International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

Hemodynamic Stability, Sedation Profile and Adverse Effects of Intravenous Dexmedetomidine versus Tramadol in Patients with Post-Spinal Anaesthesia Shivering

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OPEN ACCESS

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Received: 21-06-2026
Accepted: 22-07-2026
Available online: 25-07-2026

ABSTRACT

Background: Post-spinal anaesthesia shivering (PSAS) is a common perioperative complication associated with increased oxygen consumption, metabolic demand, patient discomfort, and interference with monitoring. Dexmedetomidine and tramadol are commonly used pharmacological agents for its management, but their comparative effects on haemodynamic stability, sedation, and adverse effects require further evaluation.

Methods: This prospective, randomized, double-blind controlled trial included 100 patients (ASA I–II, 18–60 years) who developed Grade 3 or 4 shivering following spinal anaesthesia. Patients were randomly allocated to receive intravenous dexmedetomidine 0.5 µg/kg (Group Dm, n=50) or intravenous tramadol 0.5 mg/kg (Group T, n=50). The primary outcome was time to complete cessation of shivering. Secondary outcomes included recurrence of shivering, haemodynamic parameters, Ramsay sedation score, and adverse effects.

Results: Both groups had comparable baseline characteristics and shivering severity. The mean time to cessation of shivering was 220.14 ± 35.42 seconds in the tramadol group and 210.36 ± 30.18 seconds in the dexmedetomidine group ($p=0.14$). Successful control of shivering was achieved in 98% and 100% of patients, respectively. Dexmedetomidine produced significantly lower heart rate and mean arterial pressure and higher Ramsay sedation scores than tramadol ($p<0.01$), while oxygen saturation remained comparable. Nausea and vomiting were more frequent with tramadol, whereas bradycardia occurred more commonly with dexmedetomidine.

Conclusion: Both dexmedetomidine and tramadol were highly effective in controlling PSAS. Dexmedetomidine provided superior sedation and fewer gastrointestinal adverse effects but was associated with mild reductions in heart rate and blood pressure, warranting careful haemodynamic monitoring.

Keywords*: Post-spinal anaesthesia shivering; Dexmedetomidine; Tramadol; Spinal anaesthesia; Haemodynamic stability; Ramsay sedation score; Randomized controlled trial.*

INTRODUCTION

Post-spinal anaesthesia shivering (PSAS) is one of the most common and distressing complications following neuraxial anaesthesia, with a reported incidence of 40–70%, while a systematic review of 21 studies reported a median incidence of approximately 55%.[1] Shivering is an involuntary oscillatory contraction of skeletal muscles that primarily serves as a thermoregulatory response to hypothermia, although pain, increased sympathetic activity, pyrogen release, adrenal stimulation, and anaesthetic-induced alterations in thermoregulation may also contribute.[2,3] Normally, the hypothalamic thermoregulatory centre maintains core body temperature within a narrow range of 36.5–37.5°C through a balance between heat production and heat conservation.[4,5Spinal anaesthesia disrupts normal thermoregulation by producing sympathetic blockade, peripheral vasodilatation, and inhibition of tonic vasoconstriction, resulting in rapid redistribution of heat from the core to the periphery and a fall in core temperature, particularly during the first hour after spinal block.[6,7] In addition,

neuraxial anaesthesia impairs central thermoregulatory responses by altering afferent thermal input, thereby lowering the shivering threshold and increasing the risk of perioperative shivering.[7]Although PSAS is rarely life-threatening, it has important physiological consequences. Shivering increases oxygen consumption by 100–400%, elevates carbon dioxide production and metabolic rate, and increases cardiac workload, potentially leading to hypoxaemia, lactic acidosis, tachycardia, hypertension, and myocardial stress, particularly in elderly patients and those with compromised cardiopulmonary reserve.[5,8] It also interferes with electrocardiographic monitoring, pulse oximetry, and blood pressure measurement while increasing postoperative discomfort, wound pain, and recovery room stay.[8,9]Both non-pharmacological and pharmacological strategies are used to prevent and treat PSAS. Non-pharmacological methods, including forced-air warming, warming blankets, warmed intravenous fluids, humidified gases, and maintenance of operating room temperature, reduce heat loss but may be limited by cost and equipment availability.[5,8] Consequently, pharmacological therapy remains the mainstay of treatment. Several agents, including pethidine, clonidine, tramadol, ketamine, nefopam, and dexmedetomidine, have demonstrated efficacy in controlling perioperative shivering.[2,10]Among these, tramadol and dexmedetomidine are widely used because of their rapid onset and favourable efficacy. Tramadol acts through weak μ-opioid receptor agonism and inhibition of serotonin and norepinephrine reuptake, effectively suppressing shivering, although it is commonly associated with nausea, vomiting, dizziness, and sweating.[3,11,12] Dexmedetomidine, a highly selective α2-adrenergic agonist, reduces the shivering threshold while providing sedation, analgesia, and sympatholysis without significant respiratory depression.[13] However, its sympatholytic effects may predispose patients to bradycardia and hypotension, requiring careful haemodynamic monitoring.An ideal anti-shivering agent should rapidly abolish shivering while maintaining haemodynamic stability, providing easily arousable sedation, and minimising adverse effects. Since spinal anaesthesia itself predisposes patients to hypotension and bradycardia, comparing the haemodynamic profile, sedation, and adverse effects of dexmedetomidine and tramadol is clinically relevant. Therefore, the present study was undertaken to compare intravenous dexmedetomidine and intravenous tramadol for the management of PSAS, with emphasis on haemodynamic stability, sedation profile, and adverse effects, to identify the safer and more effective therapeutic option.

MATERIALS AND METHODS

The present study was a hospital-based, prospective, randomized, double-blind controlled trial conducted at Jawaharlal Nehru Hospital and Research Centre, Bhilai, Durg, Chhattisgarh. The study was carried out over a period of two years, from October 2017 to October 2019, after obtaining approval from the Institutional Scientific and Ethics Committee. Written informed consent was obtained from all participants before enrolment.The study was conducted in the Department of Anaesthesiology at Jawaharlal Nehru Hospital and Research Centre, Bhilai, Durg, Chhattisgarh.

Study Population

The study included patients of both sexes undergoing spinal anaesthesia for elective lower abdominal, pelvic, and lower limb surgeries who developed post-spinal shivering.

Eligibility Criteria

Inclusion Criteria

Patients fulfilling all of the following criteria were included:

- Age between 18 and 60 years.
- American Society of Anesthesiologists (ASA) physical status Grade I or II.
- Patients undergoing spinal anaesthesia.
- Development of shivering of Grade 3 or Grade 4 following spinal anaesthesia.

Exclusion Criteria

Patients were excluded if they had:

- History of convulsions.
- Hypothyroidism or hyperthyroidism.
- Cardiopulmonary disorders.
- Neuromuscular diseases.
- Known allergy to dexmedetomidine or tramadol.
- Psychiatric disorders.
- Urinary tract infection.
- Severe diabetes mellitus with autonomic neuropathy.

Randomization and Group Allocation

Eligible patients were randomly allocated into two groups using computer-generated random numbers.

- **Group Dm (Dexmedetomidine Group; n=50):** Patients received intravenous dexmedetomidine 0.5 μg/kg diluted to 5 mL with normal saline.
- **Group T (Tramadol Group; n=50):** Patients received intravenous tramadol 0.5 mg/kg diluted to 5 mL with normal saline.

Blinding
The study was conducted using a double-blind design. Identical coded syringes containing the study drugs were prepared by an anaesthesiologist who was not involved in patient management or data collection. Both the patients and the observer responsible for recording study parameters remained blinded to group allocation throughout the study.

Study Procedure
All enrolled patients underwent a detailed pre-anaesthetic evaluation before surgery. Routine laboratory investigations, including complete haemogram, chest radiograph, electrocardiogram, serum creatinine, blood urea, serum electrolytes, and coagulation profile, were performed.

Patients were instructed to fast overnight before surgery. Premedication consisted of oral alprazolam 0.5 mg administered on the night before surgery and oral ranitidine administered both on the night before and on the morning of surgery.

Upon arrival in the operating theatre, standard monitoring equipment was attached, including electrocardiography (ECG), non-invasive blood pressure (NIBP), pulse oximetry (SpO_2), heart rate (HR), and axillary body temperature monitoring. Baseline values were recorded before administration of spinal anaesthesia.

An 18-gauge intravenous cannula was secured, and patients were preloaded with Ringer's lactate solution at 10 mL/kg before spinal anaesthesia. Intravenous fluids were subsequently maintained at 6 mL/kg/hour.

Spinal anaesthesia was administered under strict aseptic precautions using 15 mg of 0.5% hyperbaric bupivacaine through a 25-gauge Quincke spinal needle at either the L3–L4 or L4–L5 intervertebral space.

The operating theatre temperature was maintained between 24°C and 25°C. Supplemental oxygen was administered at 4 L/min through a face mask. Patients were covered with surgical drapes during the procedure and with a cotton blanket postoperatively. No active warming devices were used. All intravenous fluids were administered at room temperature.

The total volume of intravenous fluids administered, use of mephentermine for hypotension (mean arterial pressure <20% below baseline), atropine for bradycardia (heart rate <60 beats/min), and ondansetron for nausea or vomiting were documented. Administration of opioids during the preoperative and intraoperative periods was not permitted.

Vital parameters, including heart rate, non-invasive blood pressure, oxygen saturation, and body temperature, were recorded every minute during the first 5 minutes following spinal anaesthesia, every 5 minutes for the subsequent 30 minutes, and every 15 minutes thereafter until completion of surgery. Continuous ECG monitoring was maintained throughout the procedure.

Whenever a patient developed Grade 3 or Grade 4 shivering, the allocated study drug was administered as a slow intravenous injection according to the randomization schedule. The onset time of shivering following spinal anaesthesia (T_0), shivering grade, time required for complete cessation of shivering, Ramsay Sedation Score, and haemodynamic parameters (HR, SBP, DBP, MAP, and SpO_2) were recorded at baseline and at 5, 10, and 15 minutes after administration of the study drug (T_5, T_{10}, and T_{15}).

Failure of treatment was defined as persistence of shivering beyond 15 minutes after administration of the study drug. Recurrence of shivering was monitored until the patient left the operating theatre. Patients experiencing recurrence or treatment failure received an additional dose of the same study drug (dexmedetomidine 0.5 µg/kg or tramadol 0.5 mg/kg) according to their allocated group.
The duration of surgery was also recorded.

Outcome Measures
The primary outcome measure was the time required for complete cessation of shivering after administration of the study drug.
Secondary outcome measures included:

- Onset time of shivering after spinal anaesthesia.
- Recurrence of shivering.
- Haemodynamic parameters (HR, SBP, DBP, MAP, and SpO_2).
- Ramsay Sedation Score.
- Duration of surgery.
- Incidence of adverse effects, including nausea, vomiting, bradycardia, hypotension, and dizziness.

Ramsay Sedation Score

Sedation was assessed using the Ramsay Sedation Scale as follows:

- Grade 1: Patient anxious, agitated, or restless.
- Grade 2: Patient cooperative, oriented, and tranquil.
- Grade 3: Patient responded only to commands.
- Grade 4: Patient exhibited a brisk response to glabellar tap or loud auditory stimulus.
- Grade 5: Patient exhibited a sluggish response to glabellar tap or loud auditory stimulus.
- Grade 6: Patient was unconscious.

Shivering Grading

The severity of shivering was graded using a four-point scale:

- Grade 0: No shivering.
- Grade 1: Piloerection or peripheral vasoconstriction without visible muscular activity.
- Grade 2: Muscular activity confined to one muscle group.
- Grade 3: Muscular activity involving more than one muscle group but not generalized.
- Grade 4: Generalized muscular activity involving the whole body.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using SPSS.25statistical software. Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequency and percentage. Continuous variables between the two groups were compared using the independent Student's *t*-test, whereas categorical variables were compared using the Chi-square test or Fisher's exact test, wherever appropriate. A *p*-value of <0.05 was considered statistically significant.

RESULTS

A total of 100 patients were enrolled in the study and were equally allocated into the Tramadol group (Group T, n=50) and the Dexmedetomidine group (Group Dm, n=50).The baseline demographic and clinical characteristics of the two groups are presented in Table 1. The mean age was 38.92 ± 12.84 years in Group T and 39.74 ± 13.18 years in Group Dm (p=0.75). The mean body weight was also comparable between the groups (56.41 ± 5.62 kg vs. 57.08 ± 6.14 kg; p=0.57). Males constituted 60.0% of Group T and 64.0% of Group Dm, while ASA Grade I patients accounted for 66.0% and 58.0% of the respective groups. No statistically significant differences were observed in sex distribution or ASA physical status (Table 1).The age distribution and type of surgery performed are summarized in Table 2 and illustrated in Figure 1. Most patients belonged to the 21–30 and 41–50 year age groups in both study arms. Lower abdominal surgery was the most frequently performed procedure, followed by lower limb and pelvic surgeries. There were no significant differences between the groups with respect to age distribution (p=0.93) or type of surgery (p=0.89) (Table 2; Figure 1).The characteristics of post-spinal shivering are shown in Table 3. The mean time to onset of shivering following spinal anaesthesia was comparable between Group T (40.84 ± 8.63 minutes) and Group Dm (41.57 ± 8.29 minutes) (p=0.67). Grade 3 shivering was observed in 62.0% of patients in Group T and 58.0% in Group Dm, while Grade 4 shivering occurred in 38.0% and 42.0% of patients, respectively, with no statistically significant difference (p=0.68) (Table 3).Treatment outcomes are presented in Table 4. The mean time required for cessation of shivering was slightly shorter in the dexmedetomidine group (210.36 ± 30.18 seconds) compared with the tramadol group (220.14 ± 35.42 seconds); however, the difference was not statistically significant (p=0.14). Successful control of shivering within 15 minutes was achieved in 98.0% of patients in Group T and 100% of patients in Group Dm. Recurrence of shivering occurred in 8.0% and 4.0% of patients, respectively, while treatment failure was observed in only one patient in the tramadol group. None of these differences reached statistical significance (Table 4).The comparison of haemodynamic parameters and sedation scores at 15 minutes is shown in Table 5 and Figure 2. Patients receiving dexmedetomidine had significantly lower heart rate (73.28 ± 6.17 vs. 79.46 ± 6.88 beats/min; p<0.001) and mean arterial pressure (79.86 ± 6.95 vs. 83.94 ± 6.42 mmHg; p=0.003) compared with those receiving tramadol. Oxygen saturation remained comparable between the groups (p=0.36). Ramsay sedation scores were significantly higher in the dexmedetomidine group (2.98 ± 0.53) than in the tramadol group (2.18 ± 0.44; p<0.001), indicating greater sedation with dexmedetomidine (Table 5; Figure 2).The incidence of adverse effects is presented in Table 6 and Figure 3. Nausea and vomiting were more frequent in the tramadol group (10.0%) than in the dexmedetomidine group (2.0%), although the difference was not statistically significant (p=0.09). Bradycardia occurred more frequently in patients receiving dexmedetomidine (12.0% vs. 2.0%; p=0.05). Hypotension was also observed more commonly in the dexmedetomidine group (10.0% vs. 4.0%; p=0.24), whereas dizziness occurred equally in both groups (2.0% each; p=1.00). Overall, both drugs were well tolerated with a low incidence of adverse effects (Table 6; Figure 3).

Table 1. Comparison of Baseline Demographic and Clinical Characteristics Between the Study Groups

Variable	Group T (n=50)	Group Dm (n=50)	p-value
Male, n (%)	30 (60.0)	32 (64.0)	
Female, n (%)	20 (40.0)	18 (36.0)	0.68
ASA Grade I, n (%)	33 (66.0)	29 (58.0)	
ASA Grade II, n (%)	17 (34.0)	21 (42.0)	0.41

Table 2. Comparison of Age Distribution and Type of Surgery

Variable	Group T (n=50)	Group Dm (n=50)	p-value
Age Group, n (%)			
18–20 years	4 (8.0)	3 (6.0)	
21–30 years	13 (26.0)	14 (28.0)	
31–40 years	11 (22.0)	10 (20.0)	
41–50 years	12 (24.0)	11 (22.0)	
51–60 years	10 (20.0)	12 (24.0)	0.93
Type of Surgery, n (%)			
Lower abdominal surgery	20 (40.0)	18 (36.0)	
Pelvic surgery	12 (24.0)	14 (28.0)	
Lower limb surgery	18 (36.0)	18 (36.0)	0.89

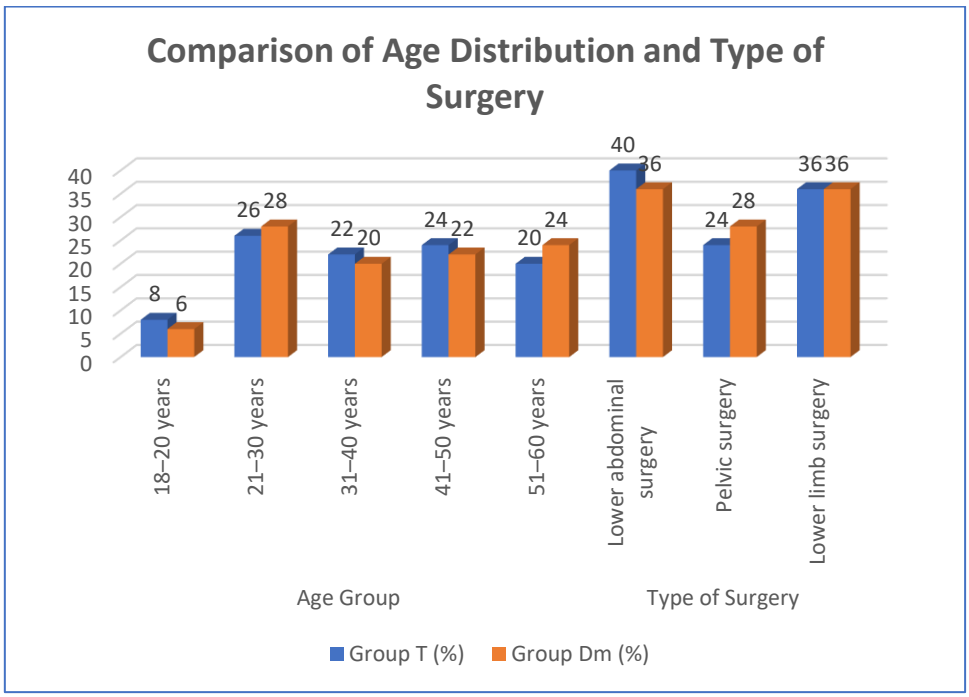

Figure 1 Comparison of Age Distribution and Type of Surgery

Table 3. Comparison of Shivering Characteristics

Variable	Group T (n=50)	Group Dm (n=50)	p-value
Time to onset of shivering (min), Mean ± SD	40.84 ± 8.63	41.57 ± 8.29	0.67
Grade 3 shivering, n (%)	31 (62.0)	29 (58.0)	
Grade 4 shivering, n (%)	19 (38.0)	21 (42.0)	0.68

Table 4. Comparison of Treatment Response

Variable	Group T (n=50)	Group Dm (n=50)	p-value
Time to cessation of shivering (seconds), Mean ± SD	220.14 ± 35.42	210.36 ± 30.18	0.14
Successful control within 15 min, n (%)	49 (98.0)	50 (100.0)	0.32
Recurrence of shivering, n (%)	4 (8.0)	2 (4.0)	0.40
Treatment failure, n (%)	1 (2.0)	0 (0.0)	0.32

Table 5. Comparison of Haemodynamic Parameters and Sedation at 15 Minutes

Variable	Group T (n=50)	Group Dm (n=50)	p-value
Heart rate (beats/min)	79.46 ± 6.88	73.28 ± 6.17	<0.001
Mean arterial pressure (mmHg)	83.94 ± 6.42	79.86 ± 6.95	0.003
SpO_2 (%)	98.36 ± 0.78	98.22 ± 0.74	0.36
Ramsay sedation score	2.18 ± 0.44	2.98 ± 0.53	<0.001

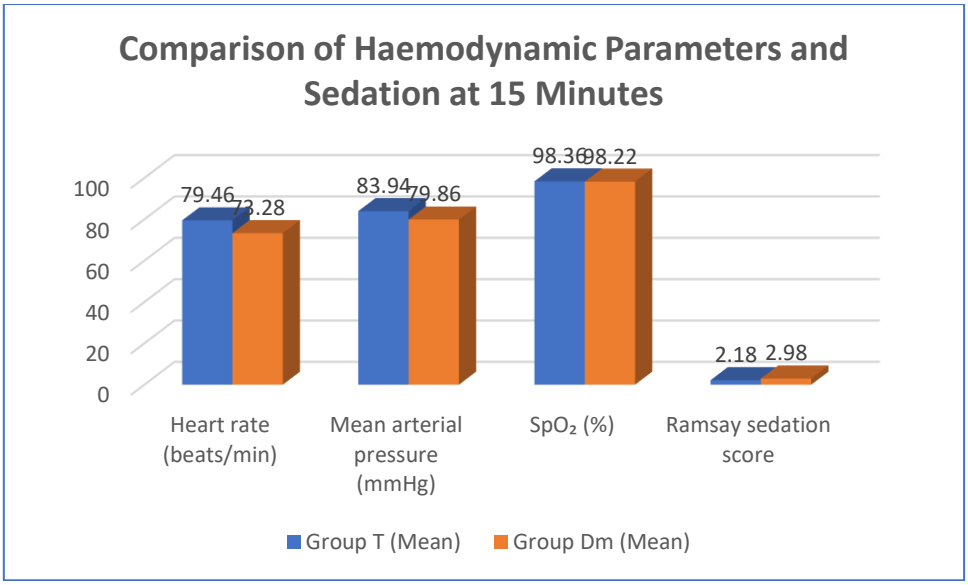

Figure 2 Comparison of Haemodynamic Parameters and Sedation at 15 Minutes

Table 6. Comparison of Adverse Effects

Adverse Effect	Group T (n=50)	Group Dm (n=50)	p-value
Nausea/Vomiting	5 (10.0)	1 (2.0)	0.09
Bradycardia	1 (2.0)	6 (12.0)	0.05
Hypotension	2 (4.0)	5 (10.0)	0.24
Dizziness	1 (2.0)	1 (2.0)	1.00

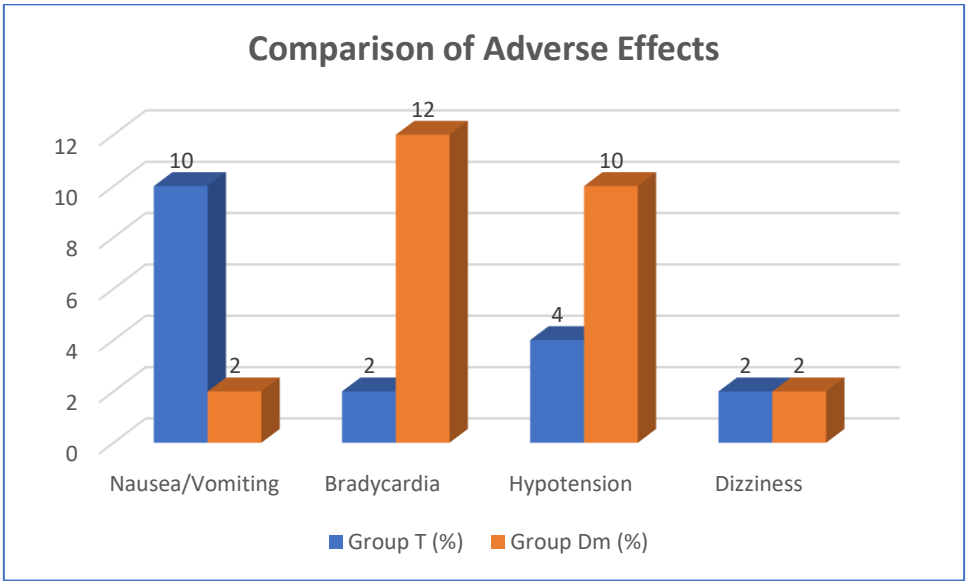

Figure 3 Comparison of Adverse Effect

DISCUSSION

Post-spinal anaesthesia shivering (PSAS) is a common perioperative complication that increases oxygen consumption, carbon dioxide production, metabolic demand, and patient discomfort. Among the pharmacological agents used for its treatment, dexmedetomidine and tramadol are widely accepted because of their effectiveness and favourable safety profiles. The present randomized double-blind study compared intravenous dexmedetomidine (0.5 µg/kg) and tramadol (0.5 mg/kg) for the management of PSAS.Baseline demographic and clinical characteristics were comparable between the two groups. The mean age, body weight, sex distribution, and ASA physical status showed no statistically significant differences, indicating adequate randomization and minimizing baseline confounding. Similar demographic comparability has been reported by Mittal et al.,[14] Singla et al.,[15] and Kundra et al.,[16] thereby supporting the validity of outcome comparisons.The onset and severity of shivering were also comparable between groups. Shivering occurred approximately 41 minutes after spinal anaesthesia in both groups, and the distribution of Grade 3 and Grade 4 shivering did not differ significantly. These findings suggest that patients in both groups had similar clinical severity before treatment, consistent

with the observations of Mittal et al.[14] and Kundra et al.,[16] who likewise reported no significant differences in baseline shivering characteristics.

The primary outcome, time to complete cessation of shivering, was numerically shorter with dexmedetomidine (210.36 ± 30.18 seconds) than tramadol (220.14 ± 35.42 seconds), although the difference was not statistically significant (p=0.14). Successful control of shivering within 15 minutes was achieved in nearly all patients, and recurrence rates were low in both groups. These findings indicate that both drugs were highly effective in treating PSAS. In contrast, Mittal et al.[14] and Kundra et al.[16] reported significantly faster shivering control with dexmedetomidine, while Singla et al.[15] also demonstrated a shorter response time with dexmedetomidine than tramadol. The lack of statistical significance in the present study may be attributable to the relatively small difference between groups and variability in patient characteristicsHaemodynamic assessment showed significantly lower heart rate and mean arterial pressure in the dexmedetomidine group at 15 minutes after treatment, whereas oxygen saturation remained stable and comparable in both groups, indicating the absence of respiratory depression. These findings are consistent with the sympatholytic action of dexmedetomidine and agree with previous reports by Mittal et al.[14] and Kundra et al.,[16] who also observed lower heart rate and blood pressure without clinically significant respiratory compromise.Sedation scores were significantly higher with dexmedetomidine than tramadol, although patients remained easily arousable and cooperative. Similar findings have been reported by Singla et al.[15] and Kundra et al.,[16] suggesting that dexmedetomidine provides desirable conscious sedation during regional anaesthesia while maintaining respiratory safety.Regarding adverse effects, nausea and vomiting were more common with tramadol, whereas bradycardia and mild hypotension occurred more frequently with dexmedetomidine. These findings are comparable to those reported by Mittal et al.[14] and Kundra et al.,[16] who also observed fewer gastrointestinal adverse effects but a higher incidence of mild bradycardia with dexmedetomidine.

CONCLUSION

Both intravenous dexmedetomidine (0.5 µg/kg) and tramadol (0.5 mg/kg) were effective in controlling post-spinal anaesthesia shivering, with high treatment success and low recurrence rates. Although the time required for cessation of shivering was comparable between the two groups, dexmedetomidine provided significantly better sedation and fewer gastrointestinal adverse effects. However, dexmedetomidine was associated with a higher incidence of mild bradycardia and hypotension, necessitating careful haemodynamic monitoring. Overall, dexmedetomidine represents a safe and effective alternative to tramadol for the management of post-spinal anaesthesia shivering, particularly when desirable sedation and close haemodynamic monitoring can be ensured.

Limitations

The present study was conducted at a single tertiary care centre with a relatively modest sample size, which may limit the generalizability of the findings. Haemodynamic and sedation parameters were assessed only during the intraoperative period, and long-term postoperative outcomes were not evaluated. In addition, only one dose of dexmedetomidine and tramadol was studied; therefore, the effects of different dosing regimens could not be compared.

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