Addis Ababa University

College of Health Sciences Department of Anesthesia

EFFECTIVENESS 0F PREOPERATIVE ORAL TRAMADOL IN PREVENTING PERIOPERATIVE SHIVERING IN PATIENT UNDERGOING TRANSURETHRAL RESECTION OF PROSTATE SURGERY UNDER SPINAL ANESTHESIA AT HAWASSA COMPREHENSIVE SPECIALIZED HOSPITAL SNNPR, ETHIOPIA, 2019: COHORT STUDY

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Thesis for Master of Science degree in Anesthesia

TITLE

Effectiveness of preoperative oral tramadol in preventing perioperative shivering in geriatric patients for transurethral resection of prostate surgery under spinal anesthesia.

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Duration of project: ----------

Thesis submission date; ----------

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List of abbreviations

ASA- American Society of Anesthesiologist

TURP- Transurethral Resection of Prostate

PO-Per Oral

SA-Spinal Anesthesia

NIBP-Noninvasive Blood Pressure

PR-Pulse Rate

SPO2-Arterial Oxygen Saturation

HR-Heart Rate

BMI-Body Mass Index

PACU-Post Anesthesia Care Unit

SAB-Subarachnoid Block

PAS-Post Anesthesia Shivering

BPH-Benign Prostatic Hyperplasia

Abstract

Background: Spinal anesthesia is widely used as a safe anesthesia technique for both elective and emergency surgeries. Shivering is a frequent complication, distressing for the patients undergoing surgery under both regional and general anesthesia. Regional anesthesia has been known to be associated with greater heat loss than general anesthesia. Post anesthetic shivering may cause discomfort to patients, and aggravate wound pain by stretching incisions and increase intracranial and intraocular pressure. Shivering increase tissue oxygen demand by as much as 500% and accompanied by increase in minute ventilation and cardiac output to maintain aerobic metabolism. Elderly patients are especially at risk of hypothermia under anesthesia, as low core temperatures may not initiate autonomic protective response.

Objective: To assess the effectiveness of oral tramadol in preventing perioperative shivering in patients undergoing TURP surgery at Hawassa university comprehensive specialized hospital from February to May 2019 GC.

Method: A prospective cohort study design was employed. Sample size was calculated by using double proportion formula with equal sample size where n1=sample for oral tramadol group, n2=sample for control group and the final Sample size became n1= n2=30

A systemic random sampling technique was used to select study participants. Data was collected by using structured questionnaire. Based on normality assumption, analysis was done by independent sample t test, $\chi 2$,Mann–Whitney *U*-test and Kaplan meier as appropriate. P value <0.05 was considered as statistically significant.

Result: The incidence of shivering was significantly less in patients who received preoperative oral tramadol group than those of control group. (13.3% vs. 80%, p<0.001).Grades of shivering were also significantly different with only grades 1-3 in oral tramadol compared to 2-4 grades of shivering revealed in those who didn't took it with p=0.006. Patients who didn't took oral tramadol experience shivering in the first 20 minutes after spinal anesthesia performed when compared to tramadol groups with log rank test -p=0.015 .

Conclusion and Recommendation: our study demonstrate that taking 50 mg oral tramadol before two hours of the operation time was effective to decrease the incidence, severity and delay the onset of shivering which occur after spinal anesthesia for geriatric patients who undergo transurethral resection of prostate surgery. Based on this we recommend that oral tramadol is one of widely available drug in our country. So ordering it as perioperative shivering prophylaxis is a good option to improve the clinical quality of our patient management.

Key word: oral tramadol, perioperative shivering, geriatrics

Contents

LIST OF TABLES

LIST OF FIGURES

1. INTRODUCTION

1.1 BACKGROUNG

shivering is defined as a spontaneous and involuntary muscular activity which increases metabolic heat production. Shivering may develop as a physiological response to hypothermia manifested as tonic muscular activity secondary to non-thermoregulatory heat preservation mechanism. The core temperature in humans varies with the circadian rhythm (and with the menstrual cycle in females), but is normally maintained within the narrow range of 36.5–37.0 °C (1)(2).

Shivering is usually triggered by hypothermia. However, it occurs even in normothermic patients during the perioperative period. The etiology of shivering is not understood sufficiently. In addition to the fact that shivering is poorly understood, the gold standard for the treatment and prevention has not been defined yet(3).

Subarachnoid (spinal) anesthesia is widely used as a safe anesthesia technique for both elective and emergency surgeries. Shivering is a frequent complication, distressing for the patients undergoing surgery under both regional and general anesthesia. Regional anesthesia has been known to be associated with greater heat loss than general anesthesia(4).It is widely accepted that complications related to surgery and delivery of anesthesia care are inevitable. Post anesthesia shivering is one of the potential complications of anesthesia which may increase patient's morbidity(2).

Shivering is a readily detectable tremor or fasciculation of face, neck, jaw, head, trunk or extremities lasting longer than 15 seconds .it is very uncomfortable and distressing for the patient, anesthesiologist and the surgeon, especially when the patient is under regional anesthesia(5).

Transurethral resection of prostate is a surgery used to treat urinary problems due to enlarged prostate. Hypothermia can complicate this procedure and geriatric patients especially are predisposed to the risk of hypothermia induced shivering under anesthesia as their lowered core temperature does not initiate protective autonomic response.(6) It is commonly performed under spinal anesthesia. Shivering occurs due to sympathetic block, leading to peripheral vasodilatation and also caused by the use of cold irrigating fluids. Most patients

undergoing TURP are elderly patients with weak autonomic protective responses, and shivering has many undesirable effects such as increased oxygen consumption, increased carbon dioxide production, and patient discomfort. These side effects increase the load on the cardio respiratory system, especially in elderly patients with low cardio respiratory reserve (7,8).

Numerous anti shivering medications have been reviewed. However, the adverse effects of medications limit their utility in many clinical settings. sufentanil, alfentanil, tramadol, physostigmine, clonidine, magnesium sulfate, Pethidine, and dexamethasone have been used for the treatment of postoperative shivering(9,3).

Tramadol has μ agonist activity as well as acts as inhibitor of serotonin and nor epinephrine uptake at the synapse to produce the analgesic and anti shivering effect. It also activates thermo aminergic receptors of the descending spinal cord, inhibiting pain pathway. Tramadol is mainly used as opioid analgesic but its role as an anti shivering agent is well established. It has less side effects (especially respiratory depression and nausea and vomiting) than other μ receptor agonists(10,(11)(12).

Opioids have significant role among the identified drugs because the effects of different opioids have been studied frequently in this regard and some of them such as pethidine are commonly used for both treatment and prevention of PAS and it considered as the most effective anti shivering drug. But some adverse effects such as respiratory depression, especially in patients with previous history of opioids and anesthetics administration, hypotension, postoperative nausea and vomiting have limited its use (12).

1.2 Statement of the problem

Shivering is both morbid and uncomfortable for patients and may interfere with monitoring of electrocardiogram, blood pressure and pulse oxygen saturation. It escalates oxygen consumption, lactic acidosis and carbon dioxide production; thus, predisposing a patient with a low cardiopulmonary reserve to potential harm. Various drugs have undergone investigative trial to reduce perioperative shivering with more or less similar efficacy, but the search for the ideal drug that can prevent perioperative shivering still continues (6).

Shivering is the one of the most commonly observed complications in anesthesia practice. It has a very high incidence in regional anesthesia ranges between 40-60 %and also the incidence in general anesthesia reaches 60%(13),(4)14).

There is a wide variety of PAS incidence reports due to PAS definition following anesthesia variations, population, sample size and study design difference. According to studies, the incidence of PAS ranges from 5% to 65% following general anesthesia and 55% after neuraxial anesthesia. The incidence also determined by other factors like type of anesthesia used, age and gender of the patient, duration of anesthesia and surgery, and type of surgery (2).

Shivering can also have deleterious metabolic and cardiovascular effects, which include increased expenditure of cardiac and systemic energy, increased oxygen consumption by approximately 100%, increased carbon dioxide production and increased cardiac work. Therefore, shivering should ideally be prevented or treated by pharmacological or by other means. This risk is more in elderly patients because they have low cardio respiratory reserve (13,11,1).

Post anesthetic shivering may cause discomfort to patients, and aggravate wound pain by stretching incisions and increase intracranial and intraocular pressure. It also increases tissue oxygen demand by as much as 500% and accompanied by increase in minute ventilation and cardiac output to maintain aerobic metabolism. This may be deleterious in patients with impaired cardiovascular reserve or a limited respiratory capacity (15).

1.3. Significance of the study

Perioperative shivering during spinal anesthesia is a common complication in patients undergoing transurethral resection of prostate (TURP) which is secondary to peripheral vasodilatation from sympathetic blockade and cold irrigating fluid. Regional anesthesia has been known to be associated with greater heat loss than general anesthesia.

Elderly patients are especially are at risk of hypothermia under anesthesia, as low core temperatures may not initiate autonomic protective response. Perioperative shivering is physically detrimental and embarrassing (4,7).

Sympathetic stimulation due to shivering elevates blood pressure, heart rate, plasma catecholamine concentrations, increased metabolic rate, increased oxygen consumption (100–600%) along with increased carbon dioxide production. These factors contribute to threefold increase in morbid myocardial outcomes(4). Most of the time, the emphasis is to treat perioperative shivering rather than prevent it. Hence this study will focus on prevention of shivering rather than treating.

Oral formulations of tramadol are easily available and also economically cost effective than its IV route as well as other drugs which we use to treat perioperative shivering like pethidine.

Opioids have significant role among the identified drugs because the effects of different opioids have been studied frequently in this regard and some of them such as pethidine are commonly used for both treatment and prevention of PAS and it is considered as the most effective anti shivering drug. But some adverse effects such as respiratory depression, especially in patients with previous history of opioids and anesthetics administration, hypotension, postoperative nausea and vomiting have limited its use(12). There this study if proved to be effective, tramadol can be a good alternative in preventing perioperative shivering with lesser risk.

As far as my knowledge and search is concerned there is no published study under this title so it can help as a background for future researchers on related topics and it may also invite scholars to research more on this area further.

2: Literature review

Shivering is a fasciculation or tremors of the face, jaw, head, trunk, or extremities lasting longer than 15 second. Tramadol, which is a weak opioid, has a role in prevention of post subarachnoid shivering as it inhibits reuptake of norepinephrine, dopamine, and serotonin (16).

Javaherforoosh F et al. in 2009, @ Iran in the study of effects of tramadol on shivering post spinal anesthesia in elective cesarean section patients shows four patients (8.8%) from study group and 39 patients (86.6%) from control group experienced shivering, thus there were significant difference between the two groups (P<0.001).but other hemodynamic stability measurements did not show statistically significant difference (11).

A study done in India by Wason R, et al in 2012 about comparison of prophylactic ketamine, clonidine and tramadol for the control of shivering under neuraxial anesthesia reveals that 20% did not shiver at all in the control group, while 82%in the ketamine group, 94% in the clonidine group and 88% in the tramadol group did not shiver at all. severity measured among patients who experienced shivering showed that In the control group, 54% exhibited grade 3 shivering; however, only 10% in the ketamine group, 4% in the clonidine group and 8% in the tramadol group exhibited grade 3 shivering which was statistically significant (P=0.001) (17).

A study done by Reda S. Abdelrahman in Egypt in 2012 on Comparison of Midazolam, Midazolam plus ketamine, Tramadol, and Tramadol plus Ketamine to prevent shivering during regional anesthesia as a prophylaxis midazolam-ketamine showed significant low incidence of shivering (5%) when compared with other groups that incidence is less than that occurred in group tramadol-ketamine (15%) but it was not statistically significant. Group tramadol-ketamine also showed a statistically significant lower incidence of shivering when compared to placebo group and midazolam group. No patients showed severe shivering in group midazolam-ketamine that was statistically significant when compared with placebo group where 30% suffered from severe shivering (P-value was 0.010). When comparing groups; group midazolam-ketamine with group midazolam (10%),group tramadol (5%) and

group tramadol-ketamine (5%),no statistically significant differences were found (p-value was 0.243,0.500 and 0.500 respectively)(15).

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TOBI KU et al,@ Nigeria (2012),a prospective double blind RCT study on tramadol effects on perioperative shivering in lower limb orthopedic surgeries under spinal anesthesia showed The incidence of shivering in the tramadol group 13.93% while that in the saline group was 16.28% which was not statistically significant but With regard to the severity of shivering, all the patients that shivered in the tramadol group had grade I shivering while five of the seven patients who shivered in the saline group had grade 2 and it was statistically significant (8).

Mahoori et al.in 2013 @ Iran did RCT by comparing ondansetron and meperedine for post op shivering reveals that shivering was controlled 59% patients taking ondasetron and 86% in meperidine group respectively(14).

Tewari, et al, in 2014 @ India studied that Oral tramadol to prevent perianesthetic shivering for patients undergoing TURP under SA by using Prospective, randomized, double-blinded,

placebo-controlled study shows that in patients who took PO tramadol the incidence of shivering was 7.5% which ranges from grade 1-3 and 92.5% didn't experience shivering at all (6).

A comparative study also from India by Tewari, et al,2014, on evaluating the prophylactic efficacy of oral clonidine and tramadol for perioperative shivering in geriatric patients undergoing TURP surgery under SA shows that in patients taking PO clonidine and PO tramadol 95% and 92.5% did not shiver, respectively. Although in the placebo group 60% exhibited no grade of shivering, the shivering was of significantly severe intensity and lasted for a longer duration in this group. No, clinically significant collateral effects were observed in patients who were administered clonidine or tramadol(18).

Study done in 2015 in Malaysia by kariscarris which compares of dexmedetomidine, pethidine and tramadol in the treatment of post-neuraxial anesthesia shivering shows out of 102 patients 60 of them (59%) experienced grade 3 or 4 shivering. those shivered patients randomly y allocated to receive one of the drug e response rate was found to be highest in the dexmedetomidine group, and it was only significant when compared to the tramadol group ($p= 0.0012$). It was noted that although the response rate was higher in the pethidine group than in the tramadol group, the difference was not statistically significant ($p= 0.082$). There was no significant difference in terms of the time that elapsed from the start of treatment to the cessation of shivering and patient-assessed treatment efficiency between the three groups (1).

Syed Ali Raza Ali Shah,et al, double blind RCT study in s2016 @ Pakistan study about efficacy of intravenous ondasetron for prevention of shivering in spinal anesthesia administered in elderly patients with a total of 80 patients were selected, divided in two groups of 40 each and shivering was present in 17.5% in patients who receives ondasetron and 40%in the controlled group which is statistically significant($p=0.026$) (13).

RCT study in 2016 @ India by Bagle, et al reveals that the incidence of shivering was significantly less in patients who received PO clonidine 10% when compared to control group 40%, experience varies grades of shivering ranging from grade 1-4 on comparison $p<0.01$ was observed implying a statistically significant difference. Changes in hemodynamic

parameters were comparable in both groups and were not significant statistically as well as clinically between them(4).

a study done in Iran by E.Alijanpouret.al(2016) on prophylactic effect of Oral Clonidine and Tramadol in Postoperative Shivering in Lower Abdominal Surgery had The incidence of shivering was significantly lower in the control and Clonidine groups than that in the Tramadol group at 15 min (P= 0.007). However, the incidence of shivering was significantly lower in the Clonidine group than that in the control group at 30 min (P= 0.020)(19).

R.Venkatramanet. al in India,(2016) a prospective, randomized, double-blinded control study on comparison tramadol, clonidine and dexmedetomidine for post spinal anesthesia shivering shows the time taken to control shivering was significantly faster in dexmedetomidine (5.76±1.14min) group than Tramadol (6.72±1.27min) and clonidine (9.48 ±0.95min) group. But dexmedetomidine groups show significantly higher sedation score (70%). The recurrence rate of shivering was significantly less in the Dexmedetomidine group 3.3% and highest in the tramadol group 23.3%.The coniine group had a recurrence rateof10% (20).

Another study done El Bakry and Ibrahim in Egypt(2016) on Prophylactic dexamethasone or pethidine, the incidence of shivering was significantly high in the control group 50% compared to dexamethasone group20% and 23% for the pethidine group which was not statistically difference between the two. The intensity of shivering was significantly higher in control group compared to others (7).

Onyekwulu, etal @ Nigeria, 2016 in double blind cross sectional study about Efficacy of Intravenous Tramadol in the Control of Shivering following Spinal Anesthesia for Caesarean Section revealed In the treatment Group 0.5, 59.6% of parturient had Grade 2 shivering and 40.4% had Grade3 shivering. There was no statistically significant difference in severity of shivering among the different groups. There was a significant difference in the time of cessation of shivering after the treatment for various groups (P=0.000). 80.1% of the parturient had marked improvement in response to shivering in treatment Group 0.5 while 80.4% of the control group recorded no response (21).

Gupta Ket al. in 2017 @ India compare the Clinical benefits of preemptive oral clonidine versus oral tramadol for abdominal hysterectomy conducted under SA shows in terms of hemodynamic parameters there was a difference between the two group after groups after 30 minutes of SAB in which HR was lower in patients of clonidine group compared to tramadol group. But there was no intra group variation with respect to BP, HR, and SPO2 during intra operative period. the incidence of shivering in clonidine group was 4 patient compared to tramadol group which is 7 patient at 30 minutes after SAB out of 30 patients in each group (10).

Lakhe et al in 2017 @ Nepal ,about Prevention of Shivering during Spinal Anesthesia which compare tramadol, ketamine and ondansetron dividing them in to 4 groups 30 in each ,the normal saline groups shows higher incidence of shivering where as the others had equal incidence. The odds ratio showed that normal saline to ondansetron found that patients receiving NS shivered 6.53 times more than those treated with the ondansetron and 11.76 times more than those treated with ketamine and tramadol (22).

Dr. Astha Palan, e tal, 2017 from India on a Prospective Randomized Comparative Study of Butorphanol with tramadol result shows that all of patients were relieved of shivering in Butorphanol 58% within 1min., 82% within 3min and 100% within 5 min. in the tramadol group 32%with in 1min, 60% with in 3 min, 98%with in 5min and 2% had no relief. There was statistically significant difference in relief of shivering at each time interval among both groups (5).

Mohamed Zein El Abedinet al, Egypt(2018) Using Pregabalin for Prevention of Post Anesthesia Shivering showed statistically highly significant difference between groups 8.1% in patients who received pregabalin and 44.3% in the control group (11).

Priyanka Gupta,etal@ Uttarak hand, India,2018,a prospective Randomized Placebo Controlled Comparison of Two Different Doses (10&20 mg) of Intrathecal Tramadol for Prevention of Post anesthesia Shivering after Subarachnoid Block showed that The incidence and intensity of shivering were significantly reduced in Group T10 versus C (incidence = 0.007; intensity = 0.002) and T20 versus C (incidence< 0.001; intensity 0.001) but comparable among groups T10 and T20 (incidence = 0.133; intensity, P = 0.142 (23).

Conceptual frame work

This conceptual framework is developed by referring different literatures related perioperative shivering in order to indicate relationships between variables. It represents set of interrelated concepts that represent an image of association between perioperative shivering and its main effects on patient perioperativey. This structure will provide guidance for the study.

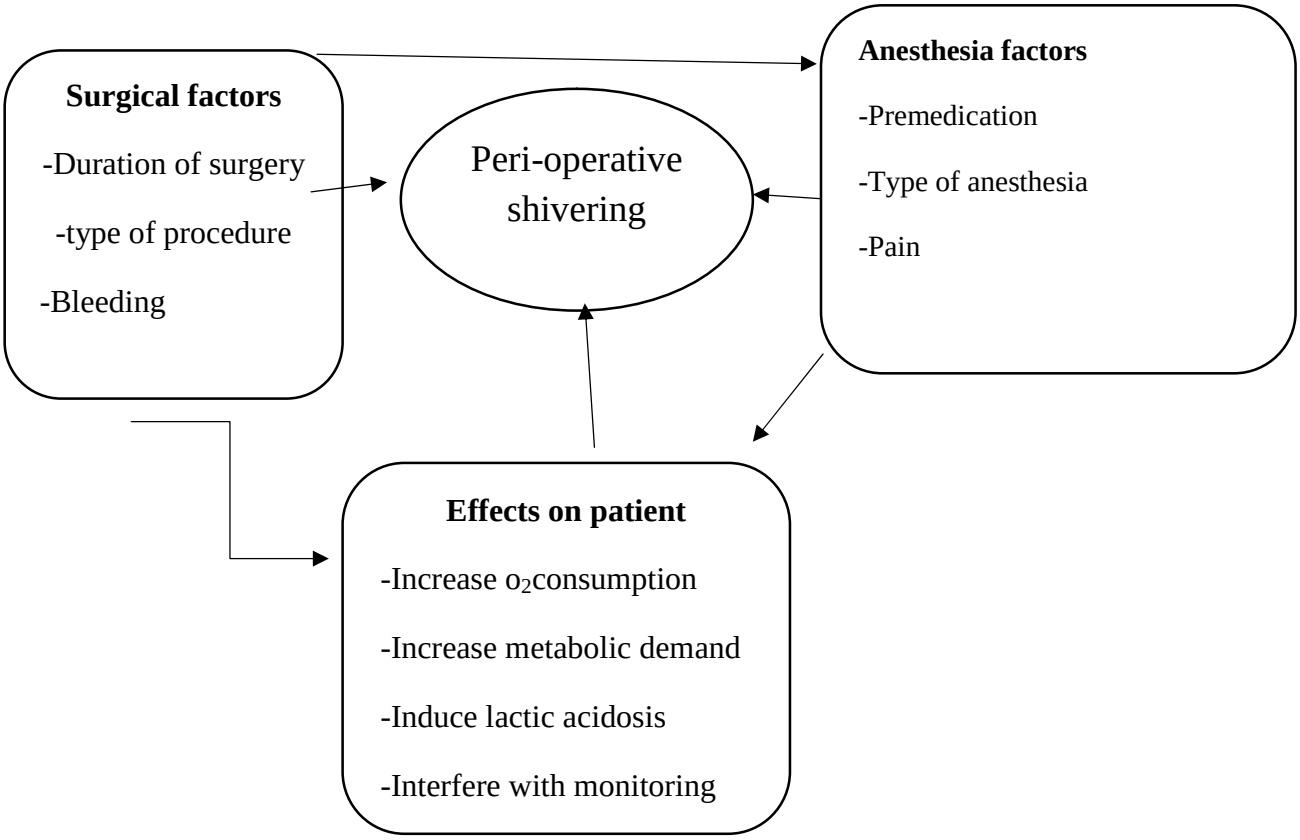

Figure 1:Conceptual frame work based on the relation between dependent and independent variable. Developed by the investigators.

Hypothesis

We hypothesize that prophylactic oral tramadol is effective to prevent perioperative shivering after spinal anesthesia

1. HO: There is no statistically significant difference in incidence PAS among groups.($p_1=p_2$)

HA: There is statistically significant difference in incidence of PAS among groups. ($p_1 \neq p_2$)

2. HO: There is no statistically significant difference in severity of PAS among groups.($p_1=p_2$)

HA: There is statistically significant difference in severity of PAS among groups. ($p_1 \neq p_2$)

3. HO: There is no statistically significant difference in onset of PAS among groups. ($p_1=p_2$)

HA: There is statistically significant difference in onset of PAS among groups. ($p_1 \neq p_2$)

3. Objective of the Study and Hypothesis

3.1 General objective

To assess the effectiveness of oral tramadol in preventing perioperative shivering in patients undergoing TURP surgery at Hawassa comprehensive specialized hospital, Ethiopia from February to May 2019 GC.

3.2 Specific objective

- To determine the association of incidence of post spinal shivering among tramadol and control groups.
- To compare the severity of post spinal shivering among tramadol and control groups.
- To compare onset of shivering among tramadol and control groups.

4. METHODS AND MATERIALS

4.1 Study area: This study was conducted at Hawassa university comprehensive specialized hospital operation theatre and PACU. This hospital is found in Hawassa city a capital city of southern nation and nationality which is 275 Km away in south direction from capital city Addis Ababa. It established in 2005 G.C and it has about 400 beds and many specialty departments like surgery, gynecology and obstetrics, internal medicine, pediatrics, orthopedics and trauma, ENT, neurosurgery, urology, psychiatry, and anesthesia. This hospital is giving service to Hawassa city, and surrounding zones of southern nation and nationality and some part of Oromia region.

4.2 Study design and period: Prospective cohort study was employed from February to May, 2019.

4.3 Population

4.3.1 Source population: All patients admitted with diagnosis of BPH and scheduled for TURP procedures under spinal anesthesia at HUCSH.

4.3.2 Study population: All elective BPH patients scheduled for TURP and fulfill inclusion criteria from February to May, 2019 at HUCSH

4.4Inclusion and exclusive criteria:

4.4.1 Inclusion criteria:

- ASA I& II geriatric patients from 60-85 years old, undergoing elective TURP surgery under spinal anesthesia and those who are willing to participate in this study during the study period.

4.4.2 Exclusive criteria

- Patients who had any history suggestive of allergy to tramadol.
- Patients who received vasodilators or vasoconstrictors, 24 hours prior to surgery and intraoperatively.

- Patients who have ischemic heart disease, cerebrovascular events, thyroid dysfunction, infection and autonomic neuropathy.
- Body temperature less than 35^0c or greater than 38^0c.
- Patients who have psychiatric disorder & taking antipsychotic drug.

4.5 Study variables:

4.5.1 Dependent variable:

- Incidence of shivering
- Severity of shivering
- Onset of shivering

❖ All other variables which assumed to affect the dependent variables like:-Socio demographic characteristics:(age, weight, height and body mass index), Hypothermia following SA, ASA physical status, duration of surgery & anesthesia, Baseline v/s (BP,HR,RR ,temp) and amount of irrigation fluid was assumed to be uniform for both the tramadol group and control group in order to be able to compare or associate the two groups in terms of incidence of shivering, severity of shivering and onset of shivering. Comaprison between the two groups were performed in terms of these socio-demographic and other variables to ensure homogeneity of the two groups in terms of these variables.

4.6 Operational definition

Shivering- is a spontaneous and involuntary muscular activity which increases metabolic heat production (24).

Perioperative shivering-the presence of shivering during intraoperatives and post-operative time until patient transferred to its ward bed.

Grades of shivering-(Crossley and Mahajan scale)(25).

Grade 0- No shivering

Grade 1 -One or more of: Piloerection: Peripheral cyanosis without other cause, but without visible muscular activity.

Grade 2 - Visible muscle activity confined to one muscle group

Grade 3 - Visible muscle activity in more than one muscle group

Grade 4 - Gross muscular activity involving the whole body

ASA status: is a surgical risk stratifications validated by American Society of Anesthesiologist; described as follows:

ASA I: a healthy patient with no organic/physiological/psychiatric problems

ASA II: controlled medical conditions with mild systemic effect and no limitation of functional ability

ASA III: medical condition with severe systemic effect, limitation in functional capacity

ASA IV: poorly controlled medical conditions associated with significant impairment in functional ability that is potential threat to life

ASA V: critical condition, little chance of survival without surgical procedure

ASA VI: brain dead patient undergoing organ donation

Geriatrics-is focused towards the health care of the elderly and a patient who is above 60 years old is considered as geriatrics(26).

Tramadol group: patients who took oral tramadol before two hours performing spinal anesthesia and surgery

Control group: those patients who didn’t took oral tramadol before two hours

4.7 Sample size and sampling technique

4.7.1 Sample size

Comparison of proportion with equal sample size for two independent sample size formula of two independent cohort based on incidence of shivering among the group where n1=sample for oral tramadol group, n2=sample for control group. Z alpha =0.05, which is 1.96, power = 80%, which is 0.84. Since there was no previous study done in the study area, result adopted from literature will be used to calculate sample size.

Previous study on India on 2014 showed that the incidence of shivering was significantly less in patients who received tramadol (7.5% vs. 40%; P < 0.01) (5).

The required sample size shows that 95% incidence of shivering difference between two groups will be calculated as:

P_1=Proportion of shivering among oral tramadol group (7.5%)

q_1 = Proportion of no shivering among tramadol group (92.5%)

$p_{2=}$ Proportion of shivering among control group (40%)

$q_{2=}$ Proportion of no shivering among control group (60%)

a= conventional multiplier for alpha =0.05, which is 1.96.

b = conventional multiplier for power = 0.80 which is 0.84.

$$n_1=n_2=\frac{(Z_{\alpha/2}+Z_{\beta})^2 * (p_1(1-p_1)+p_2(1-p_2))}{(p_1-p_2)^2}$$

$$=\frac{(1.96+0.84)^2*(0.075(0.925)+0.4(0.6))}{(0.075-0.4)^2}=23$$

using 1:1 ratio between groups and adding 25% contingency, sample size become n1= n2=30

4.7.2 Sampling technique

Systematic random sampling technique was used to select study participants on daily operation schedule list. Depending upon average values of the previous surgery per 3 months on the log book, 189 patients were operated for TURP. The sampling interval K was determined using the formula: K=N/n; where, n = total sample size, N = population per 3 months. Therefore, the sampling interval was 3 and the first study participant (random start)

was selected using lottery method after which data collector recruit 1 patient for every 3 consecutive patients undergoes TURP surgery after grouping based on whether they received oral tramadol as a prophylaxis or without taking it till the required sample size is reached.

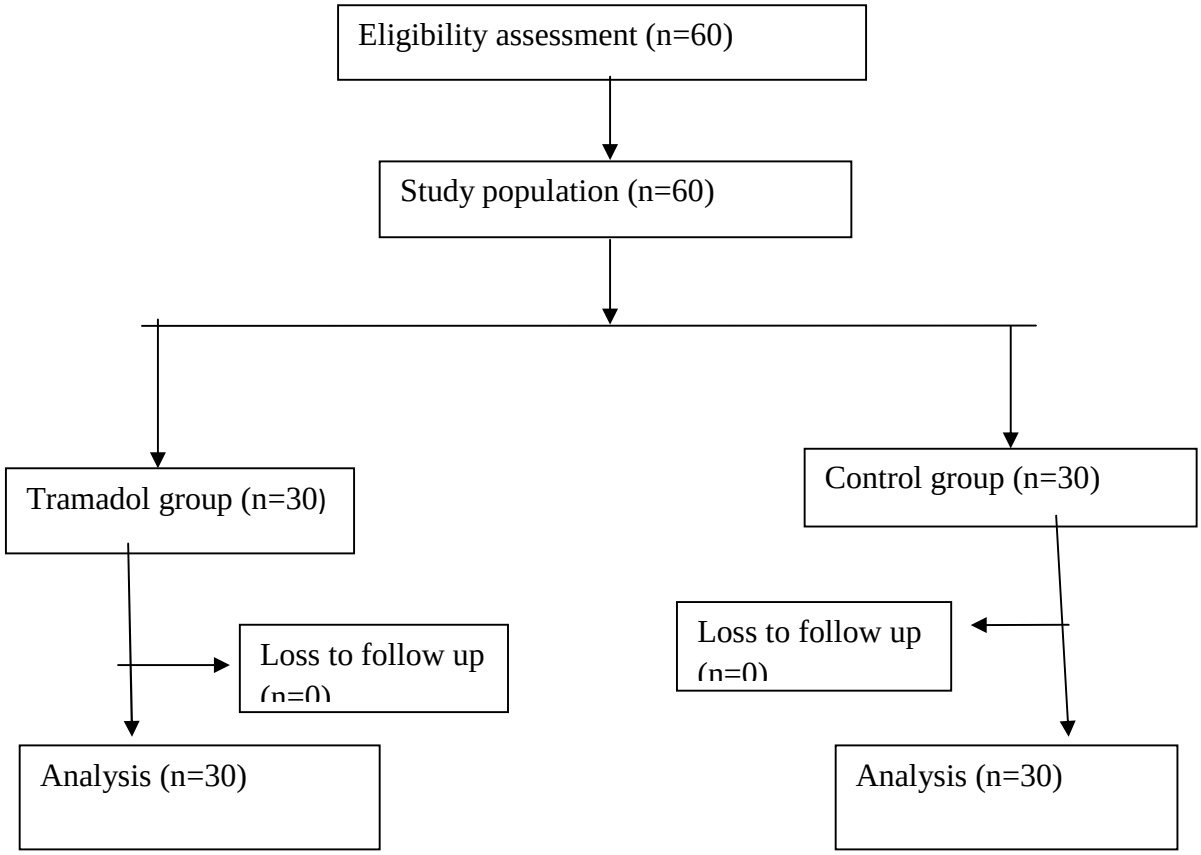

Figure 2: a study flowchart for enrolment of patients who underwent TURP surgery under SA at HUSCH

4.8 Data collection technique

Data collectors were trained before data collection and supervised by a principal investigator every week until the end of data collection period. Two MSc students from Dilla University and two trained senior BSc anesthetists of HUCSH staffs were involved for data collection process. Data was collected by using structured questionnaire starting from preoperative time at waiting area to the time patient transferred to its ward bed from PACU postoperatively. All patients who were scheduled for elective TURP who fulfill inclusion criteria and volunteer to take part in the study was thoroughly assessed before surgery by history taking, and chart review following informed consent. As on their routine practice before the day of surgery the anesthetist who did preoperative assessment had orient patients the appropriate estimated time to take PO tramadol and since the patient should have to be NPO so they informed to take with a sip of water .so in the morning of surgery patient who swallow the drug and come for the procedure and those came without taking preoperative tramadol or if the time is beyond two hours of swallowing tramadol differentiated initially. On arrival of the patients to the operation theater, and after application of the routine hospital monitoring protocol, HR, noninvasive blood pressure, SPO2 and axillary temperature has been recorded before spinal anesthesia is going to be given and every five minutes until the end of procedure. Subarachnoid block up to T9-T10 dermatome level was achieved with 0.5% bupivacaine. No means of active warming was used in the operation theatre, maintenance fluids and irrigation fluid.

PAS was recorded by the same attending anesthetist at any periods intraoperatively as per grades, since TURP procedure takes around one hour in average so the rest follow up was in the PACU by the responsible anesthetist and recovery nurses was report any critical step immediately. If shivering occurred perioperatively in any patients; it should have to be treated in the same manner in both groups with reassurance, warming blanket, pethidine or tramadol as the hospital treatment protocol.

4.10 Data quality control

To assure the reliability and validity of the data, questionnaire was pretested on 5% of the sample size before actual data collection. Training and orientation about the objectives and relevance of the study, each items included in the study tools and the whole process of data

collection was provided for data collectors and supervisors. Informed consent was obtained from the patients. During data collection, regular supervision and follow up was undertaken. Supervisors were checked each questionnaire daily with further cross check by principal investigator every week until the end of data collection period for completeness and consistency of data. Incomplete data was not entered on database prepared on Epi-info version 7. Data clean up and crosschecking of missing data was done by multiple imputation method before analysis on SPSS version 20.

4.11 Data analysis and Interpretation

Data was checked manually for completeness and then coded and entered in to EPI info version 7 then transferred to SPSS version 20 computer program for analysis. Distribution of data was tested by the Shapiro-wilk test and histogram. Descriptive statistics was used to summarize data, tables and figures to display the result. Continuous variables were expressed as mean ± SD for normally distribute data and median ± IQR for skewed data. Frequency and cross tabulation was conducted to describe relevant variables in relation to the outcome variables. After checking for the normality assumption, analysis was done by independent sample t test for comparing means of two independent samples were used for comparing baseline continuous variables. Comparisons between different categories were evaluated using the $\chi 2$ test. Ordinal and non-normally distributed variables were analyzed by using the Mann–Whitney U-test. Kaplan meier was used for survival analysis to compare time to event situation. P value <0.05 was consider as statistically significant.

4.12 Ethical Consideration

Ethical clearance was obtained from the department ethical clearance committee and got permission from HUCSH clinical director office after submission of official letter before the start of the study. The purposes and the importance of the study were explained and verbal as well as written informed consent was obtained from each participant. Confidentiality was maintained at all levels of the study by avoiding identifiers and using codes to identify patients. The participant's involvement in the study was on a voluntary basis, participants who were not willing to participate in the study and those who wish to quit their participation at any stage was informed they were allowed to do so without any restrictions.

4.13 Dissemination plan

The research will be presented for the entire department of anesthesia staff. It will also be presented at the annual research conference. The research will be submitted to journals for publication.

5: Results

5.1 Demographic and perioperative Characteristics

During the study period, a total of 60 patients were Included for final analysis based on whether they received preoperative oral tramadol before two hours of the surgery or not receiving preoperative oral tramadol before two hours.

During patient selection we tried to ensure that patients are uniform in terms of socio-demographic characteristics accordingly for tramadol and control groups having p>0.05(table 1), However this may not lead to the fact that these variables do not have an effect on the treatment outcome. In order to validate this, age was categorized into 3 and weight into 4 and run association of each of them with the two groups and found non-significant. This result is convincing to run association of the groups with the three variables in tern without considering the socio-demographic and other relevant variables.

Table 1: Socio demographic characteristics of tramadol and control groups who underwent TURP surgery under spinal anesthesia at HUSCH from February 1-may 30 2018.

	Tramadol group	Control group	p-value
Age *	65.879(3.812)	68.50(7.578)	0.96
Weight*	69.60(7.370)	67.23(6.224)	0.55
Height*	1.71(0.043)	1.69(.05)	0.40
BMI*	23.8(2.23)	23.3(1.98)	0.56
One n(%) ASA status two n(%)	18(50) 12(50)	18(50) 12(50)	1.00
Bup dose **	15(5)	15(5)	0.79
Duration of surgery*	71.5(12.4)	61.67(61.67)	0.66
Amount of irrigation fluid**	6500(2000)	6000(3000)	0.79

Hint: *=Mean (standard deviation); **= Median (interquartile range) n(%)=number of participant(percentage) BMI =body mass index bup=bupivacaine ASA= American society of Anesthesiology physical status

According to this study, there were no significant difference between the two groups regarding base line MAP(mean arterial pressure), Heart rate (HR), axillary temperature, and SPO2(saturation) of the study participants which is p>0.05(by using t-test) (table 2).

Table 2: Base line hemodynamic status among tramadol and control groups who underwent TURP surgery under spinal anesthesia at HUSCH from February 1-may 30 2018.

	Tramadol group	Control group	p-value
Preoperative MAP*	89.5(13.5)	87.4(13.4)	0.55
Preoperative HR**	68.0(8)	71.5(22)	0.09
Preoperative Axillary temp**	36.95(0.3)	36.89(0.8)	0.64
Preoperative SPO2*	96(2)	97(2)	0.62

Hint:*=Mean (standard deviation) (t-test); **= Median (interquartile range) (man withney-u test), MAP=mean arterial pressure, HR=heart rate, temp=temperature, SPO2=saturation

5.2 Comparing incidence of shivering between oral tramadol and control group

The incidence of shivering among patients who took prophylactic oral tramadol preoperatively showed that 4 patients (13.30%) did shiver while 26 patients (86.70%) did not experience shivering compared to the control group which shows 24 patients (80.00%) experience shivering and 6 patients (18.8%) did not shiver with P<0.001(using x^2 test) which is statistically significant. (table 3)

Table 3: A two by two table showing the incidence of shivering between tramadol and control groups for TURP surgeries under SA at HUCSH, 2019 GC.

Incidence of shivering	Tramadol group	Control group	Total
Yes	4	24	28
No	26	6	32
Total	30	30	60

5.3 Comparing the severity of shivering between the tramadol and control groups

During the observational periods the grades of shivering in patients who had shivering incidence was, grade one and two with the frequency of 1(3.6%),2(7.1%) and only one patient(3,6%) had grade three shivering among patients who took oral tramadol. While in the control group 2-grade 2(8.3%), 11-grade 3(45.8%) and 11 -grade 4 (45.8) shivering was recorded which has p-value <0.006 (man withney U-test) statistically significant difference regarding the severity among them.

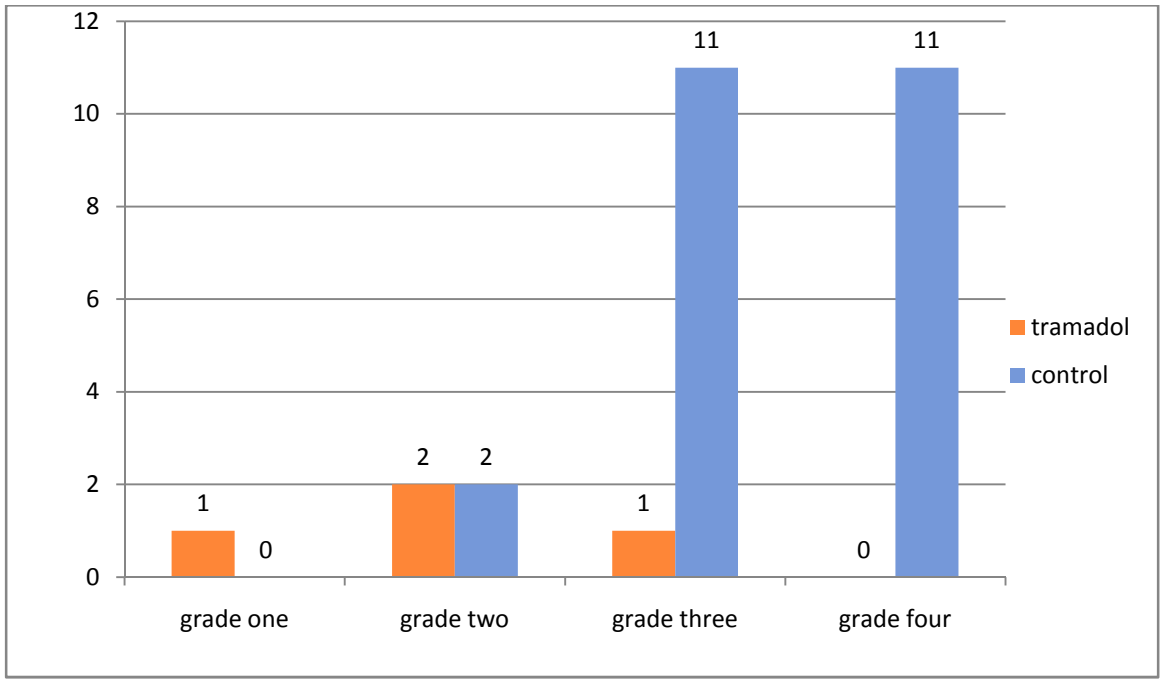

Figure 3: Bar graph which shows the grade of shivering in tramadol and control groups who undergo TURP surgery under spinal anesthesia at HUCSH, 2019

5.4 Comparing the onset of shivering between oral tramadol and control group

Results of the Kaplan–Meier survival analysis are shown in Figure 3. The Kaplan–Meier survival curves shows proportion of patients with the onset of shivering (event) time from the initiation of spinal anesthesia to the end of the study (until patient transferred from PACU). There was a significant difference between the groups with log rank test (P =0.015).In control group from the total 24 shivering events, 17(29.0%) of the shivering events were recorded in the first 20 minutes .However in the tramadol group, from the total of 4 incidence of shivering, 1(75.0%) of shivering events were recorded at 20 minutes. Particularly the patient in the tramadol Group, median time: 30minute, 95% CI: [15.30-44.70] had significantly longer time onset of shivering compared to control group median time: 15 minute, 95% CI: [13.633-16.367] (p=0.015).

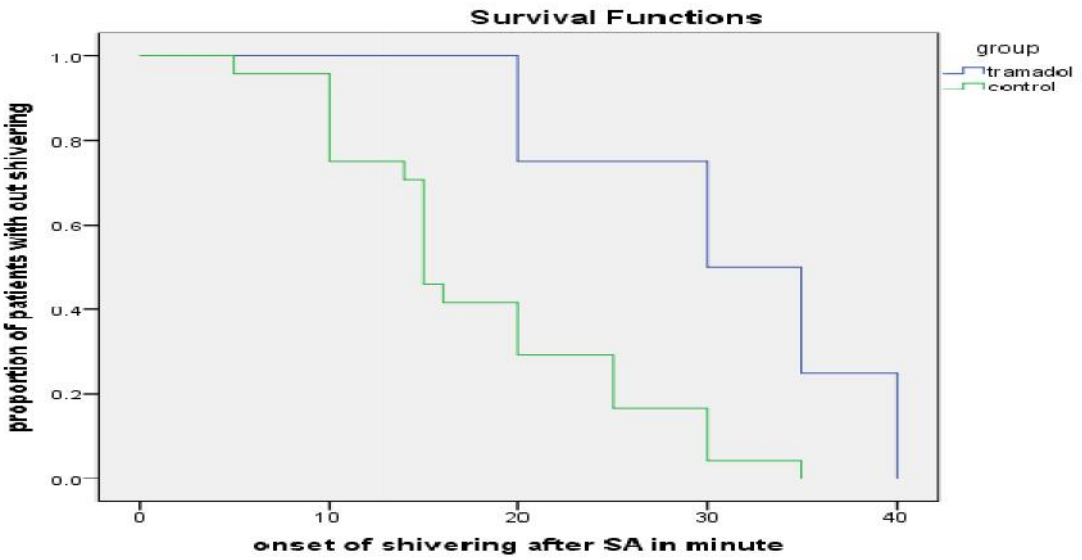

Figure 4: Kaplan –Meier survival curves showing onset of shivering among tramadol and control group from the initiation of spinal anesthesia to recovery time at HUCSH, 2019

5.5 Perioperative hemodynamic parameters

The median axillary temperature record showed that significant difference between the two groups at 5,10,20,30,40,50,60 and 70 with $p<0.004$(using man withney-u test).but preoperatively, at 80, 90 and recovery time record did not show statistically significant difference among the tramadol and control group.

Table 4: Perioperative median axillary temperature record of tramadol and control group who undergo TURP surgery under SA at HUCSH, 2019.

Median axillary temp	Tramadol group	Control group	P-value
Preoperatively	36.9(0.3)	36.9(0.8)	0.46
5min after SA	36.8(0.3)	36.1(1.2)	0.001
10 min after SA	36.9(0.2)	35.6(2.8)	0.004
20 min after SA	37.0(0.4)	35.0(2.2)	0.000
30 min after SA	37.0(0.2)	35.3(1.7)	0.000
40 min after SA	36.9(0.2)	35.8(1.9)	0.000
50 min after SA	36.9(0.2)	35.9(2.1)	0.001
60 min after SA	36.9(0.1)	36.7(1.7)	0.002
70 min after SA	37.0(0.3)	36.6(1.7)	0.026
80 min after SA	37.0(0.2)	36.8(1.1)	0.20
90 min after SA	37.0(0.2)	36.9(1.3)	0.48
At recovery	37(0.2)	36.8(0.9)	0.15

Hint: SA=spinal anesthesia, median(IQR),min=minute, p<0.05 is significant (tested by using man withney-U test)

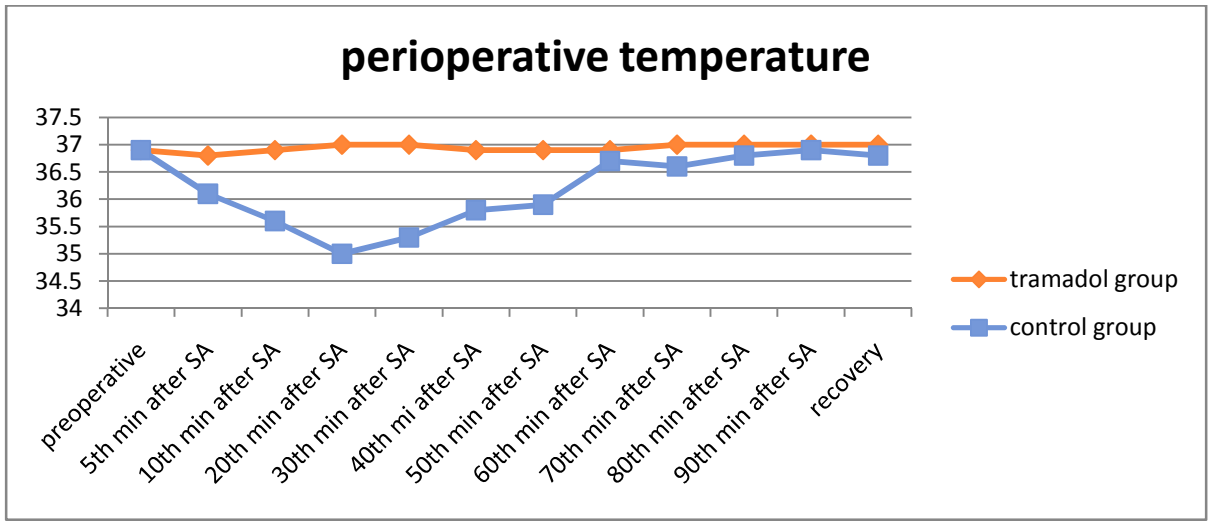

Figure 5: Line graph showing perioperative axillary temperature of patients undergoing TURP surgery under SA at HUSCH between oral tramadol and control groups.

The median perioperative heart rate record of patients in tramadol group and in control group showed that significant difference at all recording times during study period except preoperatively with p<0.039.

Table 5: perioperative median heart rate record of tramadol and control group who undergo TURP surgery under SA at HUCSH, 2019

Median heart rate	Tramadol group	Control group	P-value
Preoperatively	68.00(8)	71.50(22)	0.09
5min after SA	69.00(8)	72.00(23)	0.04
10 min after SA	64.50(23)	70.00(32)	0.002
20 min after SA	66.50(6.8)	84.60(21.6)	0.000
30 min after SA	67.00(4.9)	83.60(18.5)	0.000
40 min after SA	65.50(6.2)	79.40(15.8)	0.000
50 min after SA	66.00(6)	78.50(5)	0.000
60 min after SA	66.60(6.1)	74.80(10.4)	0.001
70 min after SA	66.70(5.7)	73.70(10.4)	0.002
80 min after SA	68.00(7)	72.50(12)	0.003
90 min after SA	67.00(7)	75.00(12)	0.002
At recovery	66.00(7)	75.00(13)	0.000

Hint: SA=spinal anesthesia ,min=minute ,median(interquartile range) p-value tested by man Whitney –U test

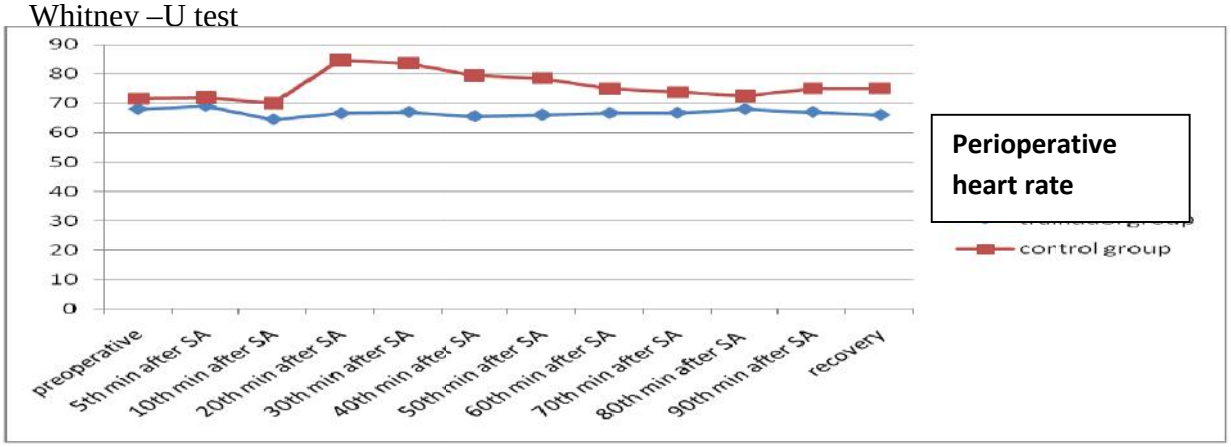

Figure 6: Line graph showing perioperative heart rate of patients undergoing TURP surgery under SA between oral tramadol and control groups at HUSCH, 2019

The perioperative mean arterial pressure of patients did not show statistically significant result throughout study period starting from preoperative period until patients transferred from PACU with p>0.189.

Table 6: Perioperative mean arterial pressure record of tramadol and control group who undergo TURP surgery under SA at HUCSH,2019

Mean arterial pressure	Tramadol group	Control group	P-value
Preoperatively	89.53(13.5)	87.0(13.4)	0.6
5min after SA	87.87(13.49)	85.3(10.5)	0.09
10 min after SA	84.2(12.7)	88.07(16.5)	0.65
20 min after SA	85.07(12.7)	87.4(15.76)	0.23
30 min after SA	85.17(12.67)	85.3(11.4)	0.42
40 min after SA	84.47(11.94)	81.4(10.2)	0.91
50 min after SA	84.13(12.99)	80.43(9.5)	0.16
60 min after SA	82.4(12.06)	80.43(9.5)	0.03
70 min after SA	82.4(12.06)	81.07(10.76)	0.4
80 min after SA	82.7(12.56)	81.5(11.46)	0.01
90 min after SA	84.87(13.64)	80(10.2)	0.01
At recovery	83.67(12.9)	80.53(10.21)	0.02

Hint: SA=spinal anesthesia, min-minute, mean (standard deviation), p-value tested by using t-test

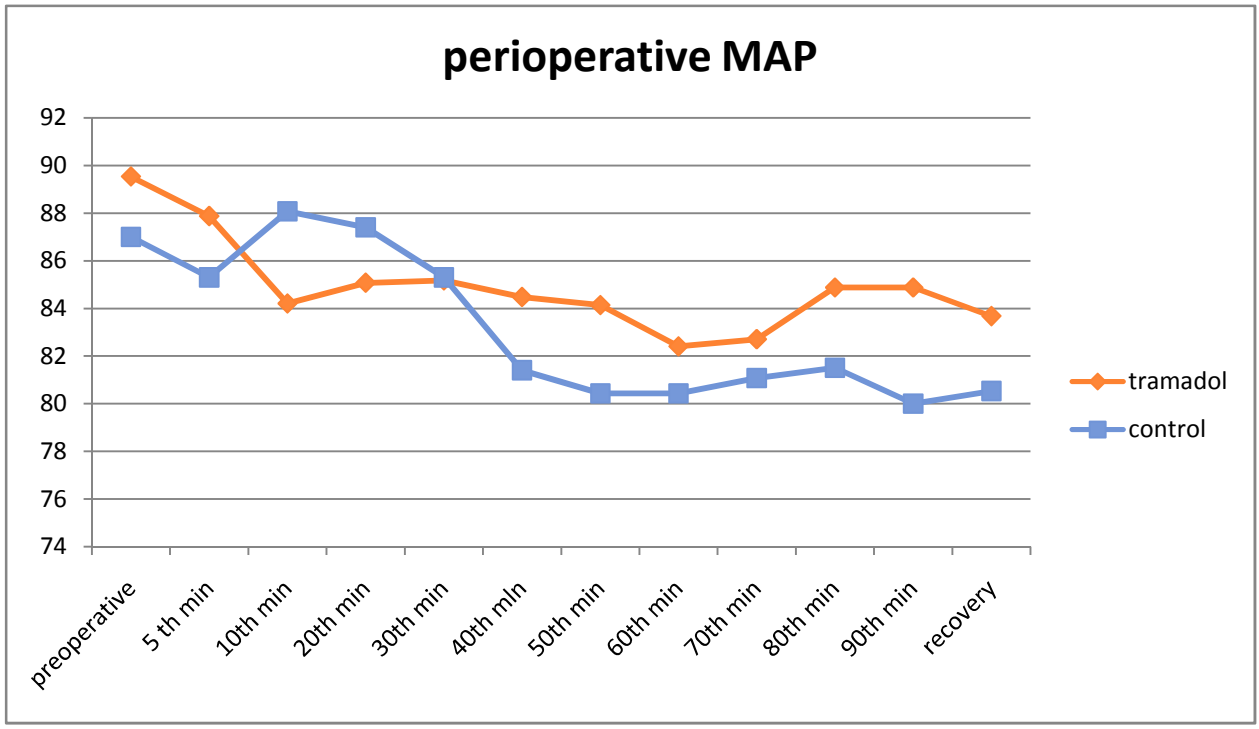

Figure 7:Line graph showing perioperative mean arterial pressure of patients undergoing TURP surgery under SA among tramadol group and control groups at HUCSH ,2019

The median perioperative saturation record of patients among tramadol group and control group showed that statistically significant result at 5,10,30,50,60,70,80 minute and recovery period recordings with p<0.004.but the preoperative,40 and 90 minutes recordings have not significant results.

Table 7: Perioperative median saturation record of tramadol and control group who undergo TURP surgery under SA at HUCSH, 2019.

Median saturation	Tramadol group	Control group	P-value
Preoperatively	96.00(2)	97.00(2)	0.62
5min after SA	95.00(3)	95.00(3)	0.012
10 min after SA	94.50(3)	96.00(3)	0.127
20 min after SA	95.00(3)	95.50(4)	0.004
30 min after SA	95.10(2)	96.60(2)	0.053
40 min after SA	95.00(3)	96.50(4	0.002
50 min after SA	95.0(4)	97.00	0.000

60 min after SA	96.00(3)	98.00(2)	0.003
70 min after SA	96.00(4)	98.00(2)	0.003
80 min after SA	95.50(3)	98.00(2)	0.007
90 min after SA	96.5(4)	98.00(2)	0.001
At recovery	95.00(4)	98.00(2)	0.032

Hint: SA=spinal anesthesia, min=minute, median (interquartile range),p-value tested by man Whitney-u test)

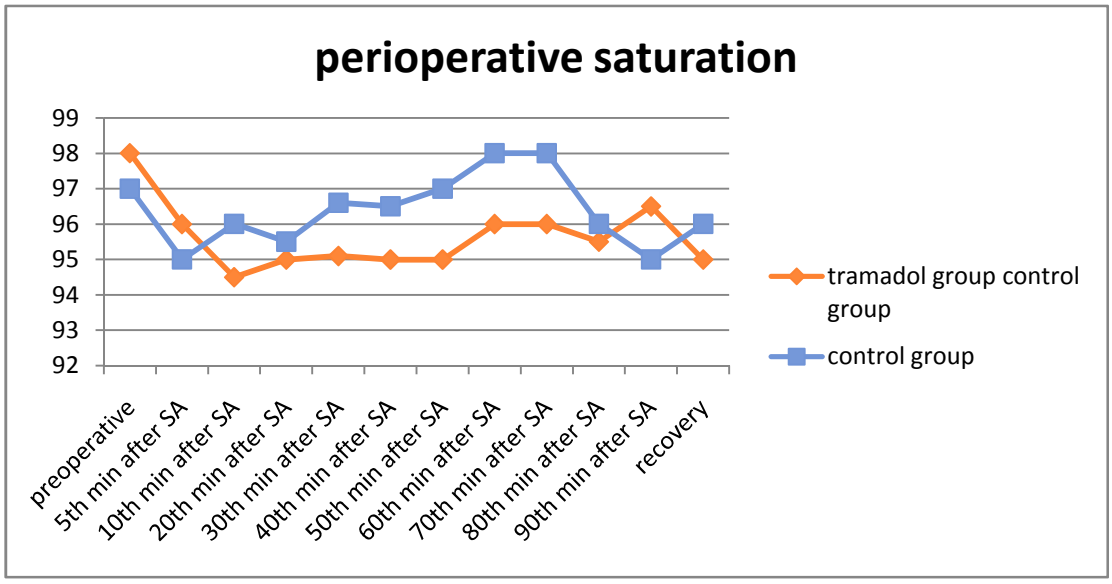

Figure 8: Line graph showing perioperative saturation of patients undergoing TURP surgery under SA at HUSCH between preoperative oral tramadol and who didn't took groups.

Chapter 6: Discussion

Shivering is a frequent complication, distressing for the patients undergoing surgery under both regional and general anesthesia. Regional anesthesia has been known to be associated with greater heat loss than general anesthesia. It is widely accepted that complications related to surgery and delivery of anesthesia care are inevitable. Post anesthesia shivering is one of the potential complications of anesthesia which may increase patient's morbidity. Despite the availability of various drugs and technologies to prevent shivering it continues to remain an ongoing problem in the perioperative period(27).

Shivering is serious complications following spinal anesthesia therefore the aim of this study was to assess the effectiveness of 50mg preoperative oral tramadol in preventing perioperative shivering in patients undergoing TURP surgery.

Tramadol hydrochloride, a centrally acting analgesic drug, is effective in the treatment of post-anesthetic shivering after general and neuraxial anesthesia. It inhibits the neuronal reuptake of nor adrenaline and 5-hydroxytryptamine (5-HT), facilitates 5-HT release and activates the μ-opioid receptors(1).

Considering the results of the present study, the incidence of shivering was high (80.0%) in those patients who did not take preoperative oral tramadol than those who took preoperative oral tramadol (13.3%).with significant difference of $p<0.001$.This finding is in line with the A comparative study done @ India on evaluating the prophylactic efficacy of oral clonidine and tramadol for perioperative shivering in geriatric patients undergoing transurethral resection of prostate; all In group of oral clonidine5%and oral tramadol 7.5% did experience shivering respectively. while in the placebo group the incidence reaches 40% with statistically significant variation was seen ($P< 0.01$)(5).

Another randomized double blind cross-sectional study, on effects of tramadol on post spinal anesthesia shivering at Pakistan in 90 elective cesarean section with 1mg/kg tramadol in 20ml(diluted by normal saline) to study group and 20ml of normal saline to control group was slowly injected intravenously. Incidence of shivering in the tramadol group (8.8%) was less frequent than in the control group (86.6%), which gives significant statistical difference ($P<0.001$) (8). There is also other Prospective, randomized, double-blinded, placebo-

controlled study on Use of oral tramadol to prevent peri anesthetic shivering in patients undergoing transurethral resection of prostate under subarachnoid blockade from India on Incidence of shivering was significantly less in patients who received tramadol (7.5% vs. 40%; P< 0.01) (9).

The severity of perioperative shivering was also another interest of this study. It was compared between the two groups and the difference showed that statically significant result with p= 0.006.in patients who took oral tramadol four patients experience shivering with specific grades ranging from 1-3.(3.6%),(7.1%) and (3.6%)experienced grade1,2 and 3 of shivering while in the control group the grade ranges from 2-4. (8.3%), (45.8%)and (45.8%) experienced Grades 2, 3 and 4 of shivering respectively. which indicates shivering in the control group is more severe than the oral tramadol groups. this result is comparable with the study done on use of oral tramadol to prevent peri anesthetic shivering in patients undergoing transurethral resection of prostate under subarachnoid blockade from India on 40 patients showed that the severity of shivering in the tramadol group ranges from grade 1-3 none had grade 4 shivering ,in the placebo group 40% experienced shivering during the whole period 37.5%,27.5%,25% and 12.5% of shivering experienced 1,2,3,4 grades of shivering respectively. On comparison p<0.01 implying statistically significant variance regarding the severity among groups(9).

A prospective, double-blind, randomized controlled trial conducted at the University of Benin Teaching Hospital on tramadol effects on perioperative shivering in lower limb orthopedic surgeries under spinal anesthesia in 95 ASA1 and ASA2 patients showed with regard to the severity of shivering, all the patients that shivered in the tramadol group had grade I shivering while five of the seven patients who shivered in the saline group had grade 2 the difference was statistically significant which implies that shivering in the placebo group was more severe than the tramadol group (19).

Another study on premedication of oral tramadol to decrease severity of post operative shivering after general anesthesia at Iran on 80 patients showed that frequency of different grades of shivering in the two study groups .prevalence of grade 3 and 4 shivering was 7.5% and 25% in the tramadol group and placebo group with p=0.03 but there was no statistically significant difference between the two groups in grade 1 and 2 shivering (p>0.05) (12).this

difference occurred may be due to the demographic factor ,anesthesia type or study design difference between the outcome of their study and our outcome variation.

This study also compares the onset of shivering , In the control group from the total 24 shivering events, 17(29.0%) of the shivering events were recorded in the first 20 minutes .However in the tramadol group, from the total of 4 incidence of shivering ,only 1(75.0%) of shivering events were recorded at 20 minutes. Our study is as effective as A comparative study evaluating the prophylactic efficacy of oral clonidine and tramadol for perioperative shivering in geriatric patients undergoing transurethral resection of prostate which revealed that shivering started earlier (within 5 min) and persisted for a longer duration in the placebo group (range = 5-90 min). On the contrary the onset of shivering was delayed (15 min) and the duration was also significantly less (range = 15-60 min) among clonidine group and tramadol group patients.(18)

The study also compares the perioperative hemodynamic status between patients under tramadol and control groups revealed that the axillary temperature showed significant difference except the preoperative and 80th minute after SA, heart rate and saturation showed significant result at different recording times after 10th minute of SA. But the mean arterial pressure didn't show any statistical significant variation throughout the whole period. Prospective, randomized, double-blinded, placebo-controlled study on Use of oral tramadol to prevent peri-anesthetic shivering in patients undergoing transurethral resection of prostate under subarachnoid blockade from India discussed that the tympanic membrane temperature showed statistically significant variation especially in the later part of the study while trends in axillary and forehead temperatures were similar throughout the study. There was also no statistical variance when the mean heart rate, systolic blood pressure, respiratory rate and SPO2 were compared (9).This study has similar result in regards to temperature and mean arterial pressure but differs in terms of saturation and heart rate measurement this difference may happened due to monitoring equipment difference or artifacts.

7. Strengths and Limitations of the study

7.1 Strengths of the study

- The two groups were comparable in socio demographic distribution.
- Type of surgery is similar in the groups.
- Confounding factors are minimized as much as possible because patients only undergo the surgery with similar anesthesia technique and drug.

7.2 Limitation of the study

- Most of the results were compared with randomized clinical trial study.
- Unable to control temperature of operation room and intravenous fluids.
- Lack of invasive monitoring to monitor BP, HR and SPO_2.
- Lack of former study on this and related title in my study area.

8. Conclusion and Recommendations

8.1 Conclusion

The findings of our study demonstrate that taking 50 mg oral tramadol before two hours the operation time was effective in decreasing the incidence, severity and delay the onset of shivering which occur after spinal anesthesia for geriatric patients who undergo transurethral resection of prostate surgery.

8.2 Recommendations

Based on the finding of this study we recommend:-

To Anesthetist-we recommend using oral tramadol during preoperative time to decrease the perioperative shivering incidence and severity which occur after spinal anesthesia in geriatric patients who undergo transurethral resection of prostate.

Oral tramadol is the one widely available drug in our country so ordering it as perioperative shivering prophylaxis is a good option to improve the clinical quality of our patient management.

To researchers-further research with large sample size and future randomized control study with this baseline data.

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Annexes

Annex 1: Declaration

I, the undersigned, senior clinical Anesthesia student declare that this thesis is my original work in partial fulfillment of the requirement for the degree of Masters of clinical Anesthesia.

Name: _____

Signature: _____

Place of submission: Department of Anesthesia, College of Health Sciences, School of Medicine Addis Ababa University.

Date of Submission: _____

This thesis work has been submitted for examination with my approval as university advisor.

Advisor

Name	Signature
_____	_____

ASSURANCE OF 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 pre terms and conditions of the research and publications office of the Addis Ababa University.

Name of the student: _____

Date: _____ Signature: _____

Approval of the advisor

Advisors

	Name	Signature	Date
1.	_____	_____	_____
2.	_____	_____	_____

Annex 2: Consent form

Dear participant:

This is a research designed on effectiveness 0f preoperative oral tramadol in preventing perioperative shivering in geriatric patients for TURP surgery under spinal anesthesia .As a chance you were included in the study. So, we kindly request your involvement in the study. Your data completely confidential and you have full right either to refuse a single question or leave the study. However, your participation to those questions will help us to asses and understand the effect. So, we are requesting you to keep participation.

Would you willing to participate in the study please? YES/NO

Thanks for taking part in the study!!!!

For further question ask investigator

Tel: - +251924302777

E-mail-dagnemeski@gmail.com

Annex 3 consent (Amharic version)

የ መ ጠ ይ ቅ ፈ ቃ ድ

ጤና ይ ስ ጥ ል ኝ

እ ኔ _____እ ባ ላ ለ ሁ ፡ ፡

በ ሐ ዋ ሳ ዩ ኒ ቨ ር ሲ ቲ አ ን ስ ቴ ዥ ያ ት ም ህ ር ት ክ ፍ ል ውስ ጥ እ የ ሰ ራ ሁ እ ገ ኛ ለ ሁ ፡ ፡

የ ዚ ህ ቃ ለ መ ጠ ይ ቅ ዋ ና ዓ ላ ማ ቀ ዶ ጥ ገ ና እ የ ተ ሰ ራ ል ዎ ት ና ከ ተ ሰ ራ ል ዎ ት በ ኃ ላ የ ሚ ከ ሰ ት ን የ ማ ን ቀ ጥ ቀ ጥ የ ጎ ን ዮ ሽ ጉ ዳ ት ከ መ ግ ባ ት ዎ በ ፊ ት የ ሚ ወ ጡ ት መ ድ ሃ ኒ ት ም ን ያ ህ ል አ ን ደ ሚ ከ ላ ከ ል ማ ወ ቅ ነ ው ፡ ፡

በ ዚ ህ ጥ ና ት ውስ ጥ በ መ ሳ ተ ፍ ም ን ም ዓ ይ ነ ት የ ጎ ላ ጉ ዳ ት የ ሌ ለ ወ ሲ ሆ ን ላ ገ ል ግ ሎ ት የ ሚ ያ ገ ኙ ት ም ጥ ቅ ማ ጥ ቅ ም አ ይ ኖ ር ም ፡ ፡ ነ ገ ር ግ ን የ ም ር ም ሩ ውጤ ት ለ ወ ደ ፊ ቱ ቀ ዶ ጥ ገ ና ለ ሚ ሰ ራ ላ ቸ ው ታ ካ ሚ ዋ ች ይ ህ ን ጉ ዳ ት ለ ማ ስ ወ ገ ድ ወ ይ ም ለ መ ቀ ነ ስ ነ ው ፡ ፡ በ ጥ ና ቱ ውስ ጥ ጥ ቂ ት ደ ቂ ቃ ዎ ች ን የ ሚ ወ ስ ዱ ጥ ያ ቄ ዎ ች ን እ ን ጠ ይ ቅ ዎ ታ ለ ን የ ቀ ሩ ት ን ደ ግ ሞ ባ ለ መ ያ ው ብ መ ሣ ሪ ያ ታ ግ ዞ ከ ሚ ያ ገ ኘ ው መ ረ ጃ ዎ ች ይ ሞ ላ ል ፡ ፡ በ ጥ ና ቱ ላ ይ ስ ም ዎ ት ን መ ፃ ፍ የ ማ ያ ስ ፈ ል ግ ና የ ሚ ሰ ጡ ት ን ም ላ ሾ ች ሁ ሉ በ ሚ ስ ጥ ር እ ን ደ ሚ ያ ዙ ል ን ገ ል ፅ ል ዎ ት እ ን ወ ዳ ለ ን ፡ ፡

ለ መ ሣ ተ ፍ ፈ ቃ ደ ኛ ነ ዎ ት ?

ለ መ ሣ ተ ፍ ፈ ቃ ደ ኛ ከ ሆ ኑ ወ ደ ሚ ቀ ጥ ለ ው ፅ ይ ለ ፉ ፡ -

ካ ል ሆ ነ አ መ ሠ ግ ና ለ ሁ ፡ ፡

ANNEX 4: QUESTIONAREES

Data collection tool for patient who will undergo spinal anesthesia for TURP surgeries at Hawassa compressive specialized hospital in 2018/19.

INSTRUCTIONS

A. Fill the blank space provided.

B. Encircle the alternatives when necessary.

C. Check the questions for completeness.

I. Identification

Code…….. Age (year)…....ASA status ……Weight:.. ....kg Height…….…meter

II. Baseline information

Vital sign before skin incision ; BP…….PR…….spo_2.....Axillaries temp……..

III. Intraoperative and postoperative observations

1. bupivacaine concentration & its dose

A. 0.5% of 15mg **B**. 0.5% of 20 mg **C.**0.75% of 15mg

2. did the patient have intraoperative incidence of shivering? **A** .yes **B**. no ---if no skip to Q no6

3. What is the onset of shivering after spinal anesthesia…….

4. What is the grade of shivering (use the table below as a reference)

A. one B. two C. three D. four

Stage	
Grade 0	No shivering
Grade 1	One or more of Piloerection, Peripheral cyanosis without other cause, but Without visible muscular activity.
Grade 2	Visible muscle activity confined to one muscle group
Grade 3	Visible muscle activity in more than one muscle group
Grade 4	-Gross muscular activity involving the whole body

5. what treatment was given for shivering

A. non-pharmacologic B.pethidine 0.5-1 mg/kg (iv) C. tramadol 1mg/kg(iv)

6. How long did the procedure takes……..

A.40min-1hr B.1-1:30' hr C. 1:30'-2 hr

7. Amount of irrigation fluid used in milli liter…….

8. Record vital sign in the table until the end of procedure and in the recovery time

TIME	MAP(mean BP)	HR	axillary Temp(0_C)	SPO_2
Preoperative				
5min after SAB				
10 min				
20 min				
30 min				
40 min				
50 min				
60min				
70 min				
80 min				
90				
Final postoperative				

Name of data collector ……..……signature……..

Name of supervisor…….signature……..