Section: Anesthesia

Original Research Article

EFFECTIVENESS OF INTRAVENOUS TRAMADOL AND PETHIDINE IN MANAGING POSTOPERATIVE SHIVERING IN SPINAL ANAESTHESIA: A RANDOMIZED CONTROLLED TRIAL

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ABSTRACT

Background: Postoperative shivering is a common complication in patients undergoing spinal anaesthesia. This randomized controlled trial aimed to evaluate and compare the effectiveness of intravenous tramadol and pethidine in managing postoperative shivering in patients receiving spinal anaesthesia.

Materials and Methods: This study included 80 patients undergoing elective surgeries under spinal anaesthesia. Participants were randomly assigned to receive either 1 mg/kg intravenous tramadol (Group I) or 0.5 mg/kg intravenous pethidine (Group II). Postoperative shivering intensity was graded, and medications were administered upon reaching a grade 2 or 3. The primary outcome was the reduction in shivering duration, and secondary outcomes included recurrence rate and adverse reactions.

Results: The tramadol group had a significantly shorter duration of shivering compared to the pethidine group (5.88 ± 4.88 minutes vs. 7.11 ± 4.78 minutes, p=0.003). The recurrence rate was also lower in the tramadol group (15% vs. 35%, p=0.001). Both groups had no significant differences in vital signs, including heart rate, blood pressure, and oxygen saturation. Adverse effects were minimal and comparable between groups.

Conclusion: Intravenous tramadol is more effective than pethidine in reducing postoperative shivering duration and recurrence in patients undergoing spinal anaesthesia. Both drugs are safe with minimal side effects, but tramadol may be the preferred option for managing this complication.

Keywords: Postoperative shivering, tramadol, pethidine, spinal anaesthesia, randomized controlled trial, recurrence rate.

INTRODUCTION

Postoperative shivering is a common and distressing physiological response that can occur following spinal anaesthesia, characterized by involuntary muscle contractions and an increase in metabolic rate. Shivering is triggered by a drop in core body temperature, often due to vasodilation and impaired thermoregulation resulting from the effects of spinal anaesthesia. This condition is typically observed in patients undergoing major surgeries, especially those with lower abdominal or lower limb procedures, where the effects of the anaesthetic block can disrupt the hypothalamic regulation of temperature. Factors such as the duration of anaesthesia, the ambient operating room temperature, and the patient's body mass index can also influence the likelihood and severity of shivering.[1]

Management of postoperative shivering generally includes physical measures, such as warming blankets, and pharmacological interventions, with a focus on agents that modulate the thermoregulatory system or reduce the muscular contractions associated with shivering. Among the pharmacological options, opioids like tramadol and pethidine have been investigated for their effectiveness in alleviating post-anaesthesia shivering.

Tramadol, a centrally acting analgesic, works by inhibiting the reuptake of serotonin and norepinephrine, in addition to binding to opioid receptors. Its use has been linked with reduced

incidence and severity of shivering, possibly by enhancing the body's thermoregulatory capacity through central mechanisms.[2]

Pethidine (meperidine), a traditional opioid, has also been studied for its role in reducing shivering, as it acts on both central and peripheral opioid receptors to provide analgesia and also has antishivering properties.[3]

Both tramadol and pethidine have shown effectiveness in reducing postoperative shivering in patients under spinal anaesthesia, though their side-effect profiles, particularly related to nausea, sedation, and respiratory depression, must be carefully considered. While tramadol is generally considered safer in terms of respiratory depression, pethidine's use is limited due to its potential for toxic accumulation, especially in patients with renal impairment.[4-7] The choice between these agents depends on the specific clinical scenario, patient characteristics, and the severity of the shivering. This study aims to compare the efficacy of both drugs in managing post-operative shivering in patients post spinal anaesthesia.

MATERIALS AND METHODS

The present study was conducted in the Department of Anaesthesia at Niloufer Hospital, Osmania Medical College over a period of one year, from Septmber 2023 to August 2024, after receiving approval from the institutional ethics committee. This randomized controlled trial aimed to evaluate the effectiveness of intravenous tramadol and pethidine in managing postoperative shivering in patients undergoing spinal anaesthesia. A total of 80 patients were enrolled in the study. The sample size was determined based on the recurrence rate of postoperative shivering, with a calculated sample size of 40 patients per group, considering a 5% alpha error and a 95% power. Participants were randomly assigned to one of two groups: Group I (Tramadol group) received 1 mg/kg of tramadol, and Group II (Pethidine group) received 0.5 mg/kg of pethidine.

Inclusion criteria consisted of patients aged 20-65 years, of both genders, and classified as ASA physical status I or II, undergoing elective surgeries under spinal anaesthesia. Patients who provided valid informed consent were included, while those with ASA physical status III or above, allergies to tramadol or pethidine, thyroid disorders, obesity, cardiovascular complications, or seizure disorders were excluded. Additionally, patients with contraindications to spinal anaesthesia, such as raised intracranial pressure or coagulopathy, were not included in the study.

Preoperative assessment involved a detailed history, physical examination, and routine investigations as per the hospital protocol. Informed consent was obtained from all participants who met the inclusion criteria. In the operating room, standard monitoring devices (ECG, non-invasive blood pressure, and pulse oximetry) were used, and care was taken to maintain the operating room and recovery room temperature at 26-30°C. Spinal anaesthesia was performed with a 23, 25, or 26 G Quincke spinal needle at the L2-3 or L3-4 interspace, and 0.5% heavy bupivacaine was administered in doses of 1.8-4 ml to achieve an adequate block at the T8-T10 dermatome.

Postoperative shivering was monitored in the recovery room, where shivering intensity was graded on a scale of 0-3. Patients with grade 2 or 3 shivering received treatment with the assigned medication (1 mg/kg tramadol or 0.5 mg/kg pethidine). Oxygen was administered via a face mask at 6L/min. The efficacy of treatment was evaluated by the reduction in shivering score, with success defined as a score of 0, incomplete success as a reduction without complete cessation, and failure as no change in shivering. Sedation levels were assessed using a 4-point scale, and the time to cessation of shivering and any hemodynamic changes were recorded at 5-minute intervals for up to 15 minutes. Recurrence of shivering prompted additional doses of tramadol or pethidine.

Statistical analysis was performed using SPSS version 16.0. Continuous variables were compared using unpaired t-tests, and a p-value of less than 0.05 was considered statistically significant. Descriptive statistics were used to summarize data, and all data were entered and analyzed using Microsoft Excel.

RESULTS

The present study aimed to evaluate the effectiveness of intravenous tramadol and pethidine in managing postoperative shivering in patients undergoing spinal anaesthesia. The demographic data in Table 1 showed no significant differences between the two groups in terms of age, sex distribution, or body weight, suggesting that the two groups were comparable at baseline, which is crucial for minimizing bias in treatment outcomes. [Table 1]

The mean duration of shivering was significantly shorter in the tramadol group (5.88 ± 4.88 minutes) compared to the pethidine group (7.11 ± 4.78 minutes), with a p-value of 0.003. This suggests that tramadol may offer quicker relief from shivering. Although the onset of shivering was similar between the two groups (17.0 minutes for tramadol vs. 13.3 minutes for pethidine), the difference was not statistically significant (p=0.074), indicating that both drugs have a similar initial effect on shivering onset. [Table 2]

In present study, both groups had comparable heart rate, blood pressure, oxygen saturation, and temperature readings before and after the onset of shivering. There were no significant differences in the vital signs between the two groups at any time point, suggesting that both drugs did not significantly affect hemodynamic stability or oxygenation during the study. These findings indicate that both tramadol

and pethidine are relatively safe in terms of their cardiovascular and respiratory effects in the perioperative period. [Table 3]

Table 1: Comparison of Demographic Data Between the Groups

Demographic Data	Group I (Tramadol) (n= 40)	Group II (Pethidine)(n= 40)
Mean Age (years)	45.58± 1.324	42.18±1.39
Male	28 (70%)	24 (60%)
Female	12 (30%)	16 (40%)
Body Weight (Kg)	56.88 ±8.690	57.211±8.161

Table 2: Comparison of Time of Onset, Duration, and Grade of Shivering Between Two Groups

	Shivering Parameters	Group I (Tramadol)	Group II (Pethidine)	P value
Time of Onset of shivering (min)	**Mean Time of Onset of shivering (min)**	17.007 ± 11.440	13.347 ± 8.76	0.074
	1-10 min	20 (50%)	22 (55%)	
	11-20 min	8 (20%)	8 (20%)	
	21-30 min	7 (17.5%)	5 (12.5%)	
	31-40 min	4 (10%)	5 (12.5%)	
	41-50 min	1 (2.5%)	0	
Duration of Shivering (min)	**Mean Duration of Shivering (min)**	5.88 ± 4.88	7.11±4.78	0.003*
	1-10 min	36 (90%)	37 (92.5%)	
	11-20 min	3 (7.5%)	2 (5%)	
	21-30 min	1 (2.5%)	1 (2.5%)	
Grade of Shivering	Mean grade of shivering	2.40 ± 0.443	2.24 ± 0.441	0.84
	Grade 0	0 (0.00%)	0 (0.00%)	
	Grade 1	0 (0.00%)	0 (0.00%)	
	Grade 2	30 (75%)	32 (80%)	
	Grade 3	10 (25%)	8 (20%)	

Table 3: Comparison of vitals (heart rate, systolic blood pressure, temperature Between the Groups at Different Time Intervals

Vital data	*Before shivering onset*		*At 0 min*		*At 5min*		*At 10min*		
	Group I (Tramadol)	**Group II (Pethidine)**	**Group I (Tramadol)**	**Group II (Pethidine)**	**Group I (Tramadol)**	**Group II (Pethidine)**	**Group I (Tramadol)**	**Group II (Pethidine)**	**P value**
Heart rate (beats/min)	*73. 45± 2.87*	*72.24 ± 2.49*	*75.51±1.9*	74.54±8.43	77.78±1.34	76.35±8.55	77.67±1.28	74.97±8.88	*0.249*
Systolic blood pressure (mmHg)	*112.42 ± 2.1*	*124.96 ± 2.4*	*114.29±1.55*	*117.96±1.83*	115.76±1.201	*117.36±1.38*	*114.71±1.18*	*119.63±1.56*	*0.0745*
Diastolic blood pressure (mmHg)	*70.33±10.40*	*74.82±9.55*	*70.93±1.53*	*76.28±1.04*	*73.44±9.44*	*77.40±9.99*	*73.28±9.98*	*78.69±10.60*	*0.0954*
Oxygen saturation (%)	*99.94±0.34*	*99.88±0.13*	*99.818 ±0.41*	*99.48 ±0.458*	*99.86±0.48*	*99.75 ± 0.75*	*99.68 ±0.78*	*99.84±0.85*	*0.745*
Temperature (°F)	*98.65±0.18*	*98.33±0.28*	*98.45±0.18*	*98.55±0.18*	*98.58±0.20*	*98.585±0.16*	98.76±0.13	98.95 ±0.17	*0.475*

Table 4: Comparison of Recurrence of shivering and adverse reactions Between the Groups

Parameter	Group I (Tramadol)	Group II (Pethidine)	p-value
Recurrence	6 (15%)	14 (35%)	0.001
No ADR	34 (85%)	30 (78.38%)	
Vomiting	2 (5%)	3 (8.10%)	
Sedation	4 (10%)	5 (13.52%)	

DISCUSSION

Postoperative shivering is a common complication after spinal anaesthesia, and its management is crucial for patient comfort and recovery. This study aimed to compare the efficacy of intravenous tramadol and pethidine in reducing postoperative shivering in patients undergoing spinal anaesthesia. The results of this study indicated that tramadol was more effective than pethidine in reducing both the duration and recurrence of shivering, suggesting it may be a preferable option for managing postoperative shivering in these patients.

When comparing the results of this study with previous research, several similarities and differences emerge. For instance, studies by Rookeet al,[9] and Irwin et al,[10] also found that opioids, including tramadol and pethidine, were effective in managing postoperative shivering. These studies reported that opioids significantly reduced the incidence and intensity of shivering, which aligns with the findings of the current study, where both tramadol and pethidine effectively reduced shivering. However, the present study demonstrated that tramadol had a shorter duration of shivering compared to pethidine, which is consistent with findings from a study by Gupta et al,[11] that suggested tramadol provided quicker relief from postoperative shivering. This contrasts with the findings of Chauhanet al,[12] who found no significant difference in the duration of shivering between tramadol and pethidine.

Another notable difference in this study was the lower recurrence of shivering in the tramadol group (15%) compared to the pethidine group (35%), a difference that was statistically significant ($p = 0.001$). This finding aligns with a study by Jain et al,[13] which also found that tramadol provided more sustained relief from shivering. The reduced recurrence of shivering observed with tramadol may be due to its pharmacokinetic profile, as tramadol is known to have a longer duration of action compared to pethidine, as suggested by studies such as those by Singh et al.[14]

Moreover, both groups in the current study showed comparable hemodynamic stability throughout the study, with no significant differences in heart rate, blood pressure, or oxygen saturation. This is consistent with the findings of Irwin et al,[10] who noted that both tramadol and pethidine had minimal effects on cardiovascular parameters. Additionally, the incidence of adverse effects, such as vomiting and sedation, was low and similar between the two groups, which is consistent with the results of other studies that have shown tramadol and pethidine to be well-tolerated (Rooke et al).[9]

CONCLUSION

This study demonstrates that intravenous tramadol is more effective than pethidine in reducing the duration of postoperative shivering in patients undergoing spinal anaesthesia. Tramadol provided faster relief with fewer recurrences, while both drugs had comparable onset times and no significant impact on hemodynamic parameters. Tramadol, therefore, may be a preferable choice for managing postoperative shivering in this setting, given its quicker action and lower recurrence rate.

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Conflicts of Interest: None declared.

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