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Original Research Article

A Comparative Study between the Efficacy of Intravenous Tramadol and Intravenous Dexmedetomidine in Prevention of Shivering Following Subarachnoid Block

Dr. Vimukta Kumari[1], Dr. Kirti Bala[2], Dr. Vineet Kumar[3*]

[1]Assistant Professor, Department of Anaesthesiology, SRIMS and Sanaka Hospitals, Durgapur, West Bengal, India.
[2]Assistant Professor Department of Pharmacology, SRIMS and Sanaka Hospitals, Durgapur, West Bengal, India.
[3*]Associate Professor, Department of Pharmacology, SRIMS and Sanaka Hospitals, Durgapur, West Bengal, India.
Corresponding Author: Dr. Vineet Kumar
Associate Professor, Department of Pharmacology, SRIMS and Sanaka Hospitals, Durgapur, West Bengal, India.

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ABSTRACT
Background: Shivering is a common complication following subarachnoid block (SAB), occurring in approximately 40–70% of patients. It increases oxygen consumption, carbon dioxide production, cardiac workload, and patient discomfort. Various pharmacological agents have been used for its prevention, among which tramadol and dexmedetomidine are commonly employed. This study was undertaken to compare the efficacy of intravenous tramadol and intravenous dexmedetomidine in preventing shivering following subarachnoid block.
Aim: To compare the efficacy of intravenous tramadol versus intravenous dexmedetomidine in the prevention of shivering following subarachnoid block.
Methods: This prospective, randomized, double-blind, controlled study was conducted in the Department of Anaesthesiology, Durgapur Steel Plant Hospital, West Bengal. Ninety ASA physical status I and II patients aged 18–50 years undergoing elective lower abdominal or lower limb surgeries under spinal anaesthesia were enrolled and randomized into two groups of 45 patients each.
Group A received intravenous tramadol 0.5 mg/kg diluted in 100 mL normal saline, while Group B received intravenous dexmedetomidine 0.5 mcg/kg diluted in 100 mL normal saline following SAB. Shivering score, onset, cessation time and duration of shivering, haemodynamic parameters, sedation score, and adverse effects were assessed at predefined intervals.
Results: The demographic characteristics of both groups were comparable. There was no statistically significant difference between the tramadol and dexmedetomidine groups regarding incidence, onset, cessation time, duration, or severity of shivering ($p > 0.05$). Haemodynamic parameters remained stable and comparable in both groups. However, patients receiving dexmedetomidine demonstrated significantly higher sedation scores without respiratory depression ($p < 0.001$).
The tramadol group showed a significantly higher incidence of nausea and vomiting compared with the dexmedetomidine group.
Conclusion: Both intravenous tramadol and intravenous dexmedetomidine are effective in preventing shivering following subarachnoid block. While their anti-shivering efficacy is comparable, dexmedetomidine provides superior sedation with fewer incidences of nausea and vomiting and without significant respiratory depression. Therefore, dexmedetomidine may be preferred when patient comfort and reduced adverse effects are desired, although cost and availability should also be considered.

Keywords: Subarachnoid Block, Spinal Anaesthesia, Shivering, Tramadol, Dexmedetomidine, Sedation, Postoperative Complications.

INTRODUCTION

Subarachnoid block (SAB) is one of the most commonly employed regional anaesthetic techniques for lower abdominal, pelvic, perineal, and lower limb surgeries because of its simplicity, rapid onset, cost-effectiveness, and reliable sensory and motor blockade.

Despite its widespread use and favourable safety profile, shivering remains a frequent and distressing complication following spinal anaesthesia, with a reported incidence ranging from 40% to 70%.[1]

Post-spinal shivering is characterized by involuntary, rhythmic muscular activity that increases metabolic heat production in response to perioperative hypothermia. Although considered a protective physiological mechanism, shivering may have several detrimental consequences, including increased oxygen consumption, carbon dioxide production, cardiac output, and metabolic demand. These changes can be particularly harmful in patients with limited cardiopulmonary reserve.[2-4]

The pathophysiology of shivering following spinal anaesthesia is multifactorial. Sympathetic blockade-induced vasodilatation promotes heat redistribution from the core to the periphery, while inhibition of thermoregulatory vasoconstriction and reduced afferent thermal input alter hypothalamic temperature regulation. In addition to hypothermia, factors such as pain, release of endogenous pyrogens, adrenal suppression, respiratory alkalosis, and uninhibited spinal reflexes have been implicated in the development of postoperative shivering.[5,6]

Various pharmacological agents have been investigated for the prevention and treatment of post-anaesthetic shivering. Tramadol, a centrally acting μ-opioid receptor agonist, exerts anti-shivering effects through modulation of serotonergic and noradrenergic pathways involved in thermoregulation. Dexmedetomidine, a highly selective α2-adrenergic agonist, reduces shivering by lowering the vasoconstriction and shivering thresholds while providing sedation and analgesia. Therefore, this study is done to compare the efficacy of intravenous tramadol and intravenous dexmedetomidine in preventing shivering following subarachnoid block.[7-10]

Aim & Objectives

Aim

To comparing the efficacy of intravenous Tramadol versus intravenous Dexmedetomidine in prevention of shivering following subarachnoid block

Objectives

1. To compare the grade of shivering.
2. To compare the time of onset of shivering (in minutes).
3. To compare the time required for cessation of shivering.
4. To monitor and evaluate any recurrences of shivering.
5. To compare hemodynamic changes (if any).
6. To compare adverse effects (if any).

MATERIAL AND METHODS

Study Design

This Prospective, randomized, double-blind, interventional controlled study was conducted in the Department of Anaesthesiology, Durgapur Steel Plant Hospital, Durgapur, West Bengal, for a period of 12 months (December 2020 to December 2021).

Study Population

Ninety patients of either sex, aged 18–50 years, belonging to ASA physical status I and II, scheduled for elective lower abdominal and lower limb surgeries under subarachnoid block were enrolled. Patients were randomly allocated into two groups of 45 patients each.

Inclusion Criteria

1. Age 18–50 years.
2. ASA physical status I and II.
3. Height between 150 cm and 175 cm.

Exclusion Criteria

Patient refusal, coagulation disorders, thyroid disease, Parkinsonism, dysautonomia, Raynaud's syndrome, cardiopulmonary disease, allergy to study drugs, need for blood transfusion, alcohol use, use of sedative-hypnotics or vasodilators, baseline temperature >37.5°C or <36.5°C, sepsis, caesarean section, and failed subarachnoid block.

Sample Size

Based on the study by Semsettin Bozgeyik et al.[11] with 95% confidence interval and 80% study power, the minimum required sample size was calculated as 45 patients per group, giving a total sample size of 90 participants.

Randomization and Blinding

Patients were randomly allocated into two equal groups. The study was conducted in a double-blind fashion. Group A received intravenous tramadol 0.5 mg/kg diluted in 100 mL normal saline, whereas Group B received intravenous dexmedetomidine 0.5 µg/kg diluted in 100 mL normal saline. Study drugs were infused over 5 minutes immediately after administration of subarachnoid block.

Anaesthetic Technique

Operating room temperature was maintained at 22–24°C. Intravenous fluids were administered at room temperature. Following placement of an 18G intravenous cannula and baseline monitoring, patients underwent subarachnoid block using hyperbaric bupivacaine. Standard monitoring included ECG, non-invasive blood pressure, pulse oximetry, heart rate, and skin temperature. No active warming devices were used. Patients were covered with standard surgical drapes intraoperatively and a cotton blanket postoperatively.

Parameters Evaluated

Scoring for shivering graded with 5-point scale validated by Crossly and Mahajan were;
0 = No shivering
1 = piloerection or peripheral vasoconstriction but no visible shivering
2 = muscular activity in only one muscle group
3 = muscular activity in more than one muscle group
4 = whole body shivering
Level of sedation was assessed by means of Ramsay sedation scale;
1 point = worried, agitated or unpeaceful
2 point = co-operative, oriented and calm
3 point = responds to oral warnings
4 point = snoozing, gives lively response to hitting between the eye brows or loud noise
5 point = snoozing, slowly responds to hitting between eyebrows or loud noise
6 point = snoozing, no response.
Hypotension episodes were defined as MAP<80% of Baseline MAP or MAP<65mmHg
Bradycardia defined as HR <60 beats/min.
Decrease of SpO2 below 90% at room temperature to be considered as hypoxemia.
Nausea and vomiting; the presence of nausea or vomiting was measured on a 4 point scale with 1– no nausea
2- only nausea no vomiting
3- frequent vomiting,
4 – severely (continuously) vomiting

Outcome Measures

Primary outcomes included incidence and grade of shivering, onset of shivering, time to cessation of shivering, and duration of shivering. Secondary outcomes included haemodynamic variables (heart rate, mean arterial pressure, oxygen saturation), sedation scores, recurrence of shivering, and adverse effects such as nausea and vomiting. The MAP (NIBP), HR, SPO2, Shivering score, shivering onset, cessation and duration, sedation score and nausea and vomiting score were recorded at intervals of 0, 15, 30, 45, 60, 75, 90, 105 and 120 min (T0 to T8).

Statistical Analysis

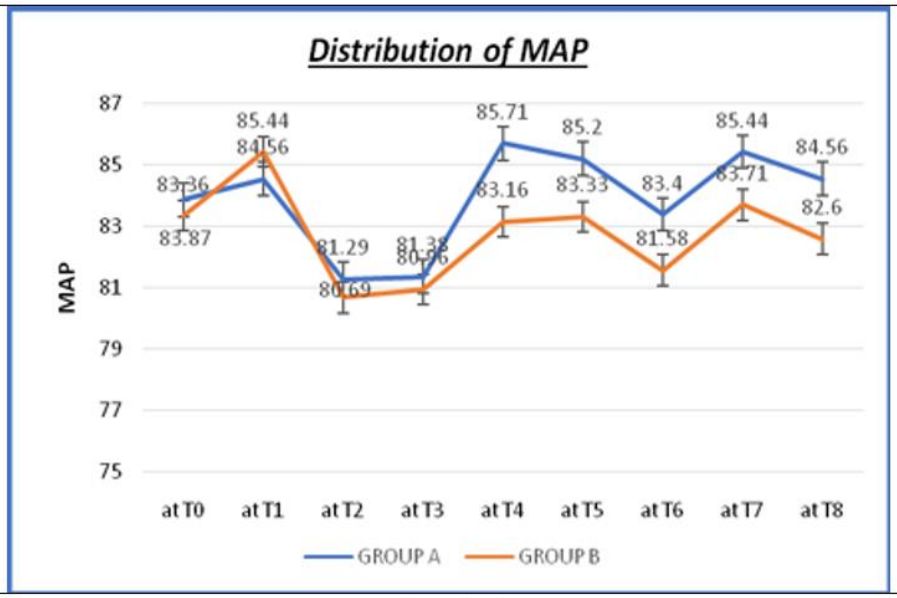
Data were analysed using SPSS version 22. Continuous variables were expressed as Mean ± Standard Deviation (SD), while categorical variables were presented as number and percentage. Intergroup comparison of continuous variables was performed using the Independent Student's t-test. Categorical variables were analysed using the Chi-square test or Fisher's Exact test as appropriate. A p-value <0.05 was considered statistically significant.

RESULTS

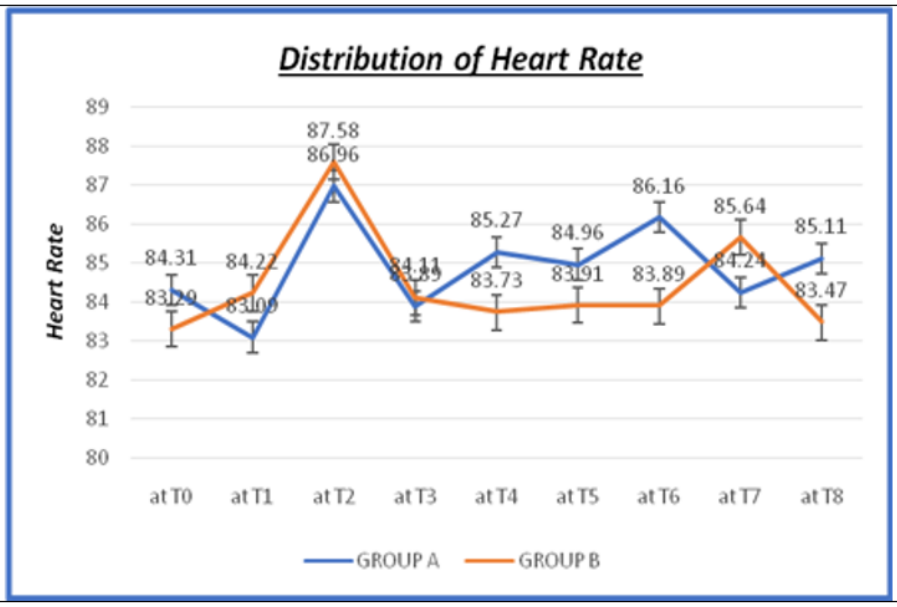
A total of 90 patients undergoing elective lower abdominal or lower limb surgeries under spinal anaesthesia were enrolled and randomized into two equal groups (n=45 each). Group A received intravenous tramadol 0.5 mg/kg and Group B received intravenous dexmedetomidine 0.5 µg/kg following subarachnoid block.
Baseline Characteristics There were no statistically significant differences between the two groups with respect to age, height, and weight (p>0.05), indicating that both groups were demographically comparable.

Demographic Data	Group A(n=45)		Group B (n=45)		P value
	Mean	SD	Mean	SD	
Age(years)	43.36	4.73	42.09	4.532	0.198
Height (cms)	156.24	4.129	155.96	4.327	0.747
Weight (kg)	64.42	7.356	62.49	6.969	0.204
Table 1: Comparison of Age, Height and Weight among two study groups					
Independent T test					

Table 1 shows that there was no statistically significant differences between the groups with respect to patient's age, height, weight (p value > 0.05). Hence, both the groups were comparable in terms of demographic parameters. Hemodynamic Variables-Mean arterial pressure (MAP) and heart rate remained stable throughout the study period in both groups. No statistically significant intergroup differences were observed at any recorded time point (p>0.05).

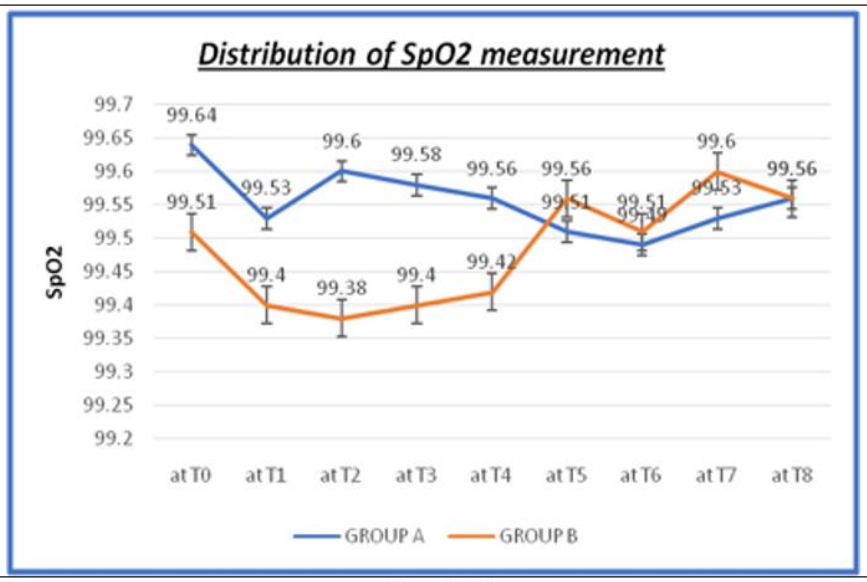


Graph 1



Graph 2

Oxygen saturation (SpO2) remained within normal limits in all patients, with no significant differences between groups.



Graph 3

The incidence and severity of shivering were comparable between the two groups. In the tramadol group, the highest incidence of shivering was observed at T5 (6.7%), whereas in the dexmedetomidine group it was observed at T3 (6.7%). However, these differences were not statistically significant (p>0.05). The mean onset of shivering was 54.0 minutes in the tramadol group and 49.4 minutes in the dexmedetomidine group. Mean duration of shivering was 9.5 minutes and 10.2 minutes, respectively. Time to cessation of shivering was also comparable between groups. No statistically significant differences were observed for onset, duration, or cessation of shivering (p>0.05).

Shivering Score

At	Shivering score	Group A		Group B		P value
		Count	%	Count	%	
T0	0	45	100	44	98	0.315
	1			1	2.2	
T1	0	44	97.8	45	100	0.315
	1	1	2.2			
T2	0	44	97.8	43	96	0.603
	1	1	2.2	1	2.2	
	2			1	2.2	
T3	0	44	97.8	42	93	0.132
	1			3	6.7	
	2	1	2.2			
T4	0	45	100	43	96	0.153
	1			2	4.4	
T5	0	42	93.3	44	98	0.306
	1	3	6.7	1	2.2	
T6	0	44	97.8	45	100	0.315
	1	1	2.2			
T7	0	45	100	45	100	
T8	0	45	100	45	100	

Table 2: Comparison of Shivering Score among Two Study Groups

Chi-square test

Incidence of shivering in group A was maximum at T5 with 6.7% with shivering score 1, while incidence of shivering was maximum at T3 with 6.7% with shivering score 1 in Group B. While comparing it was found that incidence of shivering and shivering score was statistically

insignificant (p value >0.05) in both groups at all time intervals.

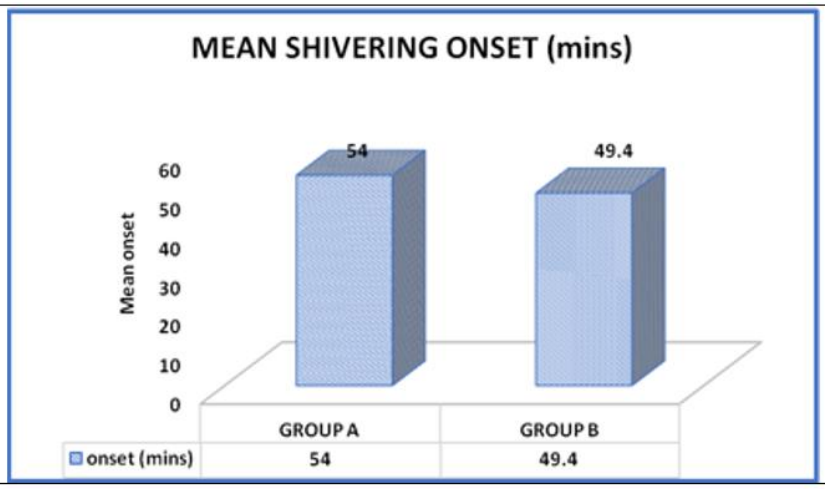
Shivering Characteristics

Shivering characteristics	Group A (n=6)		Group B (n=5)		P value
	Mean	SD	Mean	SD	
onset (mins)	54	26.268	49.4	15.534	0.739
cessation (mins)	64.17	28.209	59.6	14.588	0.752
duration (mins)	9.5	1.643	10.2	3.114	0.643

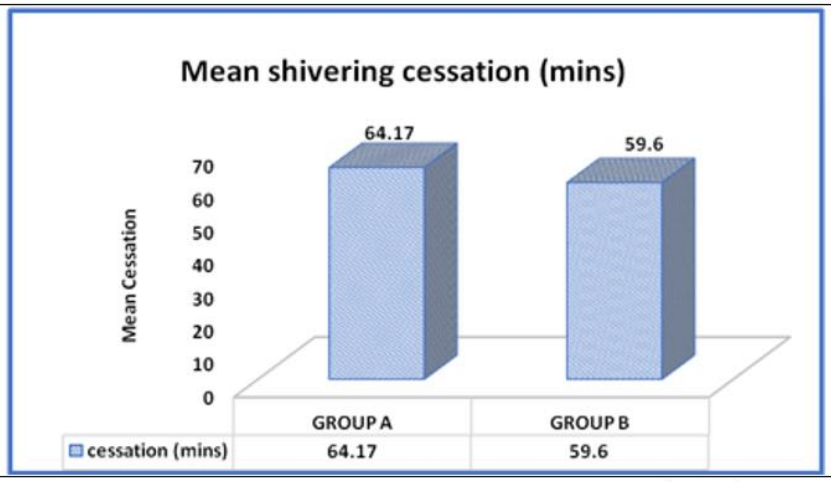
Table 3: Comparison of Onset, Cessation and Duration of Shivering among Two Study Groups

Independent T test

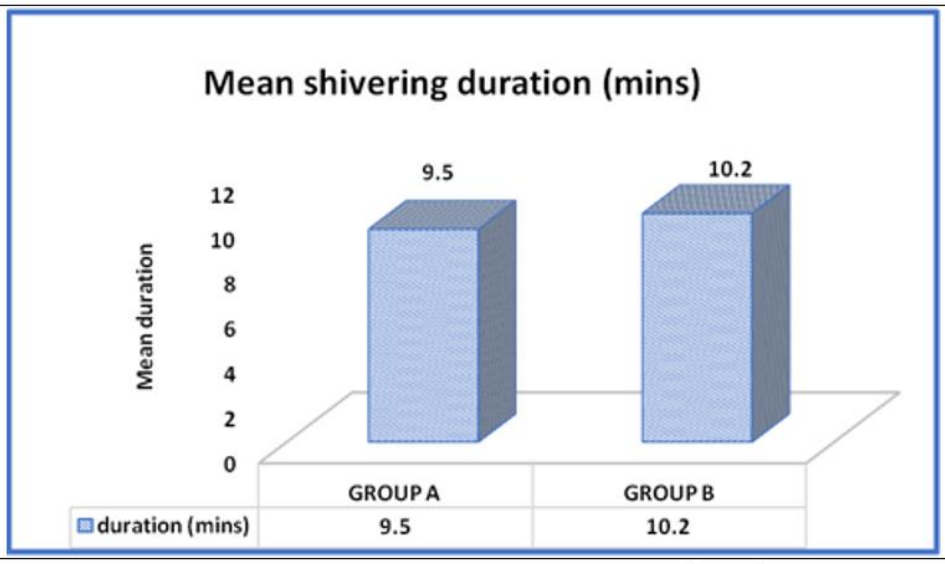
Table 3 shows that there was no statistically significant difference between the groups with respect to onset, cessation and duration of shivering (p value > 0.05). So, both the groups were comparable in terms of shivering characteristics.



Graph 4: mean onset of shivering (mins)



Graph 5: Mean cessation time of shivering (mins)



Graph 6: Mean duration of shivering (mins)

Sedation scores were significantly higher in the dexmedetomidine group than in the tramadol group ($p<0.001$). Patients receiving dexmedetomidine remained cooperative, tranquil, and responsive to verbal commands while demonstrating a greater degree of sedation.

Sedation Score

At	Sedation score	Group A		Group B		P value
		Count	%	Count	%	
T0	1	21	47	10	22	< 0.001
	2	24	53	20	44	
	3			15	33	
T1	1	17	38	8	18	< 0.001
	2	28	62	18	40	
	3			19	42	
T2	1	21	47	5	11	< 0.001
	2	24	53	14	31	
	3			26	58	
T3	1	25	56	3	6.7	< 0.001
	2	20	44	17	38	
	3			25	56	
T4	1	26	58	3	6.7	< 0.001
	2	19	42	25	56	
	3			17	38	
T5	1	23	51	3	6.7	< 0.001
	2	22	49	17	38	
	3			25	56	
T6	1	20	44	3	6.7	< 0.001
	2	25	56	21	47	
	3			21	47	
T7	1	21	47	2	4.4	< 0.001
	2	24	53	27	60	
	3			16	36	
T8	1	18	40	8	18	< 0.001
	2	27	60	21	47	
	3			16	36	

Table 4: Comparison of Sedation Score among the Two Study Groups

Chi-Square test

Table 4 shows different sedation score at different time interval. Group A had sedation score 1 and 2 only, while group B had sedation score 1, 2 and 3 at all-time interval. The difference between sedation score between the two groups when analysed by Chi -square test was found to be statistically significant ($p<0.001$).

Thus, patients of group B were more sedated than patients of group A. The incidence of nausea and vomiting was significantly higher in the tramadol group than in the dexmedetomidine group ($p<0.001$).

Nausea & Vomiting Score

At	Nausea Vomiting score	Group A		Group B		P value
		Count	%	Count	%	
T0	1	19	42	45	100	< 0.001
	2	26	58			
T1	1	23	51	45	100	< 0.001
	2	22	49			
T2	1	20	44	43	95.6	< 0.001
	2	25	56	2	4.4	
T3	1	21	47	45	100	< 0.001
	2	23	51			
	3	1	2.2			
T4	1	20	44	44	97.8	< 0.001
	2	24	53	1	2.2	
	3	1	2.2			
T5	1	17	38	45	100	< 0.001
	2	27	60			
	3	1	2.2			
T6	1	21	47	44	97.8	< 0.001
	2	23	51	1	2.2	
	3	1	2.2			
T7	1	18	40	44	97.8	< 0.001
	2	27	60	1	2.2	
T8	1	19	42	45	100	< 0.001
	2	25	56			
	3	1	2.2			

Table 5: Comparison of Nausea and Vomiting Score among the two groups

Chi-Square Test

Table 5 shows different nausea and vomiting score at different time interval. Group A had nausea and vomiting score 1, 2 and 3 while group B had nausea and vomiting score 1 and 2 only. The difference between nausea and vomiting score between the two groups was statistically significant ($p<0.001$). Thus, patients of group A had more nausea and vomiting than patients of group B.

DISCUSSION

Post-spinal shivering remains a common perioperative complication during subarachnoid block, with reported incidences ranging from 40–70%. It contributes to increased oxygen consumption, carbon dioxide production, cardiovascular stress, patient discomfort, and interference with intraoperative monitoring. Therefore, effective prophylaxis against shivering remains an important component of perioperative care. In the present prospective randomized study, intravenous dexmedetomidine was compared with intravenous tramadol for prevention of shivering following subarachnoid block in adult patients undergoing elective lower abdominal and lower limb surgeries.

The demographic characteristics of the two study groups were comparable with respect to age, weight, and height, indicating adequate randomization and minimizing the influence of confounding variables.

Hemodynamic parameters including heart rate, mean arterial pressure, and oxygen saturation remained comparable between the groups throughout the study period, suggesting that

both drugs can be administered safely under appropriate monitoring.

The primary finding of the present study was that dexmedetomidine and tramadol demonstrated similar efficacy in preventing post-spinal shivering. No statistically significant difference was observed in the onset, cessation time, or duration of shivering between the two groups. These findings are consistent with previously published studies comparing α2-adrenergic agonists and opioid-based anti-shivering agents.

Dexmedetomidine exerts its anti-shivering effect through reduction of the thermoregulatory threshold and modulation of central sympathetic outflow, whereas tramadol acts through m-opioid receptor agonism and inhibition of serotonin and norepinephrine reuptake.

The findings of the present study are in agreement with the meta-analysis by Wang et al.,[12] which demonstrated that dexmedetomidine is at least as effective as tramadol in controlling perioperative shivering and may provide superior patient comfort. Similarly, Kundra et al.[13] reported comparable anti-shivering efficacy between dexmedetomidine and tramadol without clinically significant hemodynamic instability.

In our study, the mean onset of shivering was marginally earlier in the dexmedetomidine group; however, the difference was not statistically significant.

An important secondary outcome observed in the present study was the difference in sedation profile. Patients receiving dexmedetomidine demonstrated significantly higher sedation scores compared with those receiving tramadol, while maintaining adequate respiratory function and oxygen saturation. This finding is clinically relevant because mild to moderate sedation may improve patient comfort during regional anaesthesia. The increased sedation associated with dexmedetomidine has been consistently reported in previous studies and is attributable to its action on the locus coeruleus.

Postoperative nausea and vomiting remain among the most distressing adverse effects encountered during the perioperative period. In the present study, the incidence of nausea and vomiting was higher in the tramadol group compared with the dexmedetomidine group. Similar observations have been reported by Kundra et al. and Sharma et al.,[14] who demonstrated a significantly greater incidence of nausea and vomiting following tramadol administration. The lower incidence of emetic symptoms with dexmedetomidine may therefore represent an additional clinical advantage.

Although earlier studies have reported a greater incidence of bradycardia and hypotension with dexmedetomidine, no statistically significant increase in these adverse effects was observed in the current study. The absence of major hemodynamic disturbances may be related to the relatively small sample size, careful patient selection, and the dosage regimen employed.

Taken together, the findings of the present study suggest that both intravenous dexmedetomidine and intravenous tramadol are effective agents for prevention of shivering following subarachnoid block. However, dexmedetomidine appears to provide additional benefits in the form of better patient comfort, desirable sedation, and a lower incidence of postoperative nausea and vomiting. These advantages may make dexmedetomidine a preferable option for prophylaxis against post-spinal shivering in appropriately selected patients.

CONCLUSION

Both intravenous tramadol and intravenous dexmedetomidine were found to be effective in preventing shivering following subarachnoid block. The incidence, onset, cessation time, duration, and severity of shivering were comparable between the two study groups. Haemodynamic parameters remained stable throughout the perioperative period, demonstrating the safety of both agents.

Dexmedetomidine provided significantly better sedation without causing respiratory depression and was associated with a lower incidence of postoperative nausea and vomiting compared with tramadol. Although the anti-shivering efficacy of the two drugs was similar, the superior sedation profile and lower adverse-effect burden observed with dexmedetomidine may offer additional clinical advantages.

Based on the findings of the present study, dexmedetomidine can be considered a valuable alternative to tramadol for the prevention of post-spinal anaesthesia shivering, particularly when patient comfort and minimisation of postoperative nausea and vomiting are priorities. However, the final choice of agent should also take into account cost, availability, institutional protocols, and individual patient characteristics.

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