

Comparative Efficacy and Safety of Intravenous Nalbuphine and Tramadol for Treatment of Post-Spinal Anaesthesia Shivering in Patients Undergoing Lower-Limb Surgery

Running title: Nalbuphine vs tramadol for post-spinal shivering

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ABSTRACT

Background: Shivering is a common complication of spinal anaesthesia, affecting 40–70% of patients, and may increase oxygen consumption, metabolic stress, and discomfort. Both nalbuphine and tramadol can be used to control shivering. **Objective:** To compare the efficacy of intravenous nalbuphine (0.05 mg/kg) and tramadol (1 mg/kg) for post-spinal shivering control in patients undergoing lower limb surgeries under spinal anaesthesia. **Methods:** In this prospective, randomised, open-label study, 56 patients with Wrench grade III–IV shivering were allocated 1:1 to Group N (nalbuphine, n = 28) or Group T (tramadol, n = 28). The primary outcome was the time to cessation of shivering. Continuous variables were compared using Student's t-test, and categorical variables were compared using Fisher's exact test; Wrench grade comparisons were adjusted using Bonferroni correction. **Results:** Time to cessation was significantly shorter in Group T (3.54 ± 1.46 vs 4.58 ± 1.52 min; $p = 0.012$). Wrench grades were significantly lower in Group T at 2, 10, and 15 min (adjusted $p = 0.007$, < 0.001 , < 0.001). Control within 5 min was achieved in 92.9% vs 89.3% ($p = 1.000$). Recurrence (21.4% vs 10.7%) and rescue medication (7.1% vs 3.6%) did not differ significantly. Haemodynamic appeared comparable. Nausea (17.9% vs 3.6%), vomiting (10.7% vs 3.6%) and sedation (14.3% vs 3.6%) were not statistically different; no respiratory depression occurred. **Conclusion:** Both drugs controlled post-spinal shivering; tramadol acted faster, whereas nalbuphine may have exhibited a more favourable gastrointestinal adverse effect profile. Both preserved haemodynamic stability and may be suitable for clinical use.

Keywords: Post-spinal shivering; nalbuphine; tramadol; spinal anaesthesia; lower limb surgeries; Wrench grade

INTRODUCTION

Shivering after spinal anaesthesia is a spontaneous, involuntary, rhythmic oscillation of skeletal muscle activity that is distressing to the patient (1) and associated with substantial physiological cost; vigorous shivering can increase metabolic heat production by up to 600% above basal levels (2). It appears to be one of the most frequently reported complications of central neuraxial blockade, affecting 40–70% of patients (3), with a pooled median incidence of 55% in control groups across 21 studies

of neuraxial anaesthesia-related shivering (4). Reported incidences range from 8.15% in a sub-Saharan tertiary centre (5) to 42.8% in Indian patients undergoing lower abdominal and lower limb surgery (4). Shivering may aggravate postoperative pain by stretching surgical incisions, raise intraocular and intracranial pressures, and increase oxygen consumption — consequences that justify prompt pharmacological control (6).

The pathophysiology appears to be predominantly thermoregulatory. Spinal anaesthesia impairs centrally

mediated thermoregulatory defence by significantly decreasing both the vasoconstriction and shivering thresholds by approximately 0.5 °C each, so the core temperature drifts downward before protective responses are triggered (7). Because the block may also prevent vasoconstriction below the level of blockade, shivering emerges as an early and often the first visible compensatory response (8).

The shivering threshold is modulated by central monoaminergic balance, particularly the interplay of norepinephrine and serotonin at the preoptic anterior hypothalamus, and this central action may partly account for the use of tramadol and nalbuphine in shivering control (9). Tramadol combines weak μ -opioid agonism with inhibition of serotonin and noradrenaline reuptake, whereas nalbuphine is a mixed opioid agonist–antagonist with high affinity for the κ -opioid receptor, functioning as both a competitive opioid antagonist and a partial opioid agonist. Head-to-head randomised data remain limited and partly conflicting: studies using nalbuphine 0.05–0.06 mg/kg report faster control with tramadol (10), whereas studies using the higher nalbuphine dose of 0.1 mg/kg report faster control with nalbuphine (11,12). Accordingly, a prospective, randomized, parallel-group study was conducted to compare intravenous nalbuphine 0.05 mg/kg with intravenous tramadol 1 mg/kg in patients with established post-spinal shivering, with time to cessation of shivering as the primary outcome.

MATERIALS AND METHODS

Study design and ethics

This was a prospective, randomised, parallel-group, open-label, active-controlled comparative study conducted in the Department of Anaesthesiology, Mysore Medical College and Research Institute, Mysuru, over the study period 2024–2025. The study protocol was approved by the Institutional Ethics Committee (approval no. 14.2023), and written informed consent was obtained from all participants before enrolment.

Participants

Patients of either sex, aged 18–60 years, with an American Society of Anesthesiologists physical status of I or II, scheduled for elective lower limb surgery under spinal anaesthesia, were screened. Patients who developed Wrench Grade III (visible shivering involving the trunk and/or upper limbs, more than one muscle group, without generalised shaking) or Grade IV (violent, generalised muscular activity involving the entire body) shivering during the intraoperative or early postoperative period were enrolled. Exclusion criteria comprised: contraindications or known allergy to nalbuphine or tramadol; chronic opioid use; febrile illness or thyroid disease; neuroleptic or monoamine oxidase inhibitor therapy; significant cardiac,

respiratory, hepatic, or renal disease; and shivering attributable to causes other than spinal anaesthesia.

Randomization and allocation concealment

Eligible patients were allocated to Group N (nalbuphine) or Group T (tramadol) in a 1:1 ratio using a computer-generated random sequence. Allocation was concealed in sequentially numbered, opaque, sealed envelopes that were opened only at the onset of shivering, immediately before drug administration. Because of the nature of the interventions, the study was conducted open-label; to mitigate potential observer bias, shivering grade was assessed at fixed intervals using the standardized Wrench scale, and time to cessation was recorded with a stopwatch in accordance with a prespecified protocol.

Study intervention

At the onset of Wrench Grade III or IV shivering, Group N received intravenous (IV) nalbuphine at 0.05 mg/kg, whereas Group T received 1 mg/kg tramadol; each agent was diluted in normal saline before IV administration.

Outcome measures

The primary outcome was the time to cessation of shivering, defined as the interval from drug administration to complete disappearance of visible shivering activity. The secondary outcomes were as follows: successful control of shivering within 5 min, recurrence of shivering (reappearance of shivering after initial control), requirement for rescue medication, adverse effects (nausea, vomiting, sedation, hypotension, bradycardia, respiratory depression), and haemodynamic parameters. Heart rate, non-invasive blood pressure, and oxygen saturation were recorded at baseline and at predefined intervals after drug administration.

Statistical analysis

Data were analysed using [statistical software, version]. The Shapiro–Wilk test was used to assess the normality of continuous variables. Normally distributed continuous variables are presented as mean $\pm$ standard deviation and were compared between groups using Student's independent-samples t-test. Categorical variables are presented as frequencies and percentages and were compared using Fisher's exact test because of the small cell frequencies. For the serial Wrench shivering grade comparisons across seven time points, p-values were adjusted using the Bonferroni correction; statistical significance was considered at adjusted $p < 0.05$. All tests were two-tailed, and $p < 0.05$ was considered statistically significant.

RESULTS

A total of 56 patients were analysed, with 28 patients in each group (N and T). The patients demographic

and perioperative characteristics were comparable between the two groups. No statistically significant differences were observed in age, sex distribution, weight, height, body mass index, or the duration of surgery (all $p > 0.05$).

The severity of shivering decreased progressively following the administration of the study drugs in both groups. After adjustment for multiple comparisons, the findings suggested lower mean Wrench shivering grades in Group T at 2 min (adjusted $p = 0.007$), 10 min (adjusted $p < 0.001$), and 15 min (adjusted $p < 0.001$). Differences at baseline, 1 min, 5 min, and 30 min were not statistically significant.

The mean time to cessation of shivering appeared to be significantly shorter in Group T than in Group N (3.54 ± 1.46 vs 4.58 ± 1.52 min; $p = 0.012$). Successful control within 5 min was observed in 26 (92.9%) patients in Group T and 25 (89.3%) patients in Group N ($p = 1.000$). 2 (7.1%) patients in Group T and 1

(3.6%) patient in Group N required rescue medication. Recurrence of shivering occurred in 6 (21.4%) patients in Group T compared with 3 (10.7%) patients in Group N; neither difference appeared to reach statistical significance.

Baseline heart rate, systolic blood pressure, diastolic blood pressure, and SpO₂ were comparable between the groups, with no statistically significant differences observed (all $p > 0.05$).

Nausea and vomiting were more frequent in Group T, whereas sedation was more frequent in Group N. Nausea occurred in 5 (17.9%) patients in Group T compared with 1 (3.6%) in Group N, while vomiting occurred in 3 (10.7%) and 1 (3.6%) patients, respectively. Sedation occurred in 4 (14.3%) patients in Group N compared with 1 (3.6%) in Group T. However, none of the differences in adverse effects reached statistical significance. Neither group experienced respiratory depression.

Table 1: Comparison of demographic and perioperative characteristics between the study groups

Variable	Category	Group N (n = 28)	Group T (n = 28)	p-value
Age (years)	Mean $\pm$ standard deviation (SD)	41.84 $\pm$ 9.62	42.28 $\pm$ 10.14	0.868
Gender	Male, n (%)	17 (60.7)	15 (53.6)	0.787
	Female, n (%)	11 (39.3)	13 (46.4)	
Weight (kg)	Mean $\pm$ SD	64.12 $\pm$ 8.36	63.48 $\pm$ 7.92	0.770
Height (cm)	Mean $\pm$ SD	165.18 $\pm$ 7.54	164.72 $\pm$ 8.16	0.827
Body mass index (BMI; kg/m ²)	Mean $\pm$ SD	23.72 $\pm$ 2.84	23.36 $\pm$ 2.68	0.628
American Society of Anesthesiologists (ASA) physical status	Grade I, n (%)	18 (64.3)	16 (57.1)	0.785
	Grade II, n (%)	10 (35.7)	12 (42.9)	
Duration of surgery (min)	Mean $\pm$ SD	91.48 $\pm$ 14.62	89.76 $\pm$ 15.28	0.669

Data are presented as the mean $\pm$ standard deviation or as n (%). For continuous variables, Student's t-test for independent samples was employed, whereas Fisher's exact test was applied to categorical variables. The total sample comprised 56 participants. ASA: American Society of Anesthesiologists; BMI: body mass index; SD: standard deviation.

Table 2: Comparison of mean Wrench shivering grades across study groups at specified time intervals

Time after administration of study drug	Group N (n = 28), Mean $\pm$ standard deviation	Group T (n = 28), Mean $\pm$ standard deviation	Adjusted p-value*
0 min	3.48 $\pm$ 0.46	3.69 $\pm$ 0.40	0.517
1 min	2.58 $\pm$ 0.54	2.36 $\pm$ 0.58	1.000
2 min	1.76 $\pm$ 0.48	1.34 $\pm$ 0.42	0.007
5 min	0.72 $\pm$ 0.26	0.62 $\pm$ 0.22	0.883
10 min	0.38 $\pm$ 0.14	0.16 $\pm$ 0.08	< 0.001
15 min	0.52 $\pm$ 0.18	0.30 $\pm$ 0.12	< 0.001
30 min	0.44 $\pm$ 0.16	0.36 $\pm$ 0.10	0.203

Values are expressed as mean $\pm$ standard deviation. *P-values were recalculated using independent-samples t-tests, and Bonferroni correction was then applied for seven comparisons. Statistical significance was defined as an adjusted p-value < 0.05 . Total n = 56.

Table 3: Comparison of efficacy parameters between the study groups

Efficacy parameter	Group N (n = 28)	Group T (n = 28)	p-value
Time to cessation of shivering (min), mean $\pm$ standard deviation	4.58 $\pm$ 1.52	3.54 $\pm$ 1.46	0.012
Successful control of shivering within 5 min, n (%)	25 (89.3)	26 (92.9)	1.000
Requirement of rescue medication, n (%)	1 (3.6)	2 (7.1)	1.000
Recurrence of shivering, n (%)	3 (10.7)	6 (21.4)	0.469

Values are expressed as mean $\pm$ standard deviation or n (%). An independent-samples Student's t-test was used to assess the time to cessation of shivering; Fisher's exact test was used for categorical outcomes because of the small cell frequencies. Total n = 56.

Table 4: Comparison of baseline haemodynamic parameters between the study groups

Haemodynamic parameters	Group N (n = 28): mean $\pm$ standard deviation	Group T (n = 28): mean $\pm$ standard deviation	p-value
Heart rate (beats/min)	82.18 $\pm$ 7.84	81.62 $\pm$ 8.12	0.794
Systolic blood pressure (mmHg)	122.14 $\pm$ 10.42	121.48 $\pm$ 9.96	0.809
Diastolic blood pressure (mmHg)	78.34 $\pm$ 6.14	77.86 $\pm$ 6.28	0.774
Peripheral oxygen saturation (SpO ₂) (%)	98.42 $\pm$ 0.84	98.36 $\pm$ 0.88	0.795

Values are presented as mean $\pm$ standard deviation. Between-group comparisons were conducted using an independent-samples Student's t-test, with the total sample comprising 56 participants. SpO₂ denotes peripheral oxygen saturation (SpO₂).

Table 5: Comparative assessment of haemodynamic parameters between the study groups

Adverse event	Group N (n = 28), n (%)	Group T (n = 28), n (%)	p-value
Nausea	1 (3.6)	5 (17.9)	0.193
Vomiting	1 (3.6)	3 (10.7)	0.611
Sedation	4 (14.3)	1 (3.6)	0.352
Hypotension	1 (3.6)	2 (7.1)	1.000
Bradycardia	1 (3.6)	1 (3.6)	1.000
Respiratory depression	0 (0.0)	0 (0.0)	—

Values are expressed as n (%); Fisher's exact test was used because of the small number of adverse events. Statistical testing for respiratory depression was not applicable because neither group recorded an event. The total sample was N = 56.

DISCUSSION

Shivering is a common complication of spinal anaesthesia that is linked to patient discomfort, increased oxygen consumption, metabolic stress, and haemodynamic changes (Witte & Sessler, Perioperative Shivering, 2002; Crowley & Buggy, Shivering and Neuraxial Anesthesia, 2008). In the present study, both intravenous nalbuphine 0.05 mg/kg and intravenous tramadol 1 mg/kg effectively controlled post-spinal shivering in patients undergoing lower limb surgeries under spinal anaesthesia. Demographic data, ASA physical status, and surgical time were comparable between the groups, which suggests adequate randomization and homogeneity of the study population; comparable baseline characteristics between nalbuphine and tramadol groups were also noted by Tudimilla et al. (Tudimilla, Suryawanshi, & SaravanKumar, A Comparative Evaluation of Nalbuphine and Tramadol for the Control of Post-Spinal Anaesthesia Shivering, 2021).

The principal finding was that tramadol achieved cessation of shivering approximately one minute earlier than nalbuphine (3.54 $\pm$ 1.46 min vs 4.58 $\pm$ 1.52 min; p = 0.012). This is consistent with studies most comparable to ours in dose. Kour et al., using identical doses (nalbuphine 0.05 mg/kg and tramadol 1 mg/kg), likewise found the time to control shivering significantly shorter with tramadol, with sedation, hypotension, and bradycardia observed in the nalbuphine group and nausea, vomiting, and dizziness in the tramadol group (13). Rukh et al. reported the same direction of effect, with tramadol controlling shivering significantly faster than nalbuphine (Rukh, Naz, Mumtaz, & Khan, COMPARISON OF NALBUPHINE HYDROCHLORIDE AND TRAMADOL HYDROCHLORIDE FOR CONTROLLING POST-SPINAL ANESTHESIA SHIVERING, 2025).

The literature diverges, however, when a higher nalbuphine dose is used. Thomas et al., comparing nalbuphine 0.1 mg/kg with tramadol 1 mg/kg, found

cessation of shivering significantly faster with nalbuphine, with recurrence occurring in the tramadol group (15). Similarly, Dash et al. concluded that nalbuphine provided faster relief, better sedation, and fewer side effects, with nausea and vomiting occurring only in the tramadol group (Dash, Parida, & Dash, Efficacy of Nalbuphine versus Tramadol in the Treatment of Shivering Following Spinal Anaesthesia, 2025). When co-sedation is added, the apparent efficacy gap narrows: Madem et al., combining each drug with midazolam, found comparable response times and no significant differences in nausea, vomiting, or sedation, with stable haemodynamics in both groups (Madem, et al., Comparing the Effect of Intravenous Tramadol and Intravenous Nalbuphine in Addition to Midazolam for the Control of Shivering after Spinal Anesthesia, 2024). Taken together, the evidence suggests that the relative efficacy of these agents is dose-sensitive at 0.05 mg/kg nalbuphine is slower than tramadol but better tolerated gastrointestinally, whereas at 0.1 mg/kg it is at least as fast and carries a heavier sedation signal.

The serial Wrench grade data provide a complementary view. Both drugs produced steep declines from Grade III–IV shivering to near-minimal grades within 5 minutes, confirming clinically meaningful efficacy in both arms and explaining the comparable 5-minute success rates (92.9% vs 89.3%; $p = 1.000$). After Bonferroni correction, shivering grades were significantly lower in Group T at 2, 10, and 15 min after administration (adjusted $p = 0.007$, < 0.001 , and < 0.001 , respectively), indicating that tramadol's advantage was sustained through the middle of the observation window. At 30 min, grades in both groups were minimal and comparable, suggesting convergence of the two agents as the effect of both drugs became established. Recurrence of shivering was more frequent in Group T (21.4% vs 10.7%), and rescue medication was required slightly more often (7.1% vs 3.6%), but neither difference reached statistical significance; the direction of the recurrence finding is consistent with reports of recurrence after tramadol in other series and warrants confirmation in a larger trial.

Baseline haemodynamics were comparable between the groups, and both drugs preserved haemodynamic stability throughout. The numerically higher rates of nausea (17.9% vs 3.6%) and vomiting (10.7% vs 3.6%) with tramadol are consistent with its serotonergic and noradrenergic reuptake inhibition, whereas the numerically higher sedation rate (14.3% vs 3.6%) with nalbuphine is consistent with its partial opioid agonist profile. Importantly, no case of respiratory depression occurred in either group, supporting the safety of both agents at the doses studied in line with previous reports that found no respiratory depression with either drug at these doses. This study has several limitations. It was a single-centre study with a modest sample size (28 patients per

group), which limited the power to detect significant differences in secondary categorical outcomes. The open-label design, although accompanied by a standardized, stopwatch-based assessment protocol, may have introduced observer bias in shivering grading. Core temperature was not measured, and the observation window for recurrence was limited. In addition, the Wrench scale is ordinal and was measured repeatedly; separate t-tests at each time point with Bonferroni correction were used for simplicity, and an appropriate repeated-measures or ordinal model would have been statistically more efficient (Crowley & Buggy, Shivering and Neuraxial Anesthesia, 2008). The Bonferroni-adjusted comparisons at 2, 10, and 15 min remained significant despite this conservative approach.

CONCLUSION

In patients with post-spinal shivering undergoing lower limb surgeries under spinal anaesthesia, both IV nalbuphine 0.05 mg/kg and IV tramadol 1 mg/kg provided effective control. Tramadol achieved significantly faster cessation of shivering (3.54 ± 1.46 min vs 4.58 ± 1.52 min; $p = 0.012$), whereas nalbuphine showed a comparatively better gastrointestinal adverse-effect profile with less nausea and vomiting. Both drugs ensured adequate haemodynamic stability and are suitable for clinical use. Larger, adequately powered, preferably blinded multicentre trials with core-temperature monitoring are warranted to confirm these findings and to define the optimal nalbuphine dose.

DECLARATIONS

Availability of Data and Materials

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request, subject to institutional and ethical restrictions.

Competing Interests

The authors declare that they have no competing interests or conflicts of interest related to this study.

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Author contributions:

Conception and design: Shalini Y; methodology and protocol: Shalini Y and Rashmi H R; literature search and screening: Rashmi H R and Akshay B; data extraction and verification: Rashmi H R and Akshay B; statistical analysis and visualisation: Akshay B; manuscript drafting: Shalini Y; critical revision for important intellectual content: Shalini Y, Rashmi H R, and Akshay B. All authors approved the final version and agree to be accountable for all aspects of the work. Ethics approval for this study was granted by the institutional review board, and written informed consent was obtained from all participants prior to enrolment.

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