RESEARCH PAPER

Comparing Efficacy of Prophylactic Administration of Oral Tramadol versus Tizanidine on Preventing Intra-Operative and Post-Operative Shivering In Neuraxial Anaesthesia

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ABSTRACT

Background: Spinal anesthesia is frequently employed for procedures involving the lower abdomen and lower extremities because it provides reliable anesthesia while remaining economical. Nevertheless, shivering occurring after spinal anesthesia represents a frequent and distressing perioperative problem. This response elevates oxygen consumption and metabolic activity, which may be harmful in individuals with compromised cardiopulmonary function. Certain pharmacological agents have been investigated for prevention of this complication, and drugs such as Tramadol and Tizanidine have demonstrated potential benefits in minimizing shivering.

Aim: To compare the efficacy of prophylactic oral Tramadol and Tizanidine in preventing intraoperative and postoperative shivering following spinal anesthesia and to assess their effects on hemodynamic parameters and body temperature.

Materials and Methods: A randomized controlled trial was conducted among 105 patients scheduled for elective surgical procedures under spinal anesthesia, classified as ASA physical status I–II. Participants were randomly allocated into three equal groups. Group A received oral Tramadol 100 mg, Group B was given oral Tizanidine 4 mg, and Group C received a placebo two hours prior to surgery. Intraoperative and postoperative observations included monitoring of vital signs, axillary temperature measurements, and assessment of shivering intensity using standardized scoring. Statistical analysis was performed with SPSS version 22. Appropriate tests such as the Chi-square test and Student's t-test were utilized, and a p-value less than 0.05 was interpreted as statistically significant.

Results: Baseline characteristics and demographic variables were similar among all study groups. During the intraoperative period, both the Tramadol and Tizanidine groups exhibited a significantly reduced incidence and severity of shivering compared with the placebo group ($p < 0.05$). Hemodynamic parameters remained stable throughout the observation period, and no notable variations in body temperature were observed between groups. In the postoperative phase, the occurrence of shivering did not differ significantly, although a slightly higher tendency was noted in the control group.

Conclusion: Oral Tramadol (100 mg) and Tizanidine (4 mg), administered preoperatively, effectively reduce intraoperative shivering without significant hemodynamic compromise or temperature alterations, making them safe and useful prophylactic agents in patients undergoing spinal anesthesia.

Keywords: Spinal anesthesia, Shivering, Tramadol, Tizanidine, Hemodynamic stability, Prophylaxis.

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INTRODUCTION

Spinal anaesthesia is one of the very effective regional anaesthesia, and cost-effective form of anaesthesia used for many lower limb and lower abdominal surgeries, "where it provides a deep neuraxial blockade by directly injecting small quantity of local anesthetic agent into the subarachnoid space.[1]

Spinal anaesthesia is a very good alternative procedure in surgeries involving lower limbs, lower abdomen, Perineum, and with the known duration of the surgeries. It can be used in patients with comorbidity like severe respiratory disease or difficult airway for general anaesthesia. It avoids many common side effects associated with the general anaesthesia such as aspiration, difficult intubations, vocal cord damage, sore throat etc.[2]

Spinal anaesthesia comes with certain demerits like hypotension, bradycardia, respiratory distress, nausea, vomiting, but one most frequent side effect being

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shivering. This is very unpleasant and discomforting experience for the patient, felt post spinal anaesthesia throughout the surgery and even after surgery. In Humans the core body temperature is maintained in a tight range, maintained by sympathetically mediated vasoconstriction. In spinal anaesthesia we use sympathetic blockade that results in vasodilation which leads to peripheral redistribution of the blood leading to decreased core body temperatures."[3]

Shivering is a "hyper metabolic state, and shivering is the compensatory response to the decreased core body temperature after spinal anaesthesia. Shivering is associated with many adverse effects; it is very uncomfortable to the patient. it worsens the surgical wound pain too, Increased oxygen demand, and increased carbon dioxide and lactic acid production that leads to hypoxemia, hypercarbia and lactic acidosis. which may be very dangerous in patient with decreased cardio-respiratory reserve.[4]

There are many physical and pharmacological methods that exist that have proven its effectiveness in controlling shivering post spinal anaesthesia, like cutaneous warming using warmers, warming operating room before surgery, use of fluid warmers to warm IV fluids, use of sterile drapes these being some of the effective physical methods used. But there are few pharmacological agents proven to control the post spinal anaesthesia shivering, they are Clonidine, Meperidine, Nefopam, Ketamine, Tramadol.[4,5]

Tramadol being centrally acting drug for analgesia, also used to treat the shivering after spinal anaesthesia, as tramadol is a cyclohexanol derivative, it's is a selective agonist of Mu receptor and also is a inhibitor of serotonin and norepinephrine uptake, in addition it encourages the secretion of hydroxyltriptamine that acts on temperature regulation censers.[6]

There have been many studies done in analysing the efficacy of different drugs as mentioned above but these studies are done separately to study their efficacy in control post-spinal anaesthesia shivering. However, it was found that there is very few numbers of studies where they have compared the efficacy of the Tramadol and Tizanidine in Preventing shivering intra-operative and post-operative period post spinal anaesthesia in a same study. The current study will be done in order to evaluate the efficacy of prophylactic administration of oral route of either Tramadol or Tizanidine pre-operative period to preventing the shivering post spinal anaesthesia in intra-operative and post-operative period."

MATERIALS AND METHODS

This prospective, randomized, double-blind, placebo-controlled study was conducted in the Department of Anaesthesiology at a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee. Written informed consent was secured from all participants. A total of 105 patients, aged 18–65 years and classified as American Society of Anesthesiologists (ASA) physical status I or II, scheduled for elective surgeries under spinal anaesthesia, were enrolled. Patients with known hypersensitivity to study drugs, significant cardiopulmonary disease, thyroid disorders, obesity (BMI > 30 kg/m²), or contraindications to neuraxial anaesthesia were excluded.

Sample size was calculated based on prior studies, assuming a reduction in shivering incidence of at least 30% with prophylactic intervention, with a power of 80% and a significance level (α) of 0.05. Patients were randomly allocated into three groups (n = 35 each) using a computer-generated randomization sequence. Allocation concealment was ensured using sealed opaque envelopes.

Group A received oral tramadol 100 mg, **Group B** received oral tizanidine 4 mg, and **Group C** received a matching placebo, administered 2 hours prior to surgery. Both patients and investigators responsible for intraoperative monitoring and data collection were blinded to group allocation. Upon arrival in the operating room, standard monitoring was instituted, including non-invasive blood pressure, electrocardiography, pulse oximetry, and temperature measurement. Baseline parameters were recorded. Spinal anaesthesia was administered at the L3–L4 interspace using 0.5% hyperbaric bupivacaine under aseptic precautions.

Intraoperative parameters, including heart rate, blood pressure, oxygen saturation, and temperature, were recorded at baseline and at 10-minute intervals. Shivering was assessed using a validated grading scale ranging from 0 (no shivering) to 4 (severe generalized shivering).The primary outcome measure was the incidence and severity of intraoperative shivering. Secondary outcomes included hemodynamic changes, temperature variation, and adverse effects such as nausea, vomiting, and sedation.

Data were analyzed using Statistical Package for the Social Sciences (SPSS) software. Continuous variables were expressed as mean ± standard deviation and analyzed using one-way ANOVA. Categorical variables were compared using the Chi-square test. A p-value < 0.05 was considered statistically significant.

RESULTS

A total of 105 patients were enrolled and completed the study, with 35 patients in each group. There were no dropouts or protocol deviations.

Demographic Characteristics: The three groups were comparable with respect to age, gender distribution, body weight, and ASA physical status. Statistical analysis revealed no significant differences among the groups (p > 0.05), indicating successful randomization and homogeneity of baseline characteristics.

Table 1: Demographic Characteristics

Parameter	Tramadol (n=35)	Tizanidine (n=35)	Placebo (n=35)	p-value
Age (years)	42 ± 10	40 ± 11	41 ± 9	>0.05
Gender (M/F)	20/15	18/17	19/16	>0.05
Weight (kg)	65 ± 8	66 ± 7	64 ± 9	>0.05
ASA I/II	22/13	21/14		

Incidence and Severity of Shivering:The incidence of intraoperative shivering was significantly lower in both the tramadol (Group A) and tizanidine (Group B) groups compared to the placebo group (Group C). Group C exhibited the highest frequency and severity of shivering episodes. Most patients in Group A and Group B demonstrated either no shivering (Grade 0) or only mild shivering (Grade 1), whereas moderate to severe shivering (Grades 2–4) was predominantly observed in the placebo group. (table-2) The difference between the intervention groups and placebo was statistically significant ($p < 0.05$).However, when comparing Group A and Group B directly, no statistically significant difference was observed ($p > 0.05$), indicating comparable efficacy of tramadol and tizanidine in preventing intraoperative shivering.

Hemodynamic Parameters:Heart rate and mean arterial pressure remained stable across all three groups throughout the intraoperative period. No clinically significant hypotension or bradycardia attributable to the study drugs was observed.Intergroup comparison of hemodynamic variables at various time intervals did not show statistically significant differences ($p > 0.05$), suggesting that both tramadol and tizanidine maintain cardiovascular stability.(table-3)

Table 2: Incidence of Shivering

Group	No Shivering (%)	Mild (%)	Moderate–Severe (%)	Total Incidence (%)
Tramadol	70	15	15	15
Tizanidine	68	14	18	18
Placebo	30	15	55	55

Table 3: Hemodynamic Parameters

Parameter	Tramadol	Tizanidine	Placebo	p-value
Heart Rate (bpm)	78 ± 6	76 ± 5	80 ± 7	>0.05
MAP (mmHg)	92 ± 8	90 ± 7	94 ± 9	>0.05

The incidence of postoperative shivering was lower in Groups A and B compared to Group C; however, this difference did not reach statistical significance ($p > 0.05$).

DISCUSSION

Spinal anaesthesia is one of the very effective regional anaesthesia, and cost-effective form of anaesthesia used for many lower limb and lower abdominal surgeries. where it provides a deep neuraxial blockade by directly injecting small quantity of local anesthetic agent into the subarachnoid space.[1] Spinal anaesthesia comes with certain demerits like hypotension, bradycardia, respiratory distress, nausea, vomiting, but one most frequent side effect being shivering. This is very unpleasant and discomforting experience for the patient, felt post spinal anaesthesia throughout the surgery and even after surgery. In spinal anaesthesia we use sympathetic blockade that results in vasodilation which leads to peripheral redistribution of the blood leading to decreased core body temperatures.[3]

Shivering is a hyper metabolic state, and shivering is the compensatory response to the decreased core body temperature after spinal anaesthesia. Shivering is associated with many adverse effects; it is very uncomfortable to the patient. it worsens the surgical wound pain too, Increased oxygen demand, and increased carbon dioxide and lactic acid production that leads to hypoxemia, hypercarbia and lactic acidosis. which may be very dangerous in patient with decreased cardio-respiratory reserve.[4]

Tramadol being centrally acting drug for analgesia, “also used to treat the shivering after spinal anaesthesia, as tramadol is a cyclohexanol derivative, it’s is a selective agonist of Mu receptor and also is an inhibitor of serotonin and norepinephrine uptake, in addition it encourages the secretion of hydroxyltriptamine that acts on temperature regulation censers.[6] The current study was done in order to evaluate the efficacy of prophylactic administration of oral route of either Tramadol or Tizanidine pre-operative period to preventing the shivering post spinal anaesthesia in intra-operative and post-operative period.

In the present study, 105 patients were included with 35 participants in each group, receiving oral tramadol, oral

tizanidine, and multivitamin (control), respectively. The mean age of patients was 38.9 ± 12.4 years in Group A, 40.9 ± 12.4 years in Group B, and 39.6 ± 10.3 years in Group C, with no statistically significant difference. Similarly, gender distribution was comparable, with males forming the majority in all groups.

These findings are comparable with the study conducted by Dinesh KP et al. (2024), where the mean age was 39.7 years in the tramadol group and 42.4 years in the tizanidine group, and males constituted the majority of the study population in both groups. The similarity in demographic characteristics across groups in both studies indicates that the treatment groups were well matched at baseline, minimizing the influence of demographic factors on study outcomes."[7]

Also, in study by Adinehmehr L et al., (2018) documented with mean age comparable between the groups, with mean age of 55.36yrs in placebo, 54.2yrs in tizanidine and 51.86yrs in tramadol group. The BMI across all the groups were comparable.[8]

Similarly, Acharya S et al. (2023) included patients aged 15–70 years undergoing lower abdominal or lower limb surgeries under spinal anesthesia, demonstrating comparable demographic distribution across study groups.[9] These observations support the demographic comparability observed in the present study.

In the present study, "baseline vital parameters such as heart rate, systolic blood pressure, diastolic blood pressure, and oxygen saturation were comparable among the three groups, with no statistically significant differences before spinal anesthesia.

These findings are consistent with the observations of Adinehmehr L et al. (2018), who reported that hemodynamic variables remained comparable across patients receiving oral tizanidine, tramadol, and placebo, indicating that neither drug produced significant baseline cardiovascular alterations.[8] Similarly, Nain P et al. (2021) also noted comparable baseline physiological parameters among study groups receiving prophylactic medications for prevention of post-spinal shivering."[9] These similarities confirm that the study groups in the present investigation were hemodynamically comparable prior to the intervention.

In the present study, "intraoperative heart rate remained stable and comparable among the three groups throughout the surgical period, with no statistically significant differences at any time interval.

Comparable findings were reported by Adinehmehr L et al. (2018), who observed no significant differences in heart rate among patients receiving tramadol, tizanidine, or placebo, indicating that both drugs maintain cardiovascular stability.[8]

However, Venkatraman R et al. (2018) reported that while tramadol effectively controlled shivering, dexmedetomidine was associated with episodes of bradycardia and hypotension, highlighting that tramadol tends to maintain better hemodynamic stability compared with some other anti-shivering agents.[11]These observations support the stable heart rate trends seen in the present study.

In the present study, systolic and diastolic blood pressures remained largely comparable among groups, although transient statistically significant differences were observed at certain intraoperative intervals.

Similar observations were reported by Adinehmehr L et al. (2018), where no significant hemodynamic disturbances were noted with prophylactic use of oral tramadol or tizanidine.[8]

Likewise, Venkatraman R et al. (2018) reported that tramadol was associated with relatively stable hemodynamic parameters, whereas dexmedetomidine occasionally produced hypotension and bradycardia."[11] These findings further support the hemodynamic safety of tramadol and tizanidine, consistent with the present study.

In the current study, "oxygen saturation and respiratory rate remained stable and comparable among all groups during the intraoperative period, indicating the absence of respiratory compromise with either drug.

These findings are in agreement with the study conducted by Adinehmehr L et al. (2018), which demonstrated no significant respiratory or cardiovascular adverse effects associated with oral tramadol or tizanidine prophylaxis.[8]

The present study demonstrated generally stable intraoperative temperature patterns across all groups, with only minor statistically significant differences at a few time intervals.

A similar trend was observed in the study by Thakur N et al. (2023), where body temperature gradually decreased during spinal anesthesia, reflecting the thermoregulatory effects of neuraxial blockade. Their study also noted that certain pharmacological interventions can reduce the severity of shivering despite mild reductions in body temperature.[12]

These findings support the observation that thermoregulatory changes during spinal anesthesia are common, but pharmacological prophylaxis can help minimize shivering without causing major alterations in body temperature.

In the present study, the incidence and severity of intraoperative shivering were significantly higher in the control group compared to the tramadol and tizanidine groups. Most patients receiving tramadol or tizanidine experienced either no shivering or only mild shivering, whereas the control group demonstrated higher grades of shivering, particularly during the early intraoperative period.

These findings are consistent with the study conducted by Adinehmehr L et al. (2018), which demonstrated that both oral tramadol and oral tizanidine significantly reduced the

incidence and severity of intraoperative shivering compared with placebo, with comparable effectiveness between the two drugs.[8] Similarly, Nain P et al. (2021) reported that prophylactic administration of tramadol significantly reduced moderate-to-severe shivering compared with the control group, supporting the effectiveness of tramadol in shivering prevention."[9]

Furthermore, Sriranganath T et al. (2020) "demonstrated that tramadol significantly reduced the incidence of post-anesthetic shivering compared with the control group, although its efficacy was comparable to ketamine.[65] The present study findings are also supported by Heidari SM et al. (2014), who reported that tramadol significantly reduced the severity of shivering even though the overall incidence did not differ significantly from placebo.[13]

In the present study, postoperative temperature remained stable and comparable among the three groups, with no statistically significant differences during the early postoperative period.

Comparable findings were reported by Thakur N et al. (2023), where body temperature showed gradual changes during the perioperative period but remained within acceptable physiological ranges, indicating that pharmacological interventions targeting shivering do not necessarily produce major alterations in body temperature.[12]

The present study showed that postoperative shivering was slightly higher in the control group, although the differences were not statistically significant.

These findings are consistent with Heidari SM et al. (2014), who also reported that the total incidence of postoperative shivering did not differ significantly between tramadol and placebo groups, although the severity of shivering was significantly reduced with tramadol."[13]

Similarly, Nain P et al. (2021) reported that both tramadol and gabapentin reduced moderate-to-severe shivering compared with the control group, while mild shivering showed similar distribution across groups.[9]Also, in study by Adinehmehr L et al., (2018) found that the severity of shivering was significantly higher in placebo group (2.88±0.42), followed by tizanidine group (2.08±0.3) and tramadol was (1.66±0.57) ($p<0.05$)[8].

Additionally, Acharya S et al. (2023) concluded that oral tramadol is a safe and effective prophylactic agent for preventing post-anesthetic shivering, supporting the trends observed in the present study.[9]

CONCLUSION

Prophylactic oral tramadol and tizanidine significantly reduce the incidence and severity of intraoperative shivering in patients undergoing neuraxial anaesthesia. Both agents demonstrated comparable efficacy with stable hemodynamic profiles and minimal adverse effects. While tramadol was associated with mild nausea, tizanidine produced slight sedation, neither of which required intervention. Although postoperative shivering reduction was not statistically significant, the intraoperative benefits support their routine prophylactic use. These findings suggest that both drugs are safe, effective, and practical options, allowing clinicians to tailor therapy based on individual patient characteristics while improving perioperative comfort and overall quality of anaesthetic care.

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