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COMPARISON OF NALBUPHINE HYDROCHLORIDE AND TRAMADOL HYDROCHLORIDE FOR CONTROLLING POST-SPINAL ANESTHESIA SHIVERING

Original Research

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ABSTRACT

Background: Shivering following spinal anaesthesia is a common postoperative complication that can lead to patient discomfort, increased metabolic demand, and delayed recovery. Effective management of post-spinal shivering is essential for optimizing patient outcomes and enhancing perioperative care. Among pharmacologic agents used to control shivering, tramadol and nalbuphine are widely employed due to their central mechanisms of action. However, limited data exists comparing their efficacy, particularly within the local clinical setting.

Objective: To compare the efficacy of intravenous nalbuphine and tramadol in controlling shivering following spinal anaesthesia.

Methods: This randomized controlled trial was conducted in the Anesthesiology Department of Khyber Teaching Hospital, Peshawar, from 05-February to 05-August 2024. A total of 74 patients aged 18–75 years who developed shivering after spinal anaesthesia were enrolled and randomized into two equal groups. Group A ($n = 37$) received intravenous nalbuphine hydrochloride (0.06 mg/kg) and Group B ($n = 37$) received intravenous tramadol hydrochloride (1 mg/kg), both diluted in normal saline and administered over five minutes. The primary outcome was the time to control shivering, assessed by an experienced anesthesiologist. Data were analyzed using SPSS version 23, with a p-value ≤ 0.05 considered statistically significant.

Results: The mean age was 53.30 ± 14.55 years in Group A and 51.65 ± 14.70 years in Group B. Mean time to control shivering was 4.92 ± 1.01 minutes in the nalbuphine group and 4.11 ± 0.97 minutes in the tramadol group, showing a statistically significant difference ($p = 0.001$).

Conclusion: Tramadol was more effective than nalbuphine in rapidly controlling shivering following spinal anaesthesia, making it a preferable option for prompt perioperative thermoregulation.

Keywords: Anesthesia, Hypothermia, Intravenous Injections, Nalbuphine, Postoperative Complications, Spinal Anesthesia, Tramadol.

INTRODUCTION

The autonomic nervous system plays a crucial role in maintaining core body temperature within a narrow physiological range of 36.5–37.5 °C, irrespective of external environmental variations. This thermoregulatory balance is achieved through a combination of physiological responses and behavioral adaptations. However, during the perioperative period, this homeostatic mechanism is often disrupted, primarily due to the administration of anaesthesia and the surgical insult itself. Anaesthetic agents—particularly regional techniques such as spinal anaesthesia—can significantly impair thermoregulatory control, with a notable decline in core body temperature typically observed within the first 30 minutes following administration (1,2). Such a decline is clinically significant, as even mild perioperative hypothermia has been linked to adverse outcomes including myocardial ischaemia, intensified wound pain, increased risk of surgical site infections, and challenges in intraoperative monitoring. One of the most common and distressing manifestations of perioperative hypothermia is shivering, which not only causes patient discomfort but also increases metabolic demand and oxygen consumption, potentially exacerbating existing comorbidities. Shivering in the perioperative setting is multifactorial, with major contributors being the surgical procedure itself and the effects of spinal anaesthesia. Several mechanisms have been implicated, including evaporative heat loss from exposed surgical fields, administration of unwarmed intravenous fluids, systemic release of pyrogens, postoperative pain, and most importantly, the inhibition of tonic vasoconstriction and impairment of hypothalamic thermoregulation (3,4). Spinal anaesthesia contributes significantly to shivering due to sympathetic blockade, which leads to vasodilation, subsequent heat redistribution from the body's core to its periphery, and ultimately, hypothermia (5–8). This cascade results in a high incidence of postoperative shivering, with studies reporting rates as high as 65% in patients undergoing spinal anaesthesia.

Pharmacologic strategies to manage shivering have thus garnered considerable attention, with agents like tramadol widely utilized in recent decades due to their serotonergic and dopaminergic effects, which reduce shivering by inhibiting the reuptake of these neurotransmitters (9). Another agent of interest is nalbuphine, a mixed opioid agonist-antagonist, known for its unique pharmacologic profile that enables effective modulation of the thermoregulatory threshold. Nalbuphine acts centrally, particularly at the hypothalamic level, where it binds to opioid receptors and influences alpha-2 adrenergic pathways, thus reducing the threshold for vasoconstriction and shivering (10). Comparative data have shown that both tramadol and nalbuphine can rapidly control shivering, with one study reporting mean response times of 3.63 ± 1.57 minutes for tramadol and 4.69 ± 1.64 minutes for nalbuphine (11). Despite evidence supporting the efficacy of both agents, there is a conspicuous absence of local data comparing nalbuphine and tramadol for the management of shivering following spinal anaesthesia. Given the clinical relevance of shivering and its impact on postoperative recovery, especially in resource-limited settings, there is a pressing need to identify the most effective and accessible pharmacologic intervention. Therefore, the present study aims to compare the efficacy of nalbuphine and tramadol in controlling shivering after spinal anaesthesia. This comparison will provide valuable insights to guide therapeutic choices and reduce morbidity associated with postoperative hypothermia.

METHODS

This randomized controlled trial was conducted in the Department of Anesthesiology at Khyber Teaching Hospital, Peshawar, six-month period from 05 February 2024 to 05 August 2024, following approval from the Institutional Review Board (IRB) of the hospital. Written informed consent was obtained from all participants prior to enrollment, and all procedures were performed in accordance with the ethical standards laid out in the Declaration of Helsinki. The sample size was calculated to be 74 patients based on previously reported mean times for control of shivering: 4.692 ± 1.64 minutes for nalbuphine and 3.633 ± 1.572 minutes for tramadol (11). The sample was powered at 80% with a 95% confidence interval. A non-probability consecutive sampling technique was employed, and participants were randomized into two equal groups (n=37 each) using blocked randomization. Eligible participants were aged between 18 and 75 years, of either gender, and experienced shivering following spinal anaesthesia. Patients were excluded if they had a history of cardiopulmonary disease, dysautonomia, sepsis, or pregnancy. Group A received intravenous nalbuphine hydrochloride at a dose of 0.06 mg/kg, while Group B received intravenous tramadol hydrochloride at a dose of 1 mg/kg. Both medications were diluted in normal saline and administered over five minutes. The primary endpoint was the time taken to control shivering, defined as a complication resulting from spinal anaesthesia-induced inhibition of core heat redistribution and tonic vasoconstriction, leading to hypothermia and

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shivering. The outcome was assessed by an experienced consultant anesthesiologist with over five years of clinical practice. Data were analyzed using SPSS version 23. Continuous variables such as age, body mass index (BMI), and time to control shivering were presented as means with standard deviations. Categorical variables including gender, presence of diabetes, and hypertension were reported as frequencies and percentages. The independent sample T-test was used to compare the mean time to control shivering between the two groups. Additionally, stratification was performed based on age, BMI, gender, diabetes, and hypertension to assess their influence on the outcome, also using the T-test. A p-value of ≤ 0.05 was considered statistically significant.

RESULTS

The study enrolled a total of 74 patients who experienced shivering following spinal anaesthesia, with 37 patients in each group. The mean age of participants in the nalbuphine group was 53.30 ± 14.55 years, while the tramadol group had a mean age of 51.65 ± 14.70 years. The average BMI was 25.16 ± 1.51 kg/m² in the nalbuphine group and 25.32 ± 1.32 kg/m² in the tramadol group. In terms of gender distribution, 51.4% of patients in the nalbuphine group were male and 48.6% were female, whereas the tramadol group comprised 62.2% males and 37.8% females. Hypertension was observed in 51.4% of the nalbuphine group and 43.2% of the tramadol group, while diabetes was reported in 24.3% and 21.6% of patients in the respective groups. The primary outcome—mean time to control shivering—was significantly lower in the tramadol group compared to the nalbuphine group. Patients in the tramadol group exhibited a mean time of 4.11 ± 0.97 minutes, while those in the nalbuphine group had a mean time of 4.92 ± 1.01 minutes ($p = 0.001$). Stratified analysis by age groups revealed that tramadol consistently outperformed nalbuphine in all age brackets. Among patients aged 18–35 years, the mean time was 5.20 ± 0.84 minutes with nalbuphine and 4.17 ± 0.41 minutes with tramadol. In the 36–50 years age group, mean values were 5.14 ± 0.90 and 4.09 ± 1.04 minutes for nalbuphine and tramadol, respectively. For patients aged 51–75 years, the mean time to control shivering was 4.80 ± 1.08 minutes for nalbuphine and 4.10 ± 1.07 minutes for tramadol.

Gender-based stratification showed that males in the nalbuphine group required 4.95 ± 0.97 minutes and females 4.89 ± 1.08 minutes, whereas males and females in the tramadol group required 4.26 ± 0.86 and 3.86 ± 1.10 minutes respectively, indicating a shorter duration for both sexes with tramadol. In hypertensive patients, the mean time was 4.89 ± 1.05 minutes for nalbuphine and 3.81 ± 1.05 minutes for tramadol, while in non-hypertensive patients, the times were 4.94 ± 1.00 and 4.33 ± 0.86 minutes respectively. Similarly, among diabetic patients, the mean time to control shivering was slightly longer and statistically insignificant (5.00 ± 1.12 minutes for nalbuphine versus 4.50 ± 0.76 minutes for tramadol; $p > 0.05$), whereas in non-diabetic patients, tramadol showed significantly better performance (4.00 ± 1.00 minutes versus 4.89 ± 0.99 minutes; $p < 0.05$). When stratified by BMI, patients with BMI between 18 and 24.9 kg/m² had a mean time of 5.13 ± 0.89 minutes in the nalbuphine group and 4.11 ± 0.83 minutes in the tramadol group. For those with BMI >24.9 kg/m², the mean times were 4.76 ± 1.09 and 4.11 ± 1.10 minutes respectively, with a statistically insignificant difference in this subgroup.

Table 1: Baseline profile

Baseline characteristics		Groups			
		Group A (Nalbuphine hydrochloride)		Group B (Tramadol hydrochloride)	
		n	%	n	%
Gender	Male	19	51.4%	23	62.2%
	Female	18	48.6%	14	37.8%
Hypertension	Yes	19	51.4%	16	43.2%
	No	18	48.6%	21	56.8%
Diabetes	Yes	9	24.3%	8	21.6%
	No	28	75.7%	29	78.4%

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Table 2: Comparison of time to control shivering in both groups

Time to control shivering (Mins)	Groups	N	Mean	SD	P value
	Group A (Nalbuphine hydrochloride)	37	4.92	1.010	0.001
	Group B (Tramadol hydrochloride)	37	4.11	.966	

Table 3: Stratification of comparison of time to control shivering in both groups with age

Age distribution (Year)		Groups	N	Mean	SD	P value
18 to 35	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	5	5.20	.837	P < 0.05
		Group B (Tramadol hydrochloride)	6	4.17	.408	
36 to 50	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	7	5.14	.900	P < 0.05
		Group B (Tramadol hydrochloride)	11	4.09	1.044	
51 to 75	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	25	4.80	1.080	P < 0.05
		Group B (Tramadol hydrochloride)	20	4.10	1.071	

Table 4: Stratification of comparison of time to control shivering in both groups with gender

Gender		Groups	N	Mean	SD	P value
Male	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	19	4.95	.970	P < 0.05
		Group B (Tramadol hydrochloride)	23	4.26	.864	
Female	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	18	4.89	1.079	P < 0.05
		Group B (Tramadol hydrochloride)	14	3.86	1.099	

Table 5: Stratification of comparison of time to control shivering in both groups with hypertension

Hypertension		Groups	N	Mean	SD	P value
Yes	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	19	4.89	1.049	P < 0.05
		Group B (Tramadol hydrochloride)	16	3.81	1.047	
No	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	18	4.94	.998	P < 0.05
		Group B (Tramadol hydrochloride)	21	4.33	.856	

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Table 6: Stratification of comparison of time to control shivering in both groups with diabetes

Diabetes		Groups	N	Mean	SD	P value
Yes	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	9	5.00	1.118	P > 0.05
		Group B (Tramadol hydrochloride)	8	4.50	.756	
No	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	28	4.89	.994	P < 0.05
		Group B (Tramadol hydrochloride)	29	4.00	1.000	

Table 7: Stratification of comparison of time to control shivering in both groups with BMI

BMI (Kg/m2)		Groups	N	Mean	SD	P value
18 to 24.9	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	16	5.13	.885	P < 0.05
		Group B (Tramadol hydrochloride)	18	4.11	.832	
> 24.9	Time to control shivering (Mins)	Group A (Nalbuphine hydrochloride)	21	4.76	1.091	P > 0.05
		Group B (Tramadol hydrochloride)	19	4.11	1.100	

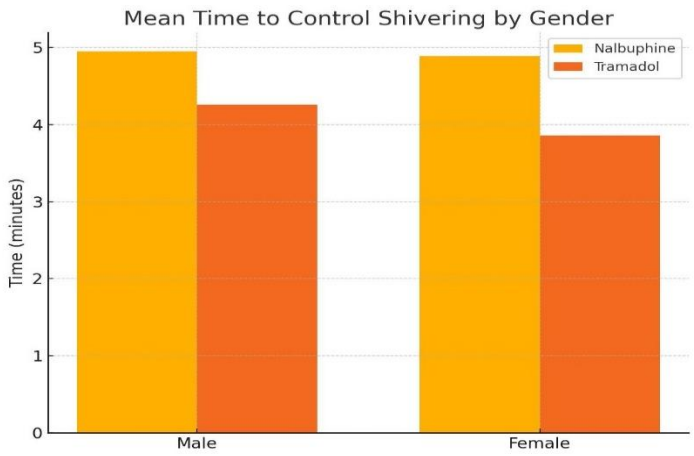

Figure 1 Mean Time to Control Shivering by Gender

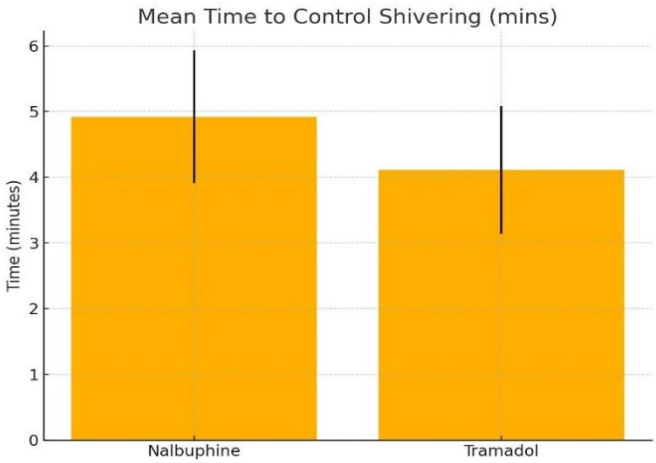

Figure 2 Mean Time to Control Shivering (mins)

DISCUSSION

The findings of the present study demonstrated that both nalbuphine and tramadol were effective in controlling shivering following spinal anaesthesia; however, tramadol showed a notably faster response in terminating shivering episodes. This difference in onset time, although modest, may have clinical implications in settings where rapid resolution is prioritized. The comparatively shorter duration to control shivering in the tramadol group may be attributed to its central monoaminergic activity, particularly the inhibition of serotonin and norepinephrine reuptake. Conversely, nalbuphine, as a mixed opioid receptor agonist-antagonist, may modulate the hypothalamic thermoregulatory threshold through its affinity for kappa and mu receptors, which could explain its slightly delayed but still effective action. The results were consistent with prior literature. In a randomized controlled trial evaluating the hemodynamic stability and response time of both drugs, it was reported that tramadol achieved shivering control more rapidly than nalbuphine, with comparable

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safety profiles and minimal hemodynamic disturbances (12-14). Similarly, another comparative study involving intravenous administration of tramadol and nalbuphine found both drugs equally efficacious, with minimal difference in onset times. The inclusion of adjunctive agents like midazolam in those trials possibly influenced sedation levels but did not substantially alter the primary outcomes related to shivering control (15,16). A multicentric investigation conducted within a local setting also reported equivalent efficacy for both drugs in patients undergoing cesarean section. Although the results highlighted therapeutic parity, the study was limited by its focus on a single surgical category, which may affect generalizability (17-19).

Interestingly, contrasting findings emerged in a separate clinical trial where nalbuphine exhibited a faster onset of action. However, this was accompanied by a higher degree of sedation, suggesting a potential trade-off between therapeutic speed and patient comfort. The same study also noted an increased incidence of nausea and vomiting in the tramadol group, aligning with the well-documented emetogenic potential of serotonergic agents (20,21). These varying outcomes highlight the nuanced pharmacological profiles of both agents and underscore the importance of tailoring treatment decisions to individual patient characteristics, clinical settings, and coexisting conditions. The strength of this study lies in its randomized design and balanced comparison between two widely used pharmacological options. By applying rigorous inclusion and exclusion criteria, as well as stratified analysis across age, gender, BMI, and comorbidities, the findings offer valuable insight into the differential response patterns within diverse patient subgroups. Furthermore, the use of a standardized dosage regimen and the involvement of a senior anesthesiologist for outcome assessment added reliability to the measured endpoints.

However, some limitations must be acknowledged. The study sample size, although adequately powered, was relatively small and confined to a single tertiary care center, which may limit the external validity of the findings. Moreover, while the primary outcome focused on the time to control shivering, secondary outcomes such as the severity of shivering, recurrence rate, sedation levels, and adverse drug reactions were not systematically assessed. The omission of this data restricts comprehensive evaluation of the safety and tolerability profiles of both drugs. Additionally, blinding was not mentioned, raising the potential for assessment bias. The study also did not account for patient-reported comfort or satisfaction, which are relevant clinical endpoints in anaesthetic care. fetFuture research should aim for larger, multicenter trials that explore these agents across a wider surgical spectrum and include extended follow-up to evaluate recurrence of shivering and long-term side effects. Incorporating objective measures of sedation and thermoregulatory biomarkers would also enhance the understanding of the underlying mechanisms involved. Despite these limitations, the present findings contribute meaningfully to the growing body of evidence supporting the clinical utility of both tramadol and nalbuphine in managing post-spinal anaesthesia shivering, providing anesthesiologists with a data-driven basis for therapeutic decision-making.

CONCLUSION

This study concludes that while both tramadol and nalbuphine are effective in managing shivering following spinal anaesthesia, tramadol demonstrated a faster onset of action, making it the more efficient option in clinical practice. The findings underscore tramadol's potential as a preferred first-line agent for prompt control of post-spinal shivering, contributing to improved perioperative patient comfort and reducing the physiological stress associated with hypothermic responses.

AUTHOR CONTRIBUTION

Author	Contribution
Gul Rukh*	Data Entry, Data Acquisition, Data Analysis, Manuscript Writing, and Manuscript Revision
Umbrin Naz	Critical Input, Study Design Conception, Final Approval of Draft
Romaila Mumtaz	Critical Input, Literature Review
Parhaizgar Khan	Critical Input, Literature Review

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