



## **DEPARTMENT OF ANESTHESIA**

**THE EFFECTIVENESS OF DEXAMETHASONE VS PETHIDINE  
AS ADJUVANT WITH BUPIVACAINE VS BUPIVACAINE  
ALONE IN PREVENTING POST-SPINAL ANESTHESIA  
SHIVERING DURING CYSTOURETHROSCOPY SURGERY IN  
TIKUR ANBESSA SPECIALIZED HOSPITAL ADDIS ABABA,  
ETHIOPIA 2022/2023 G.C; A PROSPECTIVE COHORT STUDY**

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## Declaration

I, the undersigned, declare that this thesis is my original work in partial fulfillment of the requirements for the Master of Science degree in Anesthesia. I understand that plagiarism will not be tolerated and all directly quoted material has been appropriately referenced

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## Abstract:

**Background:** Shivering is a common complication after spinal anesthesia, particularly in patients undergoing urological surgery under SA. Another study showed that it can also lead to hemodynamic instability, impairing monitoring and worsening patients' conditions by increasing cardiopulmonary workload and lengthening hospital stays, straining the country's economy and putting patients and their families at risk. Intrathecally administered dexamethasone and pethidine are believed to prevent shivering when used as adjuvants with bupivacaine. **Objective:** To compare the effects of dexamethasone versus pethidine adjuvanted with bupivacaine versus bupivacaine alone on the prevention of shivering after spinal anesthesia and the hemodynamic effect in patients undergoing TURP and TURBT surgery at TASH, Addis Ababa, Ethiopia.

**Method:** This prospective cohort study, conducted at TASH, involved 87 participants from patients who had undergone TURBT and TURP surgery in the context of SA and were ASAI and ASAIL. Study participants were selected by a simple random sampling technique. The incidence, severity, and hemodynamic effects of the shivering were assessed through observation and interviews with the participants. Data were entered into SPSS version 25 and normality was checked by the Shapiro-Wilk test. Parametric data were analyzed using one-way ANOVA and the Kruskal-Wallis test to compare nonparametric data. The chi-square test was used to analyze categorical data. A  $P$  value  $< 0.05$  was statistically significant. **Result:** The incidence and severity of shivering were statistically significant between the unexposed and exposed groups: bupivacaine alone (44.8%) and dexamethasone with bupivacaine (10.3%) and pethidine with bupivacaine (17.2%), which were significant is ( $P = 0.005$ ). Approximately 13.8% of patients in the unexposed groups developed severe tremors, while none of them developed severe shivering in the exposed groups ( $p=0.001$ ). **Conclusion and Recommendation:** This study compared the incidence and severity of shivering in different groups. Chills occurred more frequently in the non-exposed group than in the exposed group. The lowest frequencies of shivering occurred with the combination of dexamethasone and bupivacaine, and the highest rates with bupivacaine alone. We recommend the use of dexamethasone 4 mg as an alternative to pethidine 0.2 mg/kg for the prevention of shivering in patients undergoing TURP and TURBT under spinal anesthesia

**Keywords:** TURP, TURBT, Shivering, dexamethasone, pethidine, bupivacaine

## Abbreviations /Acronyms

<b>AAU</b>	=	<b>Addis Ababa University</b>
<b>ASA PS</b>	=	<b>American society anesthesiology physical status</b>
<b>GC</b>	=	<b>Gregorian calendar</b>
<b>HR</b>	=	<b>Heart rate</b>
<b>IT</b>	=	<b>Intra-thecal</b>
<b>L3</b>	=	<b>Lumber vertebrae 3</b>
<b>L4</b>	=	<b>Lumber vertebrae 4</b>
<b>MAP</b>	=	<b>Mean arterial pressure</b>
<b>mg/kg</b>	=	<b>Milligram per kilogram</b>
<b>MSC</b>	=	<b>Masters of Science</b>
<b>OR</b>	=	<b>Operation room</b>
<b>PACU</b>	=	<b>Post-anesthesia care unity</b>
<b>PO</b>	=	<b>Postoperative</b>
<b>PAS</b>	=	<b>Post-anesthesia shivering</b>
<b>RR</b>	=	<b>Respiratory rate</b>
<b>SA</b>	=	<b>Spinal anesthesia</b>
<b>SPO2</b>	=	<b>blood oxygen saturation</b>
<b>SPSS</b>	=	<b>Statistical Package for Social Sciences</b>
<b>TURP</b>	=	<b>Transurethral Resection of Prostate</b>
<b>TURBT</b>	=	<b>Transurethral resection of bladder tumor</b>

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# 1. Introduction

## 1.1. Background:

Shivering is a prominent thermogenic response in homeothermic animals, including humans, and is associated with rapid and repetitive involuntary contractions of skeletal muscle that result in thermogenesis due to inefficiency in ATP utilization. This involuntary thermoregulatory response is triggered by physiological stimuli that increase thermogenesis, such as exposure to cold environments, or by pathological stimuli, such as receipt of febrile immune signals by the brain during infection(1,2).

The pathogenesis of shivering is not fully understood, but studies suggest that it is induced by cooling of the preoptic region of the hypothalamus. The fundamental shivering frequency on the electromyogram in humans is typically around 200 Hz. This fundamental frequency is modulated by a slow, increasing and decreasing pattern at 4-8 cycles per minute. In 1972, Soliman et al. found two distinct patterns of shivering: a tonic pattern resembling normal shivering and a phasic wave pattern resembling a pathological clone (3)

Shivering is one of the most deleterious side effects of anesthesia, not only increasing the risk of death and morbidity, but also affecting a significant number of patients. In fact, about 60% of patients experience shivering during regional anesthesia, while 5-65% of patients experience shivering after waking up from general anesthesia. This shows how important it is to fix this problem and find ways to prevent it. the incidence of postoperative shivering for patients that undergoing urethroscopy surgery under spinal anesthesia has been reported in various studies ranges from ,21.9% to 43.8% and 40% to 70% (1,4,5).

The patient developed shivering after spinal anesthesia due to its effect on central and peripheral thermoregulation. It widens the cross-threshold range by increasing the sweat threshold while reducing the threshold for vasoconstriction and tremor, impaired core body temperature (poikilothermic) which can result beyond the level of sensory block, causing blockage of cutaneous afferents resulting more heat loss and more shivering than general anesthesia, which affects only central temperature regulation .After induction of anesthesia, core body temperature usually drops by 0.5-1.5°C within the first hour (6,7).

Transurethral resection of the prostate and bladder, performed under regional anesthesia, is a well-known surgery that often causes shivering. An excision cystoscope (a modified cystoscope with a metal ring that can be cut and frozen) or a cystoscope with a laser fiber is

inserted through the penis into the prostatic urethra, and the prostate gland is gradually removed with a cystoscope or green laser and continued use of irrigation fluid, which removes the excised tissue from the surgical field, also causes shivering, This treatment is frequently carried out under spinal anesthesia, which causes shivering once more. The other reason for shivering is tissue injury from surgical trauma, which triggers an inflammatory response and releases cytokines that cause peripheral vasoconstriction, chills, and fevers, which reduce body temperature and promote heat loss. Shivering is frequently a symptom of hypothermia. Also, normothermic patients do experience it throughout the surgical phase. About 70% of men in their 60's and 80% of men 70 years or older have some level of benign prostatic hyperplasia. Symptoms also vary with age, as 80% of men 80 years of age or more will have symptomatic BPH (7–11)..

Shivering increases in oxygen demand, lactic acidosis, carbon dioxide production, danger of cardiac ischemia, and metabolic rate by up to 400% are the most frequent side effects of shivering. As a result, it might be harmful to TURP and TURBT patients who have poor pulmonary and cardiac reserves. ECG, blood pressure, and oxygen saturation monitoring are also affected(10,12,13)

Post-anesthetic shiver (PAS) is a common involuntary muscle movement that can occur after surgery and can be uncomfortable for patients. Prevention and treatment of PAS are important, and factors such as age, weight, and type of anesthesia may influence them. Warming the patient before surgery and providing warm blankets and warm air during surgery may help prevent PAS. Treatment options for PAS both non-pharmacological and pharmaceutical interventions. non-pharmacological measures such as active rewarming of the patient, intravenous (IV) fluid injection, or forced air warming and supplemental oxygen are used. Despite promising findings, the efficacy of these nonpharmacological treatments is largely unknown .The severity of the shiver and the patient's overall health may influence the therapeutic approach(4,10,12,13)

Numerous pharmacological studies have been conducted employing medications like fentanyl, pethidine, clonidine, tramadol, etc. to prevent or treat shivering during spinal anesthesia. Pethidine has been cited by many authors as the gold standard for treating and preventing post-spinal shivering. It is a powerful local anesthetic that is an intermediate lipid-soluble opioid and produced sufficient sensory blocking and postoperative analgesia with an intrathecally administered dose of 0.5-1.0 mg kg<sup>-1</sup>. However, at such a large dose of intrathecal pethidine,

problems like sleepiness, pruritus, and even respiratory depression , impair neurologic exams, can also produce systemic hemodynamic instability, and be toxic to the nervous system .After general and neuraxial anesthesia, it was also very successful at preventing and treating shivering, but frequent side effects including hypotension and sleepiness were encountered, (5,12,14,15).

Dexamethasone is a medication that is used to prevent and treat post-spinal shivering due to its anti-inflammatory impact that modulates inflammatory responses. This medication acts by reducing the gradient between core and skin temperature, making it an effective treatment for patients experiencing shivering after spinal anesthesia. Furthermore, when combined with hyperbaric bupivacaine, dexamethasone provides anti-inflammatory and analgesic effects that greatly lengthen the sensory block in spinal anesthesia. This combination of medications has been shown to be very effective in providing relief from postoperative pain and reducing the need for additional pain medication. Preoperative dexamethasone has a biologic half-life of 36 to 72 hours, making it an ideal medication for improving post-discharge quality of recovery. Studies have shown that preoperative dexamethasone (8 mg) can significantly reduce nausea, vomiting, pain, and exhaustion during the early postoperative period. (14,16–19).

## 1.2. Statement of The Problem

Shivering increases O<sub>2</sub> consumption (MVO), CO production (MVCO), heart rate, blood pressure, stroke volume, and pulmonary hyperventilation capacity even impact pulse oximeter reading, while suppressing it decreases metabolic demands and myocardial work(20).

Shivering during surgery caused by spinal anesthesia causes patient discomfort due to severe muscle movements, as well as tachycardia and hypertension. Since the vast majority of patients undergoing transurethral resection of the prostate (TURP) and bladder tumors are elderly and have comorbidities such as heart or lung disease, this is worrisome because of the procedure. cystourethroscopy is associated with hypothermia and chills during surgery, and also because large amounts of irrigation fluid are used, which can cause hypothermia and chills (2,21).

In elderly patients with weak autonomic neuroprotective responses, which are common during TURP and TURBT procedures, shivering has some adverse effects. Side effects such as a 400-500% increase in oxygen consumption, increased carbon dioxide production and patient discomfort. These side effects put additional strain on the cardiovascular system, especially in elderly patients with low cardiovascular reserves. Shivering after anesthesia can have many negative consequences for the patient, such as: Discomfort due to increased cold and/or pain due to muscle contraction during surgery (9,10,14,20,22).

Shivering may treat pharmacological and non-pharmacological, looking beyond medication, there's a simple yet effective way to enhance patient comfort during medical procedures - using a forced air-warming device to increase room and skin temperature. The American Society of Anesthesiologists suggests that this technique, which minimizes heat loss and prevents shivering in high-risk patients, is a safe and low-risk option However, the main challenge is the limited availability of these devices, which can make it challenging to implement this approach(20).

From a pharmacological point of view, many opioid and non-opioid drugs, such as anti-inflammatory drugs, alpha-blockers, pethidine, dexamethasone, etc., have been developed to prevent post-spinal shivering. Although these drugs are used to relieve shivering after surgery through different mechanisms, they have been associated with side effects such as loss of consciousness, respiratory distress, itching, nausea, and vomiting(6,22).

Despite the numerous studies that have been conducted and the multiple techniques that have been used, there is still a high prevalence of post-spinal anesthesia shivering. So, using

dexamethasone as an adjuvant with bupivacaine is as effective as pethidine in preventing post-spinal anesthesia shivering in cystourethroscopy surgery. Investigating possible answers to this question is the purpose of this study, which aims to conduct investigation on this issue.

### 3.1. Justification of the study

post-spinal anesthesia shivering is a significant concern for medical professionals, particularly for patients undergoing TURP and TURBT surgery. It is crucial to prevent shivering from occurring in the first place. Unfortunately, many anesthesiologists tend to focus on treating shivering with pethidine after it has occurred, rather than preventing it. However, this approach can lead to additional issues, as the medications used to treat shivering can have side effects that may further complicate the patient's recovery. Therefore, as a response to this issue, researchers have conducted studies to determine the best methods for preventing post-spinal anesthesia shivering. The results of these studies have indicated that preventative measures are more effective than treatment methods, as they can avoid the potential complications of using medications to treat shivering. As a result, it is essential for medical professionals to prioritize the prevention of post-spinal anesthesia shivering. By doing so, they can avoid potential complications and ensure that patients have a smooth and safe recovery. Through ongoing research and collaboration, we can continue to improve our understanding of this issue and develop better methods for preventing post-spinal anesthesia shivering.

According to my search, there are few published studies in our country comparing intrathecal pethidine with bupivacaine and dexamethasone with bupivacaine for the prevention of PAS in patients undergoing cystourethroscopy surgery under regional anesthesia. Thus, these study results will help prevent shivering by using a drug that any patient can afford, has virtually no complications, and has greater benefits. The result can serve as a starting point for future studies and may indicate potential ways to prevent postoperative shivering in cystourethroscopy in resource-constrained counters like ours.

## 2: Literature Review

Shivering is a common consequence for 40–70% of people undergoing surgery under regional anesthesia.

Solhpour et al. (2016) found that the mean chill rate associated with neuraxial anesthesia was as high as 56% in a randomized, double-blind trial of 100 obstetric patients in Korea.

A randomized, double-blind study performed in Iran in 2016 comparing pethidine plus dexamethasone and ketamine plus midazolam to prevent chills during spinal anesthesia, 30 minutes after spinal anesthesia showed only 2 patients in the pethidine and dexamethasone groups had chills (2/50) and this rate was significantly lower than the control group (32/50,  $P = 0.0001$ ), pethidine group (10/50,  $P = 0.02$ ) and ketamine with the midazolam group (10/50,  $P = 0.02$ ), respectively (22).

In 2021, a randomized, double-blind clinical trial comparing intravenous ketamine with intracortical pethidine in Iran found a significant difference in tremor intensity between the three groups after initiation of spinal anesthesia (intravenous ketamine, intravenous pethidine and control group). As a result, patients in the control group had more tremors than in the other groups at all time points (20, 60, 80, 100 and 120 minutes after the start of spinal anesthesia) ( $p = 0.05$ ) (14).

In a comparative study conducted in Asia in 2016, chills were significantly higher in the tramadol group than in the pethidine group after 10, 15, 20, and 30 minutes ( $p = 0.001$ ). Some patients complained of chills in a 2022 study that compared intrathecal dexmedetomidine with dexamethasone to prevent chills after patients' cesarean delivery in those who had a cesarean section, but there was no statistically significant difference in incidence or severity of chills (five patients in the dexmedetomidine group and 7 patients in the dexamethasone groups) (23).

The efficacy of dexmedetomidine, pethidine, and tramadol in the treatment of chills after neuraxial anesthesia was compared in a prospective, double-blind, randomized block study conducted in 2015 at UKMMC in Kuala Lumpur. The response rate was highest in the dexmedetomidine group and it was only significant compared with the tramadol group ( $p = 0.001$ ). (24).

Dexamethasone was found to be more effective in preventing post-operative chills than pethidine in a randomized controlled trial conducted in Iran in 2012. Results showed that if 19

cases (47.5%) from the placebo group experienced tremors, only 4 (10 %) in the dexamethasone group did, and the difference was significant. In the pethidine group, chills occurred in 15 cases (37.5%), and there was a significant difference compared with the placebo group (P value = 0.001). They came to the conclusion that dexamethasone prevented post-operative chills better than pethidine (24).

In 2016, T. S. Luggya, R. N. Kabuye, C. Mijumbi, J. B. Tindimwebwa, and A. Kintu conducted a fascinating study in a Sub-Saharan tertiary hospital. They delved into the pervasiveness and contributing factors of post-spinal shivering, and their findings were nothing short of remarkable. According to the study, 8.15% of shivering occurs within the first 20 minutes, with hypotension and hypothermia as associated factors. These findings could prove to be incredibly valuable for medical professionals seeking to better understand and manage post-spinal shivering(24,25).

A randomized controlled comparison study conducted in 2021 at Sham University in Cairo, Egypt, comparing paracetamol with dexamethasone on patients undergoing lower abdominal and lower limb surgeries revealed that the incidence of shivering was significantly higher in the Control C, 89/100 (89.0%), the group compared to Paracetamol, 38/100 (38.0%) group, and Dexamethasone, 64/100 (64.0%) group, with statistically significant differences (1).

In 2017, a fascinating study was conducted by S. M. Moeen and A. M. Moeen at Assiut University in Assiut Egypt. The study focused on 90 male patients who underwent prostate surgery under spinal anesthesia. The researchers wanted to learn more about the prevalence of shivering among these patients. The results of the study were surprising. Despite the patients being under spinal anesthesia, a staggering 43.3% of them experienced shivering. This finding sheds new light on the effects of spinal anesthesia and raises important questions about how we can improve patient outcomes during surgery(4)

According to a cross-sectional study conducted in northwest Ethiopia, in 2015, 25.6% of patients who underwent both general and regional anesthesia experienced this shivering sensation. Even more surprising, the study found that over half of the patients who received spinal anesthesia, 53.8% to be exact, reported shivering. It's fascinating to think about how our bodies react to anesthesia and the different ways it can impact us (26).

In 2020, a team of researchers led by Belete D. conducted a fascinating study at Minilik II Hospital. Their aim was to determine if prophylactic intravenous dexamethasone or pethidine was more effective in preventing chills. The results of their prospective cohort study were

surprising.

While the rate of chills was 21.9% in the pethidine group, it was 43.8% in the dexamethasone group. Despite this large difference, the study showed no statistically significant difference between the two groups ( $p\text{-value} > 0.05$ ). This study highlights the complexities of preventing chills and the need for further research in this area (1).

## 2.1. Treatment

Shivering is the most prevalent consequence of spinal anesthetic, causing pain and discomfort in both patients and doctors. As the importance of preserving euthermia during and after anesthesia has grown, effective management of post-spinal anesthesia shivering has become critical(8).

An opioid derivative called pethidine is routinely administered to treat post-neuraxial anesthesia trembling. Both the  $\mu$  - and  $\kappa$  -receptors are agonists by the drug pethidine. Pethidine may work on  $\kappa$  -opioid receptors rather than  $\mu$  -opioid receptors, according to a study utilizing naloxone, even if the exact mechanism underlying its anti-shivering activity is yet unknown(3).

The anti-tremor effects of pethidine were inhibited by high-dose naloxone, which blocks both  $\mu$  and  $\kappa$  receptors, but not by low-dose naloxone, which blocks only  $\mu$  receptors. When the opioid receptors are active, the shivering threshold is reduced by twice as much as the vasoconstrictor threshold. On the other hand, pethidine is more likely to act directly on the thermoregulatory center rather than through receptor activation (24,27)

Non-thermoregulation is characterized as the activation of an inflammatory response that produces vasodilation and heat loss as a result of tissue injury during surgery, leading to post-anesthesia shivering. Dexamethasone, an anti-inflammatory medication, lowers the temperature differential between the core and the skin and changes the inflammatory response(8,22).

Uncontrolled shivering raises metabolic rate, undermines the neuroprotective advantages of therapeutic hypothermia, and impedes therapeutic hypothermia induction and maintenance. Terian Hospital published a meta-analysis in New York Pres in 2016 (9).

Clonidine, pethidine, tramadol, nefopam, and ketamine were reported by Park et al. However, the side effects of these drugs limit their usefulness in many therapeutic situations. Drug therapy can reduce euphoria after prolonged use, interfere with neurologic tests, cause systemic hemodynamic instability, and cause neurotoxicity(28,29).

### 2.1.2. intrathecal dexamethasone

Since dexamethasone can be safely injected into the cerebrospinal fluid and used as an adjunct to local anesthetics to improve the effectiveness of regional anesthesia, we hypothesized that it could be used as an adjunct to a local anesthetic to reduce the intensity of PAS (23). Since dexamethasone is known to alter the body's inflammatory response and reduce the difference between central and peripheral tissue temperatures, it has been used as an intravenous drug to reduce shivering. Here are some studies that have tried to explain how dexamethasone is used in the cerebral cortex to treat and prevent shivering.

S.M. Moeen and A. M. Moeen et al. conducted a prospective, randomized, double-blind study of 90 patients in Asyut, Egypt in 2017, showing that none of the patients in the dexamethasone group had recurrent shivering, but one patient in the pethidine group did. and four patients in the saline group performed. So, according to their findings, the pethidine group included five patients receiving sedation, four with hypotension, three with bradycardia, four with nausea, five with vomiting, seven with itching, and one with respiratory failure. ( $P = 0.064$ )(4,30).

### 2.1.3. Intrathecal pethidine

Despite having undesirable side effects, pethidine is unique among opioids in that it can effectively cure and prevent shivering. The study of many writers is recognized as the best available for treating post-spinal shivering. Some of them recommended the subsequent

80 patients underwent transurethral prostatectomy in a randomized controlled trial study in 2007 at Ekbatan Hospital in Hamadan, Iran, by M. Davoudi, S. H. Mousavi-Bahar, and A. Farhanchi. The patients were divided into two groups, one receiving pethidine with bupivacaine and the other receiving saline with bupivacaine. Eleven (27.5%) patients in the control group exhibited shivering, whereas none of the patients in the experimental group shivered ( $P = .001$ )(23).

An intrathecal pethidine with bupivacaine and saline with bupivacaine prospective randomized double-blinded study performed in Yonsei University College of Medicine in 2010 revealed that the incidence of shivering was lower in the pethidine group than in the saline group (1/25 vs. 8/25,  $P = 0.012$ ). In the pethidine group, the average level of shivering was 1, whereas in the saline group, it was 2.5 (with a range of 1-4). Four patients who took pethidine reported group pruritus. Patients in the saline groups did not exhibit pruritus.

According to their findings, shivering can be minimized by adding a low dose of pethidine (15 mg) to the intrathecal anesthetic combination. Finally, they conclude that combining 0.2 mg/kg pethidine with intrathecal bupivacaine lowers the occurrence and severity of shivering in elderly ureteroscopy surgery patients(26).

## Effects on hemodynamic

Shivering is uncomfortable for patients, can impede monitoring procedures, increase heart rate and blood pressure, and increase the risk of consequences. In patients with low pulmonary or cardiac reserve, vigorous shivering can triple oxygen consumption and increase carbon dioxide generation, potentially resulting in demand ischemia(25).

Shivering is a common problem during spinal anesthesia because hypothermia lowers the shivering threshold, causing tachycardia, hypertension, and a 400-500% increase in oxygen consumption. It also affects ECG and blood pressure monitoring (20).

A double-blind randomized controlled trial (RCT) of 150 patients scheduled for orthopedic surgery under spinal anesthesia in Iran in 2021 and divided into three groups receiving intrathecal pethidine, intravenous ketamine and intravenous saline found significant differences in MAP and heart rate between the three groups, Reductions occurred as early as 20 to 60 minutes after initiation of spinal anesthesia (22,23).

A randomized controlled trial was conducted in Jammu in 2021 comparing intrathecal dexmedomidine with intrathecal dexamethasone for the prevention of post-anesthesia shivering in patients who had undergone a cesarean section. They assessed intraoperative and postoperative hemodynamics every 5 minutes and 15 minutes, and concluded that there was no statistical difference between the two groups in terms of systolic blood pressure (SBP) and diastolic blood pressure (DBP) (24,27).

A randomized controlled trial comparing paracetamol and dexamethasone for the prevention of post-spinal shivering was conducted in Egypt in 2021, with measured MBP(5 min, 10 min, 15 min, 20 min, and 25 min after intrathecal injection values turned out to be repeated, was statistically significant in the paracetamol group compared with the dexamethasone group, with a mean difference (-14.2, 95% CI:-15.3--13.1), which was statistically higher in the dexamethasone group than in the control group, with a moderate difference (13.8, 95% CI:

12.6-15.0) (P<0.001) There was no statistically significant difference between paracetamol and control groups (21,31).

A 2015 South African study comparing dexmedetomidine, pethidine and tramadol in the prevention of post-anesthesia shivering found that dexmedetomidine caused hypotension in 5 patients and bradycardia in 2 patients, and tramadol caused hypotension in 5 patients and bradycardia in 2 patients. pethidine did not cause hypotension in any of the patients (11,18) .

## Research hypothesis

H0: There is no statistically significant difference in the incidence of shivering between the groups

H0: There is no statistically significant difference in the severity of shivering between the groups

H0: There is no hemodynamic difference between the groups

H1: There is statistically significant difference in the incidence of shivering between the groups

H1: There is statistically significant difference in the severity of shivering between the groups

H1: There is statistically significant difference in hemodynamic between the groups

### 3: Objectives

#### 3.1. General Objective;

To compare dexamethasone vs pethidine as adjuvant with bupivacaine vs bupivacaine alone in preventing post spinal shivering and hemodynamic effect for TURP and TURBT surgery at Tikur Anbessa Specialized Hospital from December, 2022- march, 2023 G.C.

#### 3.2. Specific Objective:

- ✓ To compare incidence of shivering between the groups
- ✓ To compare the degree of shivering between the groups
- ✓ To compare the hemodynamic effects between the groups

## 4: Methods and Materials

### 4.1. Study Area

The study was conducted at the Endourology Unit of the Tikur-Anbessa Specialist Hospital (TASH) in Addis Ababa, the capital of Ethiopia. With an area of 527 square kilometers and 10 sub-cities, it is the largest city in the country. The city has 14 public hospitals. TASH is Ethiopia's largest referring hospital. It provides diagnosis and treatment for approximately 370,000 to 400,000 patients per year, performing nearly 8,000 surgeries annually in 14 operating rooms (ORs). The hospital offers endourology, open urology and many other diagnostic and surgical medical services. The hospital has an operating room for endourological surgeries, which are performed as elective procedures. The average number of procedures performed in the hospital is three to four per day.

### 4.2. Study Design and Study period

An institutional based prospective cohort study was conducted from December, 2022 - march 2023.

### 4.3. Population

#### 4.3.1. Source Population

Elective surgical patient undergoing endourology surgery under spinal anesthesia at Tikur Anbessa Specialty Hospital.

#### 4.3.2. Study Population

Elective surgical patients who underwent TURP and TURBT procedures under spinal anesthesia at Tikur Anbessa Specialized Hospital during study period.

### 4.4. Inclusion and exclusion Criteria's

#### 4.4.1. Inclusion Criteria

ASA 1 and ASA2 patients

Patients scheduled for transurethral resection of the prostate under spinal anesthesia during study period

Patients scheduled for transurethral resection of bladder tumor during study period

#### 4.4.2. Exclusion Criteria

A history of allergy to the study's drugs

A patient has a neurological disorder and neuromuscular disease

Baseline body temperature <35 and >38 degree centigrade

Failed spinal

Patients who take an a2 agonist

Patient with hyperthyroid disease,

Parkinson's disease patient

#### 4.5. Variables

##### 4.5.1. Dependent Variables

Incidence of shivering

Severity of shivering

Hemodynamic parameters changed, PR and MAP

##### 4.5.2. Independent Variables

Socio demographic variables (Age and BMI)

Baseline body temperature

Room temperature

ASA status of the patient

Duration of the procedure

Types of study drugs used

Amount of irrigating fluid used

Amount of Blood loss

Site of spinal anesthesia given

Dose of bupivacaine

## 4.6. Operational definition

**Cystourethroscopy:** the procedure that allows the urologist to visually examine the inside of the bladder and urethra(32).

**Ureteroscopy:** It is a procedure in which a small scope (like a flexible telescope) is inserted into the bladder and ureter and it is used to treat or resect bladder or prostate tumor

**Spinal anesthesia:** is a neuraxial anesthesia technique in which local anesthetic is injected directly into the intrathecal space (subarachnoid space) to produce anesthesia for the lower body part

**Post-Anesthesia Care Unit:** This is the unit where patients are temporarily admitted after any surgical procedure.

**Postoperative period:** from the time the patient is admitted to the recovery room to the first 30 minutes

**Shivering:** is defined as a syndrome of involuntary contractions of skeletal muscles that involve fasciculation of muscles of the face, jaw, or head or that lasts longer than 15 seconds(33).

**Cystoscopy:** is a procedure to look inside the bladder using a thin camera called a cystoscope

**Nausea:** is the condition of feeling sick and anticipating vomiting

**Vomiting:** is the involuntary, forceful expulsion of the contents of one's stomach through the mouth and sometimes the nose.

**Hypothermia:** In humans, hypothermia is a medical emergency that occurs when your body loses heat faster than it can produce heat, resulting in a body core temperature of less than 35.0 °C (95.0 °F)(34).

**Hyperthermia:** is defined as dangerous raised temperature above 100.4°F (38°C)(34).

**Failure of spinal anesthesia:** It occurs when the subarachnoid space is not reached or when surgical analgesia is inadequate after the injection of a local anesthetic.

**Unexposed:** participants not taking both pethidine and dexamethasone with bupivacaine

**ASA status:** surgical risk stratification validated by the American Association of Anesthesiologists.

**Baseline vital sign:** Vital sign before giving spinal anesthesia

Shivering intensity was assessed with a five point scale validated by Crossly and Mahajan(4).

Grade0 = No shivering,

Grade1 = piloerection or peripheral vasoconstriction but no visible shivering,

grade2 = muscular activity in only one muscle group,

Grade 3 = muscular activity in more than one muscle group, and

Grade 4 = whole body shivering

Grade 0=No shivering

Grade1-4= yes

Severity of shivering

Grade1 =mild shivering

Grade 2=moderate

Grade3 and 4=severe

## 4.7. Sample size and sampling technique

### 4.7.1.sample size

Utilizing the epi-info sample size computation, the sample size for the cohort was determined. According to estimates from a prior study carried out in Egypt (4)the incidence of shivering among the unexposed is 43% using a power of 80%, a confidence interval of 95%, and a ratio of exposed to unexposed of 1:1. The exposed groups are estimated to be 7% for dexamethasone and 10% for pethidine

We selected the largest sample size after comparing the two groups, pethidine and dexamethasone, to the control group. The sample size for each of the three groups (bupivacaine alone, dexamethasone with bupivacaine, and pethidine with bupivacaine) was 29 after a 10% attrition rate, for a total of 87 study participants.

### 4.7.2. Sampling technique

Based on the situation analysis performed at the study hospital, a total of 144 TURP and TURBT procedures would be performed in three consecutive months. This is (175/87) and

gives a K value of about two ( $k \approx 2$ ). The first selected participant was selected using a simple random sampling technique, a lottery method. Beginning with random selection by lottery, each selected kth participant was assigned to one of the two groups (whether receiving dexamethasone with bupivacaine, pethidine with bupivacaine, or bupivacaine alone) based on the management plan of the responsible anesthetist. This continued until the desired sample was reached in each group.

#### 4.8. Data collections techniques

Before data collection began, the anesthesia residents received training and briefings on the degree of shivering and the hemodynamic changes induced by the shivering. Crossly and Mahajan validated a five-point shivering scale used for data collection. All patients who are scheduled for cystourethroscopy surgery, who met the inclusion criteria and who volunteered to participate in the study in the morning, were briefed by on-duty anesthesia residents to describe shivering and other unpleasant effects

Patients underwent standard monitoring and vital signs were recorded before SA institution. Depending on his/her decision and desire, the anesthesiologist in charge of the research room administered either intrathecal dexamethasone with bupivacaine, intrathecal pethidine with bupivacaine, or bupivacaine alone to the patients undergoing TURP and TURBT. They used a 3-4 mL dose of 0.5% bupivacaine at L3/L4 level with 0.2 mg/kg pethidine for 29 patients, 4 mg dexamethasone for the remaining 29 patients, and bupivacaine alone for the remaining 29 patients and brought head up position. Sensory block was then assessed with a pinprick (needle stick), shivering was assessed using the tools provided, and each patient's hemodynamic change, heart rate and MAP, SPO<sub>2</sub>, and axillary and room temperature were documented every 10 minutes in the operating room. At the end of the operation, patients were taken to the recovery room and standard monitoring was performed and vital signs recorded first, then every 15 minutes until they left the recovery room. Grade III and IV shivering were treated with tramadol and nasal oxygen support

#### 4.9. Data quality control

Prior to data collection, the data questionnaire was pre-tested at 10% of the sample size to ensure its validity and reliability. In addition, the data collectors received a brief introduction to the assessment tools and training on the objectives and applicability of the research. The person who collects and monitors the data received has access to all components of the study tools as well as the entire data collection process. Regular monitoring and follow-up were

carried out during data collection. Every day, the principal researcher carries out cross-checks to ensure accurate and consistent results.

#### 4.10. Data analysis and Processing

Data were imported into SPSS version 25 for analysis. The histogram and Shapiro-Wilk test were used to determine the normality of quantitative data; A one-way analysis of variance (ANOVA) was used to compare parametric data. such as age, BMI, weight, OP temperature, MAP, heart rate, baseline SPO<sub>2</sub>, and baseline body temperature, and the Kruskal-Wallis test was used to analyze nonparametric data such as height, intraoperative SPO<sub>2</sub>, and intraoperative body temperature. The hoc Mann-Whitney U test was used for pairwise comparison of groups.

A chi-square test was performed to examine categorical data such as ASA, gender, incidence of shivering, and shivering severity. Data were presented as mean  $\pm$ SD for normally distributed data, mean $\pm$  IQR (25th-75th percentile) for nonparametric data, and categorical data were presented as numbers and percentage (%). A P-value < 0.05 was considered statistically significant

#### 4.11. Ethical Consideration

Before the start of the study, the Department of Anesthesia, the College of Health Sciences, the Faculty of Medicine and the Ethical Review Board of the Ethics Committee of Addis Ababa University gave their approval. Each participant provided verbal informed consent after being verbally informed about the study goals and importance. Participation by participants in the study was voluntary, and those who did not wish to participate or who had at any point changed their mind about participating were told that they could do so without restrictions

#### 4.12. Dissemination of the result

Addis Ababa University College of Medical and Health Science, Tikur Anbesa Specialty Hospital, Ethiopian Anesthetist Association and other relevant organizations will receive the results of the study. The results are presented in numerous seminars, meetings, conferences and workshops at the College of Health and Medical Sciences. In addition, efforts are being made to publish and disseminate research results in other scholarly journals and publications.

## 5. Results

### 5.1 Demographic and perioperative characteristics

During the study period, 87 patients were recruited for analysis (29 in each group), regardless of whether they were taking bupivacaine alone, bupivacaine plus dexamethasone, or bupivacaine plus pethidine. There were no significant differences between groups for gender, ASA, height, weight, or BMI. In addition, there were no significant differences between the groups in terms of the extent of blockage, puncture site, procedure time, amount of fluid used for irrigations, blood loss, and intravenous fluid administered (P value > 0.05).

Table 1 demographic and baseline parametric of the patients in perioperative period

	<b>Bupivacaine alone(n=29)</b>	<b>Dexamethasone with bupivacaine(n=29)</b>	<b>Pethidine bupivacaine(n=29)</b>	<b>with P value</b>
<b>Age(years)</b>	64.97±7.495	63.97±6.428	64.07±7.488	.843•
<b>Sex male</b>	22(33.3%)	22(33.3%)	22(33.3%)	1.000#
<b>female</b>	7(33.3%)	7(33.3%)	7(33.3%)	
<b>Height(cm)</b>	165(165-170)	170(165-178)	170(165-177)	.113*
<b>Weight(kg)</b>	59.14±7.105	58.93±6.984	59.69±5.751	.904•
<b>BMI</b>	21.23±2.83	20.66±2.857	20.93±2.069	.701•
<b>ASA I</b>	15(35.7%)	14(33.3%)	13(31.0%)	.871#
<b>II</b>	14(31.1%)	15(33.3%)	16(36.6%)	
<b>OR Temp(0C)</b>	23.5483±.58225	23.6276±.37692	23.6000±.26049	.774•
<b>Base map</b>	95.28±15.149	94.10±13.284	93.76±10.976	.901•
<b>Baseline HR</b>	85.03±15.921	85.07±15.955	84.93±11.976	.999•
<b>Baseline SPO2</b>	95.76±1.380	95.34±1.696	95.59±1.500	.588•
<b>Baseline temp.(0C)</b>	36.5379±.14246	36.5172±.12837	36.5069±.12798	.666•
<b>Irrigation fluid(liter)</b>	1(1-2)	2(1-2)	2(1-2)	.176*
<b>Duration of surgery(hrs.)</b>	1(0.00-1.00)	0(.00-1.00)	0(0.00-1.00)	.420*

<b>Recovery room temp(0C)</b>	22.5(22.35-22.50)	24(22.35-22.50)	25(22.40-22.60)	.357*
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NB: •=ONE WAY ANOVA, \*=Kruskal Wallis H test, #=chi-square, Values are presented as: Mean  $\pm$ SD, Number (%), Median (IQR), One-Way ANOVA test, Chi-square test, Kruskal's-Wallis H test and P<0.05 is statistically significant.

## 5.2 comparison between the groups in terms of the occurrence of the shivering

Our results showed that the incidence of shivering was 44.8% in the bupivacaine group, 10.3% in the dexamethasone and bupivacaine group, and 17.2% in the pethidine and bupivacaine group. The Chi-square test revealed a statistically significant difference between the three groups ( $X^2(2) = 10.424$ ,  $P = 0.005$ ), so the incidence of shivering was assessed by using Mann-Whitney U test. There was a significant difference between bupivacaine alone and dexamethasone plus bupivacaine ( $p = 0.004$ ), as well as between bupivacaine alone and bupivacaine plus pethidine ( $p = 0.024$ ), and the differences between dexamethasone plus bupivacaine and pethidine plus bupivacaine were not statistically significant. ( $p=0.450$ ).

Table 2 comparison occurrence of shivering between the groups

<b>Shivering occurrence</b>	<b>Bupivacaine alone(n=29)</b>	<b>Dexamethasone with Bupivacaine (n=29)</b>	<b>Pethidine with bupivacaine(n=29)</b>	<b>P-value</b>
<b>NO</b>	16(55.2%)	26(89.7%)	24(82.8%)	<b>0.005</b>
<b>YES</b>	13(44.8%)	3(10.3%)	5(17.2%)	

Values are presented by: numbers and percentages, chi-square test is used and p value <0.05 is statistically significance

## 5.3. Comparison of severity of shivering between the groups

Shivering severity: In the bupivacaine group, 5 patients had mild, 4 moderate, and 4 severe shivering; two patients developed a mild shiver, and one patient had a moderate shiver in bupivacaine with dexamethasone groups. With the combination of bupivacaine and pethidine, 3 patients developed mild shiver and 2 patients developed moderate shiver.

Shivering severity was assessed using the Chi-square test and was found to be statistically significant between the three groups ( $X^2(2) = 13.331$ ,  $P = 0.001$ ). A post hoc

Mann-Whitney U test showed a significant difference between bupivacaine alone and dexamethasone with bupivacaine (P= 0.001) and a significant difference between bupivacaine alone and bupivacaine with pethidine (P = 0.016). There were no statistically significant differences between dexamethasone with bupivacaine and pethidine with bupivacaine. (P=.237).

Table 3 comparison severity of shivering between the groups

	<b>Bupivacaine alone(n=29)</b>	<b>Bupivacaine with dexamethasone(n=29)</b>	<b>Bupivacaine with pethidine(n=29)</b>	<b>Pvalue</b>
<b>Mild</b>	5(17.2%)	2(6.9%)	3(10.3%)	.001
<b>Moderate</b>	4(13.8%)	1(3.4%)	2(6.9%)	
<b>Severe</b>	4(13.8%)	0(0%)	0(0%)	

Value is presented by Number and percentage, P value<0.005 is significant

### **Hemodynamic and body temperature**

Intraoperative mean arterial pressure, heart rate, oxygen saturations and body temperature were assessed throughout the procedure every 10 minutes and post-operative in the PACU, as we analyzed by using ONE WAY ANOVA there was no statistically significant difference in mean arterial pressure and heart rate between the groups (P>0.05).

Others oxygen saturation and body temperature were assessed by Kruskal-Wallis H test since they are non-parametric there was no statistically significant difference between the groups(p>0.05).

Mean arterial pressure was determined every 15 minutes for all groups and analyzed with one-way Anova. Compared to the exposed groups (pethidine and dexamethasone), there was some decrease in the unexposed group (bupivacaine alone), but it was not statistically significant when we compared dexamethasone with pethidine almost equal. (See Figure 1)

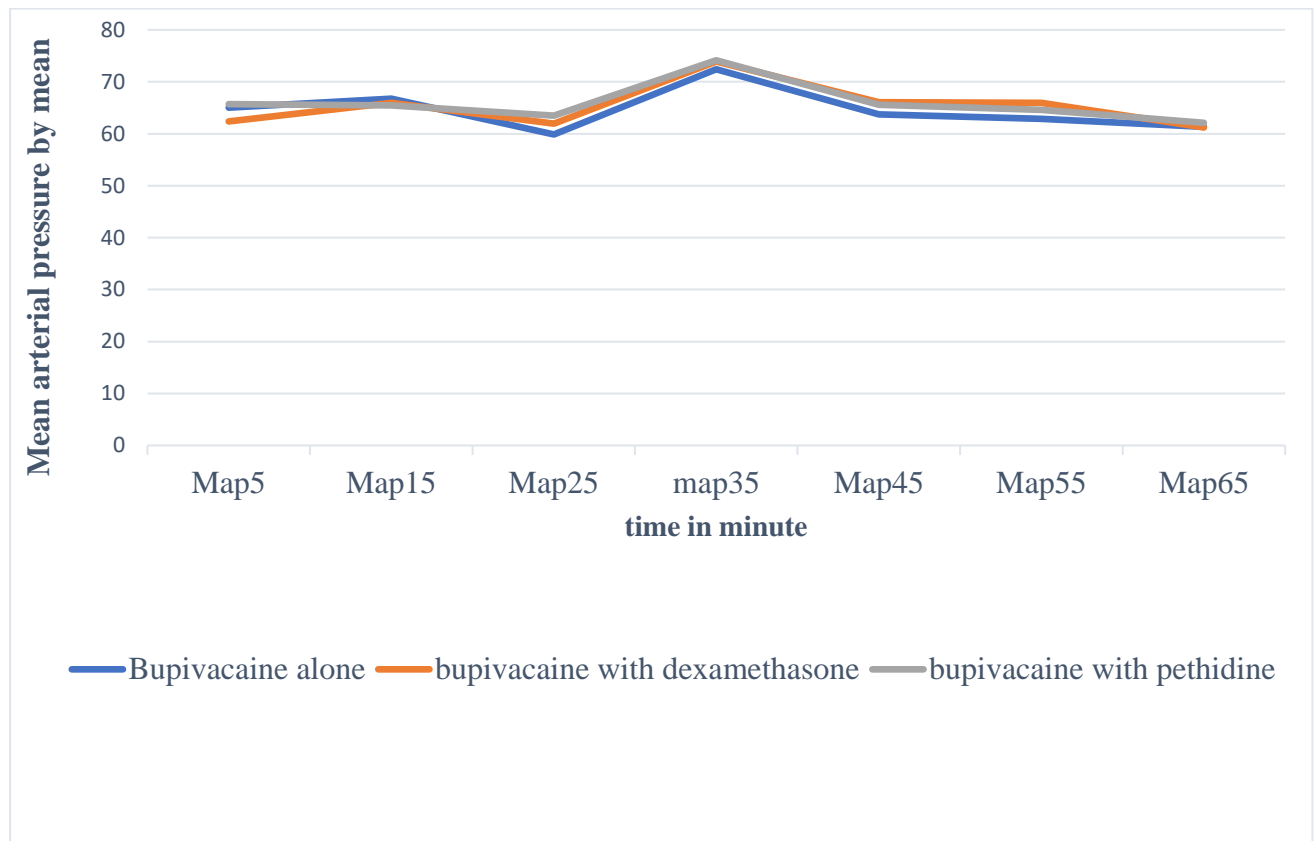


Figure 1 graphical presentation of mean arterial pressure between the groups. Data presented by mean and standard deviations, as analyzed by One-Way Anova there were no significant difference between the groups as ( $P > 0.05$ )

We compare heart rate between groups clinically when we see that with bupivacaine alone heart rate decreases, but there is no difference with either dexamethasone or pethidine. Overall, there is no statistically significant difference between groups as we analyzed with one-way Anova,  $P > 0.05$ . (See Figure 2)

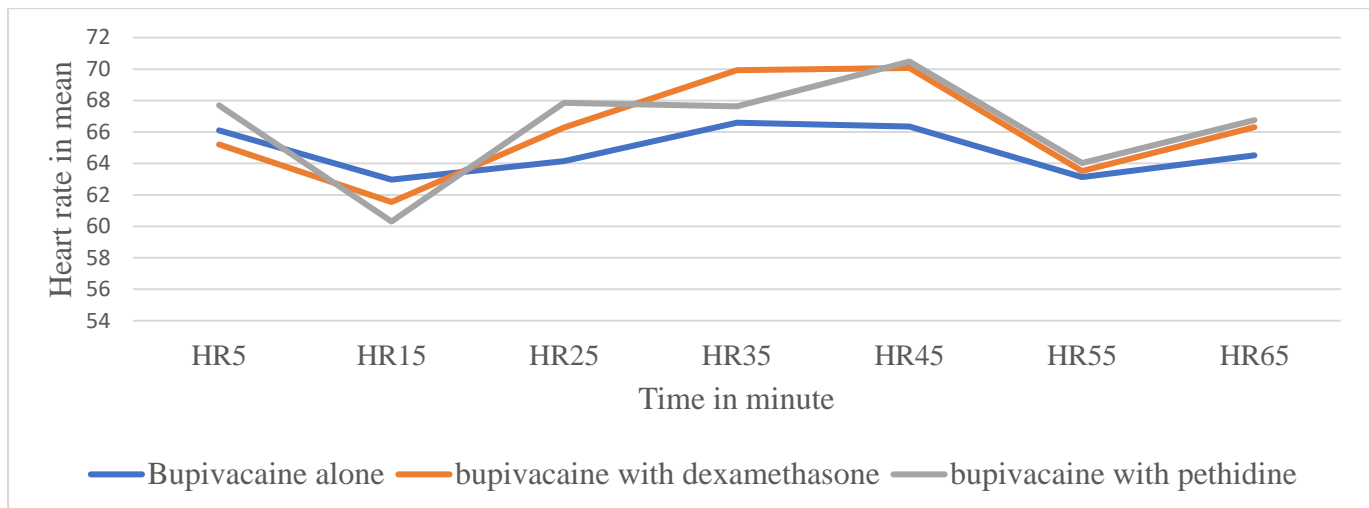


Figure 2 graphical presentation of heart rate between the study groups. As analyzed by One-Way Anova there is no significant difference between the groups in heart rate. data present by mean and standard deviation.

Oxygen saturation was measured at 15-minute intervals and analyzed between groups using the Kruskal's-Wallis test. When we see the results between dexamethasone and bupivacaine, at first, they are the same, but after 15 minutes the oxygen saturation is high for the dexamethasone group and a little low for the pethidine group. The bupivacaine group was lowest throughout the procedure, but not statistically significant. (See Figure 3)

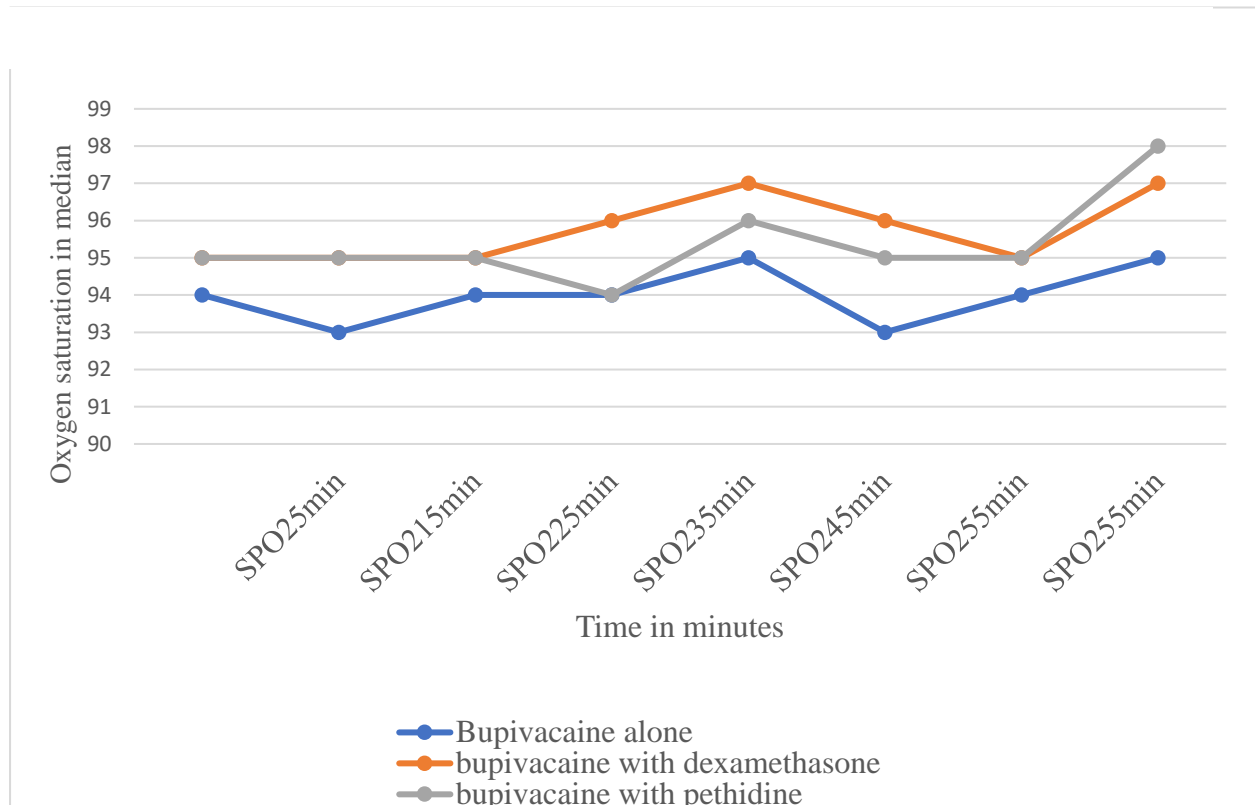


Figure 3. graphical representation of oxygen saturation between the study groups. Data were present by median and interquartile range, as analyzed by Kruskal's Wallis test there were no significant difference between the groups, ( $P>0.05$ )

Axillary temperature was measured between groups and analyzed. Temperature was the same in the dexamethasone and pethidine groups, but body temperature was reduced with bupivacaine alone, requiring clinical intervention. But not statistically significant. (See Figure 4)

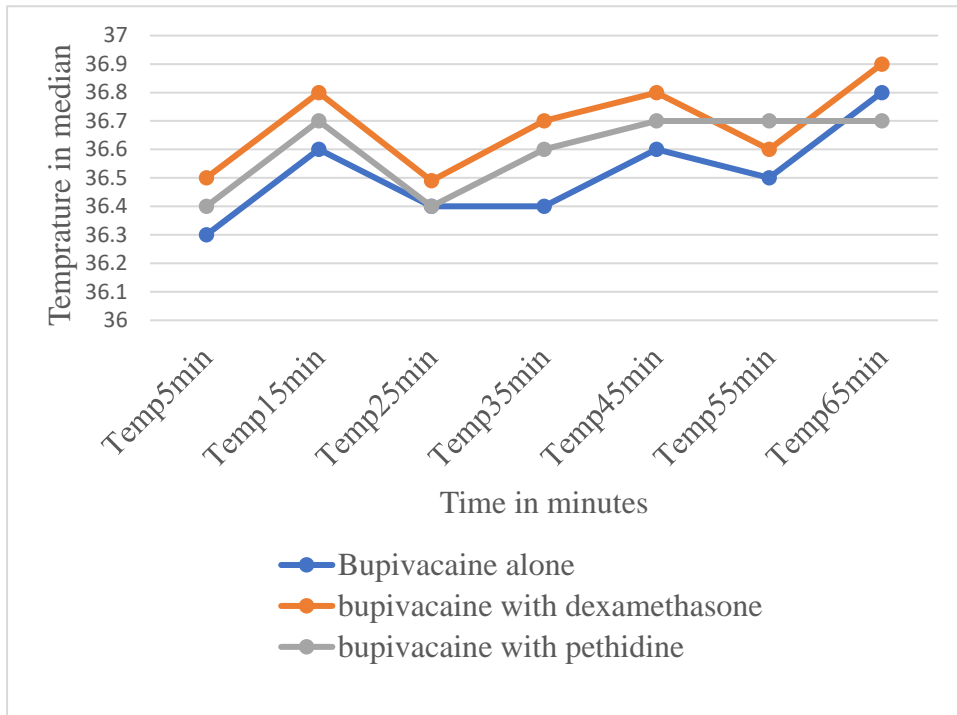


Figure 3 graphical presentation of body temperature between the study groups. Axillary temperature was analyzed by Kruskal's test and no significant difference between the groups, ( $P > 0.05$ )

## 6: Discussions

In this study, we found that the incidence of shivering in the bupivacaine alone, dexamethasone with bupivacaine, and pethidine with bupivacaine group was 13 (44.8%), 3 (10.3%), and 5 (17.2%) respectively, ( $P = .001$ ). These study results suggest that intrathecal dexamethasone (4 mg) was as effective as intrathecal pethidine (0.2 mg/kg) plus bupivacaine in preventing the occurrence and severity of shivering in patients undergoing cystourethroscopy when we compared them to an unexposed group. Consistent with our findings, other studies reported that intrathecal dexamethasone was effective in preventing post spinal shivering (2,4,23,27).

a fascinating study done in Egypt in 2017, found that the incidence of shivering was 13 (43.3%), 2 (7%), and 3 (10%) for the bupivacaine with saline, bupivacaine with dexamethasone, and bupivacaine with pethidine groups, respectively ( $P=0.001$ ).

They concluded that for patients who underwent cystourethroscopy surgery, intrathecal dexamethasone with bupivacaine is just as beneficial as intrathecal pethidine with bupivacaine in preventing post-spinal shivering(4).

The result may be different due to difference in the populations, anesthetic delivery techniques, and study design employed.

In a cohort study done by Belete D. et al. in Addis Ababa in 2020 by comparing intravenous dexamethasone and pethidine as prophylaxis in the prevention of post-spinal shivering for patients who have underwent TURP. They found that 21.9% of the pethidine groups and 43.8% of the dexamethasone groups developed shivering, but this difference was statistically insignificant ( $P=0.11$ ).

the variation may be the result of different pharmacological dosages and administration routes. They utilize dexamethasone and pethidine intravenously, but we employed them as adjuvants intrathecally, which is a better explanation for the differences between their and our methods of preventing post-spinal shivering(1).

Another study was conducted in Iran in 2016 by Solhpour et al. To prevent shivering during spinal anesthesia, they compared pethidine plus dexamethasone, pethidine; ketamine plus midazolam and control groups. The incidence of shivering was 20% in pethidine plus ketamine groups, 20% in pethidine groups, 4% in dexamethasone plus pethidine, and 64% in control groups ( $P=0.001$ )(22).

They concluded that, when compared to other treatments, the combination of dexamethasone and pethidine is more successful at preventing post-spinal shivering. The discrepancy might be caused by the fact that their surgical technique of choice, population, drug dosage, and anesthetic techniques were different from ours. In our study, we employed dexamethasone for one group, pethidine for other groups, and control groups. They also combined two medications for one group, and the ways they used were different, which caused a discrepancy.

Another study by Atri et al. in India in 2022 to compare intrathecal dexmedetomidine versus dexamethasone to prevent post-spinal shivering in cesarean section parturient, there were only a few patients who complained of shivering (16.7% of patients in the dexmedetomidine group and 23.3% of patients in the dexamethasone group, with no statistically significant difference(27).

The disparity may result from the populations studied, the study's design, or the anesthetic methods they employed.

In this study, we also evaluated the degree of shivering between an exposed group and the nonexposed group, in the nonexposed group, there were 4 (13.8%) cases of moderate shivering, 5 (17.2%) cases of mild shivering, and 4 (13.8%) cases of severe shivering. In the Dexamethasone group 2 (6.9%) patients had mild shiver and 1 (3.4) patient developed moderate shiver and for the pethidine group 3 (10.1%), 2 (6.7%), were mild, moderate, respectively and none of them had grade 3 or 4, (severe shivering) from an exposed group.

In contrast this study, a prospective, double-blind, randomization study by Fern and Misiran et al. in 2015 at UKMMC Kuala Lumpur compared the effectiveness of dexmedetomidine, pethidine, and tramadol on the treatment of post-neuraxial anesthesia shivering and discovered that the response rate was highest in the dexmedetomidine group and was only statistically significant when compared to the tramadol group ( $p=0.001$ ). According to their analysis, grade 3 or 4 shivering occurred in 60 out of 102 patients (59%) (35).

This difference may be the result of a different population, a different study design, or various techniques that is used.

When comparing our study to the one by Desta Belete et al., grade I was 0 (0%) in the pethidine groups, whereas it was 4 (12.5%) in dexamethasone.

grade II 4 (12.5%) in the pethidine groups and 6(18.8%) dexamethasone groups,

Grade III 3(9.4%) in the pethidine group and 4(12.5%) in dexamethasone(1).

The disparity can be explained by the fact that they lacked control groups in our study that showed statistically significant differences.

According to a 2017 study in Egypt the severity of shivering between the groups revealed that, 2 patients experienced grade III shivering from dexamethasone, 2 patients grade III and 1 grade IV shivering from pethidine groups, and 2 patients in grade I, 7 patients in grade III, and 4 patients experience grade IV from control groups. This difference was statistically significant between the groups ( $P=0.01$ )(4).

the difference could be the result of different populations and study designs used in their research methods compared to ours.

There was a decrease in mean arterial pressure and heart rate across all groups when we compared baseline to after spinal anesthesia began, but there was no statistically significant difference between the groups, rejecting the alternative hypothesis

In a 2017 study in Egypt, found that, 2 patients in the dexamethasone groups, 4 patients in the pethidine groups, and 8 patients in the control groups all suffered hypotension, In the dexamethasone, pethidine, and control groups, respectively, 0, 3, and 4 patients exhibited statistically insignificant bradycardia(4).

This difference may be due to differences in the dose of bupivacaine used, the degree of spinal block, and preloading or co-loading.

Another study was conducted in India in 2022 by Atri et al. They evaluated hemodynamics, including systolic, diastolic, mean, and heart rate (HR) blood pressure. No statistically significant differences between the groups, they concluded.

Another study done in Egypt in 2021 by Ibrahim M. Esmat and Mohamed by comparing paracetamol versus dexamethasone for the prevention of post spinal shivering and assess hemodynamics instability revealed that MAP was statistically significantly lower in the Paracetamol group than in the Dexamethasone group with a mean difference (-14.2, 95% CI: -15.3--13.1) whereas they were statistically significant higher in the Dexamethasone group than in the Control group with a mean difference (13.8, 95% CI: 12.6-15.0) ( $P 0.001$ ), there were no statistically significant differences between the Paracetamol and Control groups (17).

The disparity could be a result of their usage of various medicines, study design, and study demographics. Image demonstrates how dexamethasone clinically reduces hemodynamic instability.

## 7. Strength and Limitation

### 7.1. Strength

The study groups are comparable in terms of socio demographic distribution and perioperative factors that affect study outcome and the same surgical, procedure hence the difference observed may probably be due to the exposure factors.

### 7.2. Limitation

This study has certain limitations, the use of RCTs for comparison and the limited availability of similar studies. This study could not generalize to all surgical patients undergoing surgery under spinal anesthesia.

## 8: Conclusion and Recommendation

### 8.1. Conclusion

Shivering occurred more frequently in the unexposed group than exposed group. The combination of dexamethasone (4 mg) and bupivacaine had the lowest rates, and bupivacaine alone had the highest rates of shivering. The severity of shivering was significantly higher in the unexposed group than in the exposed group, and there was no significant hemodynamic instability in either group. Therefore, we conclude that dexamethasone (4 mg) is as effective as pethidine (0.2 mg/kg) in preventing post spinal shivering when used intrathecally with bupivacaine as an adjuvant to minimize the frequency and severity of shivering and reduce hemodynamic instability

### 8.2. Recommendation

#### **For Anesthesia professionals**

This study highlights the effectiveness of different treatments in reducing shivering and improving patient discomfort during medical procedures. So, we offer dexamethasone (4mg) as an alternative to the conventional anti-shivering medication pethidine with bupivacaine as an adjuvant for shivering prevention in patients undergoing TURP and TURBT procedures under spinal anesthesia.

#### **For Anesthesia department and Researchers**

A randomized control trial with a suitable follow-up time is recommended, as is a postoperative complication study.

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## Annexes

### Annex I information sheet

This questionnaire is designed to assess the effectiveness dexamethasone vs pethidine as adjuvant with bupivacaine vs bupivacaine alone in the prevention of post spinal anesthesia shivering for the patients who undergoing TURP and TURBT under spinal anesthesia at TASH, Addis Ababa, Ethiopia, 2023. There is no risk to take part in the study, all information is confidential. Their names will not keep in the form. Their participation in the study will be voluntary: They are not obliged to participate and may discontinue at any time. Moreover, this research thesis is approved by Ethical review board of AAU and college of health science, department of Anesthesia.

### Annex II consent form

#### **Greeting**

Hello, I am -----, I am working in the research team of Addis Ababa University department of anesthesia.

The goal of this questionnaire is to collect data on the effectiveness of intrathecal pethidine with bupivacaine, dexamethasone with bupivacaine, and bupivacaine alone in preventing post-spinal shivering and the effect on hemodynamic stability for patients undergoing cystourethroscopy surgery under spinal anesthesia at Tikur Anbesa specialized hospital department of endourology. The study will benefit those who had cystourethroscopy surgery to prevent post-spinal shivering with an effective anti-shivering drug with fewer side effects.

We will only ask you a few questions that will take a few minutes each at three different times.

The answers to those questions should be kept private.

We will not include your name in the survey. You have the right to refuse to answer any of the questions and to interrupt the interview at any time.

Do I have your permission to continue? 1. If yes, continue to the next page 2. If no, skip to the next participant.

Interviewer: Code \_\_\_\_\_ Name \_\_\_\_\_ signature \_\_\_\_\_

Date of interview \_\_\_\_\_ Time started \_\_\_\_\_ Time completed \_\_\_\_\_

Result of interview: 1. Completed 2. Respondent not available 3. Refused 4. Partially completed

Supervisor (Checked): Name \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_

### Annex III Data collection tool

#### Section-1; Socio demographic characteristics

No	Questions	Response
101	Age --- Sex	Ht----- Wt----- M-----F-----
102	ASA physical status	ASA I ASA II
103	Room temperature	_____ Then every 15min after SA given 15min__ 30min__ 45min__ 60min__
104	Allergy to any of these drugs	Pethidine__ Dexamethasone__ Local anesthetics__ Other specify_____
105	Does the patient has preexisting medical diseases	1.yes 2. No If yes specify_____

#### Section- 2, hemodynamic parameter

No	Questions	Response
201	Base line parameter	Body temperature:1. Axillary____PR____, SPO2_____, MAP____, RR-----

202	Hemodynamic after SA given	<p style="text-align: center;">Body T0C   HR   MAP   SPO2   RR</p> <p>At 5min        -----    -----    -----    -----</p> <p>Every 10min</p> <p>10min -----</p> <p>20min -----</p> <p>30min -----</p> <p>40min -----</p> <p>50min -----</p> <p>60min -----</p> <p>At the time of discharge from OR to PACU</p> <p style="text-align: center;">-----,</p>
203	Hemodynamic at PACU	<p>At reception time: Body T0C   HR   MAP   SPO2   RR</p> <p style="text-align: center;">-----</p> <p>15min        Body T0C   HR   MAP   SPO2   RR</p> <p style="text-align: center;">-----</p> <p>30min -----</p> <p>45min -----</p> <p>60min -----</p> <p>At time of discharge, -----</p>

Section -3, occurrence of shivering and its severity

No	Questions	Response	
301	Does shivering occur	1.No    2. Yes	
302	If answer yes, answer question no 302	<p>&lt;10min----</p> <p>10-20min_-----</p> <p>20-30min-----</p> <p>30-40min-----</p> <p>40-50min</p> <p>50-60min</p> <p>1hr-2hrs</p> <p>After 2hrs</p> <p>After discharge from PACU--</p> <p>-----</p>	<p>SPO2-----</p> <p>MAP-----</p> <p>PR-----</p> <p>RR-----</p>

303	Severity of shivering	Grade0----- Grade 1----- Grade2----- Grade3----- Gdade4-----	
304	Drug used to treat shiver	Tramadol Pethidine other (specify)-----	

#### Section-4 spinal anesthesia related

No	Questions	Response
401	Drug used for SA	Dexamethasone with bupivacaine Pethidine with bupivacaine Bupivacaine alone
402	Site of injection	L2/L3 L3/L4 L4/L5
403	Level of sensory block	Up to T10 Above T10 Up to T6 Other (specify)-----

#### Section -5, surgery related

No	Questions	Response
501	Duration of surgery	<1hr 1-2hr >2hr
502	Amount of fluid used for irrigation	<500ml 500ml-1000ml 1000ml-2000ml >2000ml

503	Fluid used for irrigation	Warm Cold
504	Bleeding	<500ml 500ml-1000ml >1000ml

### Section-6 complications occurred

No	Questions	Response
601	Does TURP Syndrome occurred	Yes No If yes specify the intervention----- -----
602	Other adverse effects	Pruritus'      Nausea      Vomiting
		yes no      yes no      yes no

### Shivering intensity assessment tool

Grade0 = No shivering,

Grade1 = piloerection or peripheral vasoconstriction but no visible shivering,

grade2 = muscular activity in only one muscle group,

Grade 3 = muscular activity in more than one muscle group, and

Grade 4 = whole body shivering

Severity of shivering

Grade1 =mild shivering

Grade 2=moderate

Grade3 and 4=severe