DOI: https://doi.org/10.54393/pjhs.v6i10.3322

PAKISTAN JOURNAL OF HEALTH SCIENCES
(LAHORE)
https://thejas.com.pk/index.php/pjhs
ISSN (E): 2790-9352, (P): 2790-9344
Volume 6, Issue 10 (October 2025)

Original Article

OPEN ACCESS

Comparison of Effectiveness of Intrathecal Tramadol versus Intravenous Tramadol in Prevention of Post-Anesthesia Shivering in Patients Undergoing Lower Limb Orthopedic Surgeries under Subarachnoid Block: A Comparative Study

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ARTICLE INFO

Keywords:
Tramadol, Post-Anesthesia Shivering, Subarachnoid Block, Intravenous

How to Cite:
Khalid, S., Ahmad, H., Khalid, M., & Khalid, M. (2025). Comparison of Effectiveness of Intrathecal Tramadol versus Intravenous Tramadol in Prevention of Post-Anesthesia Shivering in Patients Undergoing Lower Limb Orthopedic Surgeries under Subarachnoid Block: A Comparative Study: Intrathecal vs Intravenous Tramadol in Post-Anesthesia Shivering. Pakistan Journal of Health Sciences, 6(10), 26-30. https://doi.org/10.54393/pjhs.v6i10.3322

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Received Date: 8th July, 2025
Revised Date: 26th September, 2025
Acceptance Date: 16th October, 2025
Published Date: 31st October, 2025

ABSTRACT

Shivering is a common spinal anesthetic side effect that occurs in 40-60% of people who have had subarachnoid block. Shivering is typified by spontaneous, involuntary, rhythmic fasciculation or skeletal muscular activation that resembles tremors. Hypothalamic thermoreceptors attempt to increase heat synthesis by shivering when they sense this drop in core body temperature due to peripheral heat redistribution. **Objectives:** To compare anti-shivering effects of intravenous versus intrathecal tramadol in patients receiving subarachnoid block for lower limb orthopedic operations. **Methods:** This Quasi-experimental study included 130 patients scheduled for elective orthopedic surgery under spinal anesthesia in the Operation Theater, Allied Hospital, Faisalabad. Patients were randomly divided into two groups: Group A (intrathecal tramadol with bupivacaine) and Group B (intravenous tramadol with intrathecal bupivacaine). The frequency of post-anesthesia shivering was recorded in both groups. **Results:** The mean ± SD of sensory and motor block duration in Group A was 331.72 ± 33.09 and 231.14 ± 11.22 minutes, respectively, while in Group B it was 228.12 ± 12.15 and 157.42 ± 10.02 minutes, respectively ($p<0.001$). Post-anesthesia shivering occurred in 9 (13.84%) patients in Group A and 23 (35.38%) patients in Group B ($p<0.050$). **Conclusions:** Post-anesthesia shivering was significantly higher in patients receiving intravenous tramadol (Group B) compared to those receiving intrathecal tramadol (Group A).

INTRODUCTION

Regional anesthesia is a conventional anesthesia technique which is comparatively easy with less complications [1]. Most of the orthopedic surgeries are done in spinal anesthesia because it provides excellent perioperative and postoperative analgesia with less blood loss [2]. However, one of the most common and challenging complication of this safer and preferred anesthesia technique is post spinal shivering (PSS) which occurs in 40-70% patients. Shivering is hypothesized to be a physiological response to perioperative hypothermia which occurs due to anesthesia induced inhibition of thermogenesis and peripheral vasodilatation causing heat loss. However, this thermoregulatory response has distressing effects on patients making vitals monitoring

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difficult [3]. Perioperative complications of shivering include increased oxygen consumption, hypercarbia, metabolic acidosis, tachycardia and hypertension which has deleterious effects especially on patients with reserved cardiac function [4]. Postoperative complications include delayed wound healing, increased wound pain and prolonged hospital stay. High incidence of PSS along with risk for several intra and post-operative complications makes its prophylaxis crucial. Several pharmacological and non-pharmacological interventions have been proposed for prevention of PSS. Non-pharmacological measures include use of blankets, surgical drapes, warm fluids, use of radiant heat and air warmers but are less effective and some are costly [5]. Pharmacological agents include pethidine, clonidine, low-dose ketamine, dexmedetomidine, dexamethasone, tramadol and magnesium sulfate [6-8]. There is no single globally agreed drug for prevention of PSS. However, tramadol is one of the most common agents used for shivering because of its low cost, easy availability and less side effects [9]. Tramadol is a weak synthetic opioid which acts as agonist of μ receptor and also inhibits reuptake of norepinephrine and 5-hydroxytryptamine which gives tramadol its thermoregulatory function [10]. There are many studies showing efficacy of intravenous tramadol in control of shivering. Previous studies compared intravenous nalbuphine 0.05 mg/kg to IV tramadol 1 mg/kg administered to treat post-spinal anesthesia shivering. He found that tramadol took less time to eliminate shivering than nalbuphine. Both medications had modest side effects and hemodynamic abnormalities. Recent researches have sparked interest in using tramadol as an adjuvant to bupivacaine given intrathecally, despite the fact that tramadol has been used intravenously for a long time to prevent and cure shivering. However, data in our local population is scarce. According to Abd El Azeem and his colleagues, they found that 8 patients (18.6%) in the intravenous group and 2 patients (4.6%) in the intrathecal group had post spinal shivering. (p=0.047).

Post-anesthesia shivering (PSS) remains a common and distressing complication of spinal anesthesia, affecting up to 40–70% of patients undergoing lower limb surgeries. While intravenous tramadol has been widely used for prophylaxis, data on the efficacy of intrathecal tramadol in the local population is limited. Furthermore, comparative studies assessing the optimal route of tramadol administration for reducing PSS and prolonging analgesia remain scarce, highlighting the need for evidence-based evaluation in our setting. This study aims to compare anti-shivering effects of intravenous versus intrathecal tramadol in patients receiving subarachnoid block for lower limb orthopedic operations.

METHODS

This Quasi-experimental study was conducted over six months from May 2024 to October 2024 at Allied Hospital, Faisalabad, after approval from the Institutional Ethical Committee (Ref. No. 48.ERC/FMU/2022-23/286), Faisalabad Medical University. A consecutive sampling technique was used to enroll 130 patients undergoing elective orthopedic surgery. Informed consent was obtained, and patients underwent pre-anesthesia evaluation a day before surgery and were instructed to fast for at least 8 hours. Randomization was done using random table number sequence using sealed envelopes, opened by the anesthesia team member to determine group allocation and prepare medications, ensuring blinding and minimizing bias. On the day of surgery, all patients received intravenous access, preloading with warmed Ringer's lactate (15 ml/kg) over 30 minutes, and standard monitoring was attached including heart rate, blood pressure, oxygen saturation, ECG, and temperature. Metoclopramide (10 mg) was given intravenously before surgery, and spinal anesthesia was given in sitting position with a 25-gauge Quincke needle. Patients were maintained on warmed intravenous fluids and closely monitored. Hypotension and bradycardia were defined as a 20% fall in systolic blood pressure and heart rate <50 beats/min, respectively, and treated accordingly. Post-spinal shivering was assessed using the Bedside Shivering Assessment Score (BSAS) within 24 hours, with grade 3 or 4 shivering treated using intravenous tramadol (0.5 mg/kg). The inclusion criteria were patients aged 21–60 years of either gender with ASA grades I and II, while exclusion criteria included uncontrolled comorbidities, major systemic disease, allergy to tramadol or bupivacaine, drug abuse, contraindications to spinal anesthesia, surgeries lasting >120 minutes, or failed spinal anesthesia requiring conversion to general anesthesia. Patients were divided into two groups: Group A (intravenous tramadol 25 mg) and Group B (intrathecal tramadol 10 mg with bupivacaine 15 mg). Sample size was calculated using the WHO calculator for two proportions with 95% confidence level, 80% power, P1=18.6% and P2=4.6% [11], yielding 130 patients. Data were analyzed using IBM-SPSS version 23.0, with quantitative variables (age, BMI, onset of block, duration of analgesia) expressed as Mean ± SD and qualitative variables (ASA grade, gender, shivering, complications) as frequencies and percentages. Chi-square test was applied with significance at $p < 0.050$.

RESULTS

The mean ± SD age of patients was 40.38 ± 10.56 years in Group A and 38.14 ± 7.53 years in Group B (p = 0.166). The gender distribution was comparable between the groups (31 males and 34 females in Group A; 27 males and 38

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females in Group B, p = 0.597). ASA grade I and II were distributed as 30 and 35 in Group A, and 31 and 34 in Group B, respectively (p = 1.000). The mean ± SD BMI was 24.54 ± 2.13 kg/m^2 in Group A and 24.96 ± 2.06 kg/m^2 in Group B (p = 0.264)(Table 1).

Table 1: Clinic-Demographics of Both Groups of Patients N=130

Variables	Group A (Intrathecal Tramadol, N=65)	Group B (Intravenous Tramadol, N=65)	p-Value
Age (years, Mean ± SD)	40.38 ± 10.56	38.14 ± 7.53	0.166
Gender (Male: Female)	31: 34	27: 38	0.597
ASA grade (I: II)	30: 35	31: 34	1.000
BMI (kg/m^2, Mean ± SD)	24.54 ± 2.13	24.96 ± 2.06	0.264

The mean ± SD of sensory and motor block duration in Group A was 331.723 ± 33.09 and 231.138 ± 11.22 minutes and in Group B was 228.123 ± 12.15 and 157.415 ± 10.02 minutes respectively (p-value <0.001)(Table 2).

Table 2: Comparison of Subarachnoid Block Characteristics Between the Two Groups (N=130)

Subarachnoid block characteristics	Group A (Intrathecal Tramadol, n=65) Mean ± SD	Group B (Intravenous Tramadol, n=65) Mean ± SD	p-Value
Duration of surgery (minutes)	91.15 ± 5.04	90.43 ± 5.05	0.416
Motor block duration (minutes)	231.14 ± 11.22	157.42 ± 10.02	<0.001*
Sensory block duration (minutes)	331.72 ± 33.09	228.12 ± 12.15	<0.001*
Frequency of analgesic demand (24h)	2.09 ± 0.42	3.80 ± 1.07	<0.001*

*p-value ≤ 0.050 considered significant

Post-anesthesia complications were mostly comparable between the two groups, except for shivering which was more frequent in Group B (Table 3).

Table 3: Complications after Subarachnoid Block (N=130)

Complications	Group A (n=65)	Group B (n=65)	p-Value
Post-anesthesia shivering	9	23	0.064
Bradycardia	1	1	
Hypotension	1	2	
Nausea and vomiting	9	6	

*p ≤ 0.050 considered statistically significant

Post-anesthesia shivering, assessed using the Bedside Shivering Assessment Score (BSAS), occurred in 13.84% of patients in Group A and 35.38% in Group B, showing a statistically significant difference (p=0.008)(Table 4).

Table 4: Post-Anesthesia Shivering Comparison Between Groups (N=130)

Shivering Status	Group A (n=65)	Group B (n=65)	p-Value
Present	9 (13.84%)	23 (35.38%)	0.008*
Absent	56 (86.15%)	42 (64.61%)	

*p-value ≤ 0.050 considered significant

DISCUSSIONS

Post-anesthesia shivering is a complex phenomenon influenced by various factors, including operating room temperature, patient heat distribution, pain, and sympathetic activity. Tramadol, a synthetic opioid, has been shown to effectively prevent shivering due to its unique mechanism of action. Oral tramadol has been reported to significantly reduce post-anesthetic shivering, with only 7.5% of patients experiencing shivering compared to 40% in the placebo group [12]. Multiple studies have examined different doses of intrathecal tramadol in patients undergoing urological procedures, cesarean sections, and for shivering prophylaxis in comparison to other adjuvants or placebo [13-15]. Additional evidence supports its role in cesarean section patients, and both tramadol and nalbuphine have been shown to be effective in controlling post-spinal shivering [16, 17]. The present study compared the analgesic effects of intrathecal tramadol (10 mg) versus intravenous tramadol (25 mg) in preventing post-anesthesia shivering in patients undergoing elective lower limb surgeries. Results showed that patients receiving intrathecal tramadol experienced significantly less shivering compared to those receiving intravenous tramadol, which is consistent with previously published findings [2, 18]. When compared with intrathecal dexmedetomidine added to bupivacaine, tramadol as an adjuvant with bupivacaine for the intrathecal route significantly extended the duration of the pain-free period after subarachnoid anesthesia [19]. Furthermore, this study found that the intrathecal group had longer sensory and motor block duration and postoperative analgesia, consistent with earlier reports [20]. Intrathecal tramadol has also been shown to be superior to intrathecal fentanyl in preventing shivering during cesarean section [21]. This study used a fixed dose of 25 mg intravenous tramadol and 10 mg intrathecal tramadol, consistent with the recommended dosage range for shivering prophylaxis. The results support the use of intrathecal tramadol as a safe and effective method for preventing post-anesthesia shivering and providing postoperative analgesia. A single dose of intrathecal tramadol may reduce the need for systemic intravenous supplementation, making it a convenient and efficient treatment option.

The main limitation of this study was that it was conducted at a single center. Further multicenter studies with larger sample sizes are recommended to strengthen the clinical evidence. Future research should involve multicenter trials with larger sample sizes to validate these results. Additionally, exploring different intrathecal dosages and patient populations could help establish the most effective and safe protocol for preventing post-anesthesia shivering while optimizing postoperative analgesia.

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CONCLUSIONS

Current study found that administering 10 mg of tramadol intrathecally as a prophylactic effectively prevents postoperative shivering in patients having lower limb procedures that need large amount of fluids for cleaning during debridement cases. Intrathecal tramadol increases motor block time and duration of analgesia, reducing the need for post-operative analgesics while minimizing adverse effects such nausea, vomiting, and hypotension. It is recommended to compare the antishivering effect of tramadol at different intrathecal dosages to find out the optimum dose for better results.

Authors' Contribution

Conceptualization: SK
Methodology: HA
Formal analysis: HA
Writing and Drafting: MK[1], MK[2]
Review and Editing: MK[1], MK[2], HA, SK

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

Source of Funding

The author received no financial support for the research, authorship and/or publication of this article.

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