24, 25)

In 2021, Chih and his colleagues conducted research in Malasia on the preventive effects of dexamethasone on shivering. showed that there was no discernible variation in the incidence between the control and dexamethasone groups. (p value = 0.49, 55%, 50%, and 50%, respectively); however, the dexamethasone group had a lower incidence of visible muscular shivering, and there was a smaller core temperature drop and a comparable MAP drop. According to the findings of this investigation, dexamethasone reduces the incidence of obvious muscle shivering as well as the variation between core and peripheral temperature. (31)

In line with this study masood and entezaria, 2012 compared preventive effect of dexamethasone in comparison for pethidine in general anesthesia,) incidence of shivering is 47.5 %, 10 %, 37.5% in placebo, dexamethasone and meperidine group respectively with p value of < 0.001. this study concluded effectiveness of dexamethasone even with low dose. in our study we use lowest dose of dexamethasone

as a prophylaxis and confirmed its effectiveness. This has been shown in other study too (30,31,32).

Dexamethasone, at a dose of 0.6 mg/kg, was shown by Yared et al. (1998) to dramatically lowers shivering by 33% compared to the control group. The highest dose they used, the type of anaesthesia general anaesthesia and the drugs in general anaesthesia could decrease incidence of shivering—could be the possible reasons for the higher response rate. They also used active rewarming. Additional research also supported similar findings (8).

Overall, the effectiveness of dexamethasone has approved with different study similar to ours in different doses mainly in general anesthesia in which dexamethasone mainly prescribed validated on preventing PONV.

Studies also have done the effect of dexamethasone in prevention of shivering in spinal anesthesia in obstetric patients. at Ghandhi memorial hospital in Addis Ababa by **Moges** 2018 on the prophylactic administration of dexamethasone for prevention of post spinal shivering on 88 obstetric patient showed incidence of shivering of 32 % for dexamethasone group and 67% for non-dexamethasone groups the result was statistically significant they concluded by suggesting the prophylactic administration of dexamethasone for prevention of post spinal shivering for cesarean section procedure. (23,38)

The severity of shivering dexamethasone groups is for grade 1 is 5 (16%), grade 2 is 4 (13%) in grade 3 is 2 (6.6%). as in pethidine for grade 1 is 3 (1%), grade 2 (6.7%) p value of (0.263). chih and his colleagues in there study showed decreased incidence of visible muscular shivering in dexamethasone group p value of (0.003), belete et al severity of shivering was comparable between the two groups. This result was also supported by Mohsen and his colleague which compared prophylactic effect of ketamine, pethidine and dexamethasone, the incidence and severity of shivering was lowered in dexamethasone group with o value of 0.009. from previous study done on incidence of post spinal shivering in the same center grade 3 (severe) shivering account for 52 % but in our study only 2 patient has grade 3 (11%) shivering from this we can concluded that the effectiveness of both drugs in preventing visible muscular shivering (34, 35)

(34,35)

Median consumption of anti-shivering medication for severe shivering was only for two patients in dexamethasone group, none of patient in pethidine group required rescue treatment. This was supported by other studies. (26,36)

Incidence of adverse effects like nausea, vomiting and sedation was comparable between the groups.

7. CONCLUSION

Based on our study we concluded that dexamethasone 0.1 mg /kg is as effective as pethidine a standard drug used for prevention of post spinal shivering in patient undergoing urologic surgery by decreasing visible muscular shivering as well has less adverse effects. we strongly believe in prophylactic administration of ant shivering medication considering incidence, untoward complication mainly in high-risk patients. considering the limitation of our study we recommend study at larger level.

8. LIMITATION OF THIS STUDY

single centre, single blinded, and excludes severe intraoperative blood loss and fluid shift surgery, uncontrolled room and fluid temperatures, no core temperature monitoring, and a non-exposed group.

9. RECOMMENDATION

We recommend the use of prophylactic medication for preventive measure of visible muscular shivering, in this study both dexamethasone was as effectives as conventional drug pethidine. Supporting the lowest incidence of associated side effects, we recommend use of dexamethasone. Still there are scarce studies we recommend to do more studies

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11. ANNEXES

ANNEX 1

ANNEX 2: SUBJECT INFORMATION SHEET

Addis Ababa University

School of medicine

Subject information sheet

Hello, my name is -----, I am here in behalf of Dr. Elisabeth Temesgen a student in Addis Ababa University School of medicine department of anesthesiology of critical care and pain medicine. She is conducting a research on “comparative study on dexamethasone versus pethidine in the prevention of post spinal shivering at Addis Ababa University, college of health sciences, 2023, Addis Ababa, Ethiopia”. She has received permission from Addis Ababa University School of medicine and Tikur Anbessa Specialized Hospital officials to conduct the study.

You are selected to participate in this study because you are currently are going to have elective surgery in black lion Your participation in this study will only be based on your willingness to participate. You have the right to choose not to take part in this study. If you are willing, you have the right to stop at any time or withdraw without giving any reason which you will not be subjected to any ill-treatment. There will be no direct benefit by participating in this study but in future information gathered by this study will helps policy makers, programmers and researchers to give appropriate attention on issues of interest and design specific treatment options.

The information that you provide will be kept confidential by using only code numbers and locking the data. Only the members of the study team will have the access to the non-coded data and the data will not be used for purposes other than the study. Your willingness and active participation is very important for the success of this study.

If you need any further information or explanation regarding to the study, you can have this address to contact.

Name: Dr. Elisabeth Temesgen

Tel- +251-946066162

Email-

gen.elbet22@gmail.com

Annex 3: INFORMED WRITTEN CONSENT

Consent Form

TITLE OF STUDY

Dexamethasone versus meperidine in the prevention of post spinal shivering at Addis Ababa University, college of health sciences

PRIMARY

RESEARCHER

Name – Dr Elisabeth Temesgen ACCPM resident

Primary Advisor- Dr Rahel Tilahun

Department - ACCPM

Address – Addis Ababa

Phone – (251)0946066162

Email – gn.elbet22@gmail.com

PURPOSE OF STUDY

To compare the efficacy of tramadol versus meperidine in the management of post spinal shivering

PROCEDURES

Randomized control trial, patient in black lion hospital undergoing elective urological surgery will be asked to take part in this study and data will be collected while operation

RISKS

There is no anticipated risk to you if you participated in this study

BENEFITS

You will be contributing to the development of anesthesia in Ethiopia

CONFIDENTIALITY

Every effort will be made by the researcher to preserve your confidentiality including the following by assigning code names/numbers for participants that will be used on all research notes and documents

CONTACT

INFORMATION

If you have questions at any time about this study, you may contact the researcher whose contact information is provided above.

VOLUNTARY

PARTICIPATION

Your participation in this study is voluntary. If you decide to take part in this study, you will be asked to sign a consent form. After you sign the consent form, you are still free to withdraw.

CONSENT

I have read and I understand the provided information and have had the opportunity to ask questions. I consent to take part in the research study of “dexamethasone versus pethidine in the prevention of post spinal shivering at Addis Ababa university college of health science, Ethiopia”

Participant's Signature _____ **Date** _____

Researcher's Signature _____ **Date** _____

ANNEX 4

Section 1 demography of the patient

No	Question	Response	
	Age		
	Baseline parameters	Body Temperature 1. Axillary..... 2. Tympanic HR----- ----- MAP----- SPO2----- RR-----	
	Allergy to any of the following drugs	local anesthetics Pethidine Others (specify....)	
	does the patient has preexisting medical problem	1. Yes 2. No If yes specify _____	

Section-2; Hemodynamic parameters and anesthesia given

number	Question	Response																																										
		Body Temperature 1. Axillary..... 2. Tympanic HR----- MAP----- ----- SPO2----- RR-----																																										
	Spinal anesthesia																																											
	Dose																																											
	Level																																											
	Position																																											
	Sensory level																																											
	hemodynamic parameters after SA is given	<table><tr><td></td><td>TO</td><td>HR</td><td>MAP</td><td>SPO2</td><td>RR</td></tr><tr><td>At 1 min-</td><td>----</td><td>-----</td><td>----</td><td>----</td><td>.....</td></tr><tr><td>10 min</td><td>----</td><td>-----</td><td>-----</td><td>.....</td><td></td></tr><tr><td>20min</td><td>-----</td><td>-----</td><td>-----</td><td>.....</td><td></td></tr><tr><td>30min</td><td>-----</td><td>-----</td><td>-----</td><td>.....</td><td></td></tr><tr><td>40min</td><td>----</td><td>-----</td><td>----</td><td></td><td></td></tr><tr><td>50 min</td><td></td><td></td><td></td><td></td><td>.....</td></tr></table>		TO	HR	MAP	SPO2	RR	At 1 min-	----	-----	----	----		10 min	----	-----	-----			20min	-----	-----	-----			30min	-----	-----	-----			40min	----	-----	----			50 min					
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section .3 Shivering and Severity of Shivering

	Is there shivering	yes or no
	severity of shivering	Grade 0 Grade 01

		Grade 02 Grade 03
	Anti shivering medication used	YES NO If Answer yes what medication used and its dose Pethidine dose.....

section .4 Surgical related factors

	Duration of surgery	less than 1hr between 1hr and 2hr greater than 2hr
	Blood loss	less than 500ml Between 500ml and 1000ml Greater than 1000ml
	Irrigating fluid	Warm fluid Cold fluid
	Amount of irrigating fluid used	less than 500ml Between 500ml and 1000ml Greater than 1000ml

Section 5 associated side effect

	Associated side effect	nausea	vomiting	sedation
	Yes or no			