IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 25, Issue 3 Ser. 4 (March. 2026), PP 75-81
www.iosrjournals.org

"Clinical Study: Prophylactic Tramadol Versus Dexmedetomidine For Prevention Of Post Spinal Anaesthesia Shivering"

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Abstract
The aim of this study is to evaluate the efficacy of dexmedetomidine verus tramadol when used prophylactically to prevent post spinal shivering. In this prospective double-blind randomized controlled clinical study, 60 American Society of Anaesthesiologists grade-l (ASAI) patients aged between 18 and 65 years scheduled for various orthopedics and plastic lower limb surgeries under spinal anaesthesia, were selected. The patients were divided into two groups: Group D(n=30) comprised of patients who received dexmedetomidine 0.3mg/kg intravenously (IV) and Group(T) patients who received tramadol 1 mg/kg IV, given 5 minutes before administering spinal anaesthesia. The number of patients having any incidence of shivering(17 in Group T , 6 in Group D; p value 0.0079) , onset of shivering(6min+/- 2.32 in Group T, 9 min+/-1.17 in Group D; p value <0.0001) and the mean duration of shivering(8 min+/- 3.43 in Group T , 5min +/- 2.22 in Group D; p value 0.0002) were noted. Hemodynamic changes including heart rate and blood pressures were also compared in both the groups, however no significant disturbances were noted. Side effects like drowsiness(p value-0.6707), nausea and vomiting(p value 0.0211) . incidence of nausea and vomiting were significantly higher in Group T . Overall , we conclude that dexmedetomdine has a significantly better outcome in comparison to tramadol in terms of lower incidence of shivering along with lesser duration and lesser incidence of post spinal nausea and vomiting.

Keywords: *Shivering, prophylactic dexmedetomidine, tramadol, nausea vomiting*

Date of Submission: 17-03-2026 Date of Acceptance: 27-03-2026

I. Introduction

Shivering is defined as an involuntary, oscillatory muscular activity that serves to generate heat and restore core body temperature in response to hypothermia [1]. It is a common and clinically significant complication of neuraxial anaesthesia, including both spinal and epidural techniques, with reported incidence rates ranging from 40% to 65% [2–4]. Specifically, in patients undergoing spinal anaesthesia, the incidence can reach 50% to 65% [4,5].

The pathophysiology of shivering during spinal anaesthesia is multifactorial. While central thermoregulatory mechanisms remain functional, spinal anaesthesia induces vasodilation and core-to-peripheral heat redistribution, resulting in hypothermia and subsequent shivering [4,5]. Additional contributing factors include exposure to a cold operating room, evaporative heat loss during surgery, unwarmed intravenous fluids, sympathetic blockade impairing thermoregulatory responses, and reduced ability to shiver in anaesthetized areas [3,6].

Perioperative shivering is not merely uncomfortable; it can have significant physiological consequences. It increases oxygen consumption, carbon dioxide production and may lead to hypoxemia, myocardial ischemia, elevated intracranial and intraocular pressure[3,7,8]. These effects are particularly hazardous in patients with any existing cardiorespiratory or neurological comorbidities.

Management strategies for shivering include both non-pharmacological and pharmacological methods. Non-pharmacological approaches aim to prevent or minimize heat loss and include forced-air warming systems, warmed IV fluids, heated gowns and controlling operating room temperature [9–12]. For example, pre-warming patients for just 15 minutes before anaesthesia significantly reduces shivering during cesarean section [9].

Pharmacologic therapies include agents like pethidine, tramadol, clonidine, dexmedetomidine, ondansetron, ketamine, dexamethasone and magnesium sulfate [13–15]. Tramadol, a centrally acting μ-opioid agonist, exerts anti-shivering effects by inhibiting norepinephrine and serotonin reuptake, but may cause nausea and vomiting [16]. Dexmedetomidine, an α2-adrenoceptor agonist, provides both central thermoregulatory modulation and sedation, and has shown promise for both shivering prevention and treatment, without respiratory depression [2,17]. However, further research is needed to define its optimal role, particularly in comparison with other agents.

Given the high prevalence and clinical impact of shivering, especially in resource-limited settings, there is a need to develop evidence-based, cost-effective, and practical guidelines tailored to available infrastructure and drug accessibility [18].

II. Methodology

Study Design and Setting

This study was designed as a prospective, randomized, double-blind, controlled trial conducted in the Department of Anaesthesiology, Gajra Raja Medical College, Gwalior. Ethical approval was obtained from the Institutional Ethical Committee (Ref No. 571/Bio/MC/Ethical, and written informed consent was secured from all participants prior to enrollment.

Study Population

Sixty adult patients (aged 18–65 years), of either sex, with height 150-170 cm, weight 50-80 kg, classified as American Society of Anesthesiologists (ASA) physical status I or II [24] and scheduled for elective lower limb short-duration(approxiamately 1 hour) procedures and plastic surgeries under spinal anaesthesia were included. Participants were randomly assigned into two equal groups (n = 30):

- Group D (Dexmedetomidine): Received intravenous dexmedetomidine 0.3 mcg/kg.
- Group T (Tramadol): Received intravenous tramadol 1 mg/kg.

The exclusion criteria for the study included patients with known hypersensitivity to either of the study drugs or those who were unwilling to participate. Individuals scheduled for procedures likely to require blood transfusion were also excluded. Patients with obesity, defined as a body mass index (BMI) greater than 35, and those with endocrine disorders such as hyperthyroidism or hypothyroidism, were not considered. Subjects with severe diabetes mellitus or evidence of autonomic neuropathy were excluded due to potential complications affecting autonomic regulation. Additionally, individuals with any psychiatric illness or a history of alcohol or substance abuse were not included in the study. Patients with significant cardiac, pulmonary, renal, or hepatic disease were excluded to avoid confounding factors related to systemic comorbidities. Those with baseline bradycardia (heart rate <60 bpm), as well as pregnant or lactating women, were also excluded to ensure participant safety and data consistency.

These criteria were based on prior studies evaluating perioperative use of dexmedetomidine and tramadol [16,17].

Randomization and Blinding

Randomization was performed using a computer-generated random number sequencing (www. randomization.com). Allocation concealment was ensured using sealed, opaque envelopes, consistent with CONSORT recommendations [13]. Upon development of shivering, an independent OT nurse(blinded to study outcomes) opened the assigned envelope and prepared the study drug in an unlabeled 5 ml syringe diluted with normal saline. The drug was administered intravenously over 10 minutes.

Anaesthetic Technique and Intraoperative Monitoring

Operating room temperature was maintained between 22+-2 degree celsius. Patients underwent standard preoperative evaluation and were fasted for at least six hours. Baseline parameters—heart rate (HR), non-invasive blood pressure (NIBP), oxygen saturation (SpO_2), electrocardiogram (ECG) and axillary temperature—were recorded [5].

The study drug , which was already diluted and unknown to the anaesthesiologist was then given to the patient slowly intravenous with close monitoring of the vitals. 5 min later, under all aseptic precautions , spinal anaesthesia was then performed in the sitting position at the L3–L4 or L4–L5 interspace using a 25G Quincke spinal needle. After confirming free flow of cerebrospinal fluid, 15 mg of 0.5% hyperbaric bupivacaine was injected intrathecally [24]. Sensory block was confirmed to the T10 dermatome via pinprick testing. Patients received 4 L/min oxygen via face mask . Intraopertaive fluid management was done in relation to body weight and intraoperative losses.Vital parameters (HR, NIBP, SpO_2) were monitored every 5 minutes for the first 30 minutes, every 15 minutes for the next hour and hourly thereafter until the end of surgery. Postoperatively, all patients were transferred to the Post-Anaesthesia Care Unit (PACU). Intravenous fluids were continued at room temperature. No active warming devices were used. Monitoring was done for the next 2 hours.

Assessment Parameters

Shivering

Shivering was graded using the Bedside Shivering Assessment Scale (BSAS) [7]:

Grade 0: No shivering

Grade 1: Localized shivering (one muscle group)
Grade 2: Shivering involving more than one muscle group, not generalized
Grade 3: Generalized moderate shivering
Grade 4: Generalized intense shivering

Only patients exhibiting Grade 3 or 4 shivering within 2 hours of post operative monitoring , were considered for drug failure. Rescue drug for shivering was tramadol at a dose of 0.5mg /kg for all patients, if needed.

Motor Block Assessment
Motor block recovery was assessed using the Modified Bromage Scale [8]:
Grade 3: Unable to move feet or knees
Grade 2: Able to move feet only
Grade 1: Able to move knees
Grade 0: Full movement of knees and feet

Sedation Assessment
Sedation was assessed using the Modified Ramsay Sedation Scale [9]:
Grade 1: Anxious, agitated
Grade 2: Cooperative, oriented
Grade 3: Responds to commands
Grade 4: Brisk response to stimulus
Grade 5: Sluggish response
Grade 6: No response to stimulus

Adverse Effects and Management
Bradycardia ((>20% reduction from baseline): Treated with IV atropine 0.6 mg [24]
Hypotension (>20% reduction from baseline): Managed with IV mephentermine 6 mg bolus doses [24]
Vomiting: Treated with IV ondansetron 4 mg [12]

Statistical Analysis

All data were analyzed using standard statistical software. Continuous variables were compared using Student's t-test, and categorical variables were analyzed using the Chi-square test.

- A p-value <0.05 was considered statistically significant.
- A p-value <0.001 was considered highly significant.

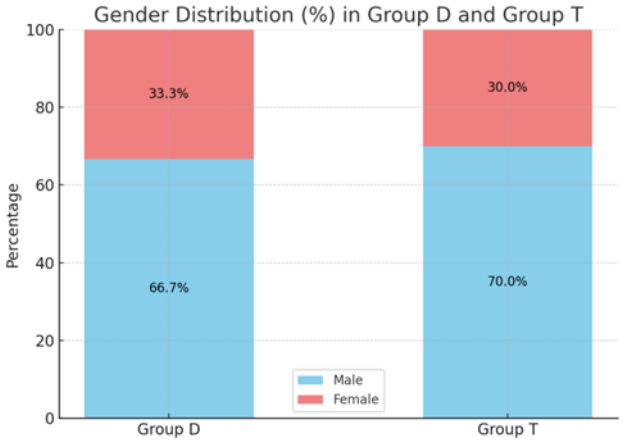
III. Results

A total of 86.61% of patients who received dexmedetomidine and tramadol experienced no shivering, demonstrating that both the medications were effective in reducing shivering. There was no significant difference between the two groups regarding SBP, DBP, axillary temperature, oxygen saturation, baseline heart rate. Group T experienced more complications than Group D in terms of nausea, which was significantly higher in Group T (36.88%) compared to 0% in Group D (P = 0.002). Vomiting occurred in 5.34% of patients in Group T but was absent in Group D (P = 0.05). Bradycardia was reported in 0.48% of patients in Group D, while none were affected in Group T (P = 0.412). No patients in either group experienced itching or hypotension. Patients in Group D received deeper sedation than those in Group T. Grade 4 sedation was observed in 12.32% of Group D patients, while 29.55% experienced Grade 2 sedation. In contrast, all patients in Group T had Grade 1 sedation (P < 0.001). These findings suggest that while both dexmedetomidine and tramadol effectively reduce shivering, dexmedetomidine provides better sedation with fewer side effects, making it a preferable option in this context.

Table 1: Age And Sex Distribution Of Two Groups

	GROUP D	GROUP T	P VALUE
AGE MEAN ± SD	36 ± 11.4	34 ± 10.4	0.567
MALE	20	21	0.546
FEMALE	10	19	0.578

DURATION OF SURGERY(MINUTE) MEAN ± SD	56±11.04	53±12.08	**0.724**



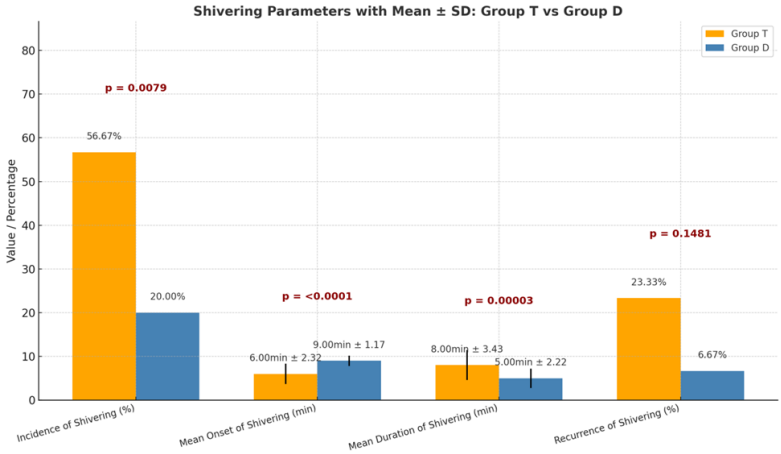
In this study, both Group D (Dexmedetomidine) and Group T (Tramadol) were comparable in terms of demographic characteristics and surgical parameters. The mean age of patients in Group D was 36 ± 11.4 years, while in Group T it was 34 ± 10.4 years, with no statistically significant difference (p = 0.567). The sex distribution was also similar between the groups; Group D had 20 males and 10 females, while Group T had 21 males and 9 females, with respective p-values of 0.546 and 0.578, confirming that the groups were well matched for age and gender. No significant difference in view of height , weight and BMI is present.

Regarding the duration of surgery, the mean surgical time in Group D was 56 ± 11.04 minutes, and in Group T it was 53 ± 12.08 minutes, with no statistically significant difference (p = 0.724), suggesting that surgical duration did not confound the outcomes assessed. Additionally, Modified Bromage Scale scores, used to assess the degree of motor blockade, were found to be comparable and statistically similar in both groups, indicating that the degree of motor block achieved post-spinal anaesthesia was equivalent and did not influence the incidence of shivering or other parameters evaluated in this study.

These findings validate that both groups were demographically and clinically comparable, allowing for a reliable comparison of the primary outcome variables**.**

Table 4. Comparative Analysis

Parameter	Group T (n=30)	Group D (n=30)	P-value	Significance
Incidence of Shivering (%)	17 (56.67%)	6 (20.00%)	0.0079	Significant
Mean Onset of Shivering (min)	6 ± 2.32	9 ± 1.17	< 0.0001	Significant
Mean Duration of Shivering (min)	8 ± 3.43	5 ± 2.22	0.0002	Significant



In this comparative study between Group T (Tramadol) and Group D (Dexmedetomidine), each comprising 30 patients, four parameters were evaluated: incidence, onset and duration of shivering following spinal anaesthesia along with the side effects. The incidence of shivering was significantly higher in Group T, with 56.67% of patients (17 out of 30) affected, compared to only 20.00% (6 out of 30) in Group D ($p = 0.0079$), indicating a clear advantage of dexmedetomidine in reducing shivering episodes.

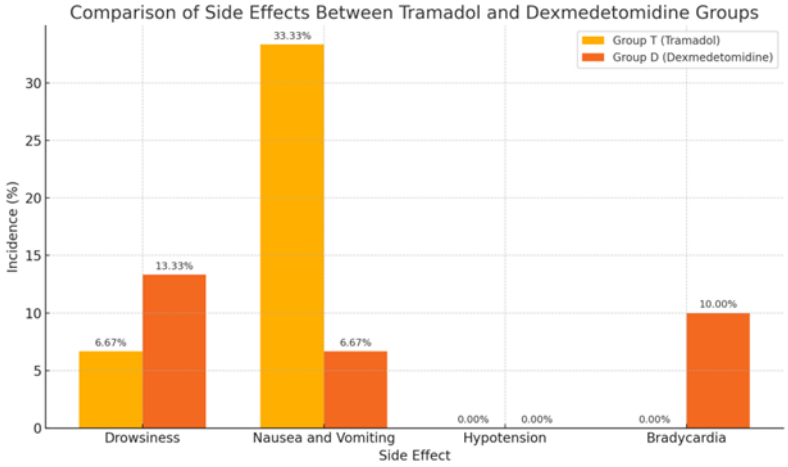
The mean onset of shivering was significantly delayed in the dexmedetomidine group (9 ± 1.17 minutes) compared to the tramadol group (6 ± 2.32 minutes), with a highly significant p-value < 0.0001, suggesting a slower and more controlled response in patients receiving dexmedetomidine. Similarly, the mean duration of shivering was considerably shorter in Group D (5 ± 2.22 minutes) versus Group T (8 ± 3.43 minutes) and this difference was statistically significant ($p = 0.0002$), demonstrating that dexmedetomidine not only reduces the frequency but also the persistence of shivering.

Table5: Incidence of Side Effects in Group T vs Group D"

Side Effects	Group T (n=30)	Group D (n=30)	P-value	Significance
Drowsiness	**2 (6.67%)**	**4 (13.33%)**	**0.6707**	**Not significant**
Nausea and Vomiting	**10 (33.33%)**	**2 (6.67%)**	**0.0211**	**Significant**
Hypotension	**0 (0.0%)**	**0 (0.0%)**	**1.0000**	**Not significant**
Bradycardia	**0 (0.0%)**	**3 (10.0%)**	**0.2373**	**Not significant**

In the analysis of side effects between Group T (Tramadol) and Group D (Dexmedetomidine), the most notable finding was a significantly higher incidence of nausea and vomiting in the tramadol group, observed in 33.33% (10 out of 30) of patients, compared to only 6.67% (2 out of 30) in the dexmedetomidine group ($p = 0.0211$). This statistically significant difference highlights the superior gastrointestinal tolerability of dexmedetomidine over tramadol.

Other adverse effects such as drowsiness were slightly more common in the dexmedetomidine group (13.33%) than in the tramadol group (6.67%), but this difference was not statistically significant ($p = 0.6707$). Bradycardia occurred exclusively in the dexmedetomidine group (10%) but did not reach statistical significance ($p = 0.2373$). Importantly, hypotension was not reported in either group.



Overall, the findings suggest that while both drugs are generally well tolerated, dexmedetomidine offers a lesser side effect profile, particularly with significantly less nausea and vomiting compared to tramadol.

IV. Discussion

This prospective, randomized trial compared the anti-shivering efficacy of intravenous dexmedetomidine (0.3 mcg/kg) and tramadol (1 mg/kg) in patients who were given spinal anaesthesia for lower limb orthopedics and plastic surgery procedures.Shivering is a well-recognized and distressing complication during neuraxial anaesthesia. It is primarily caused by core-to-peripheral redistribution of body heat and impaired thermoregulation due to sympathetic blockade, vasodilation and altered hypothalamic function as described by Zhang et al. [1] and Kamal et al. [5].The incidence of post-spinal anaesthesia (SA) shivering varies between 40–60%, as documented in several studies including Shukla et al. [19].In our study, incidence of shivering was significantly higher in the tramadol group (56.67%) compared to the dexmedetomidine group (20.00%), with a p-value of 0.0079, suggesting superior prophylactic and therapeutic potential of dexmedetomidine. This is consistent with findings by Usta et al. [2] and Bajwa et al. [21], who also noted lower shivering rates with dexmedetomidine in spinal anaesthesia.

Interestingly, the onset of shivering control was slower in the dexmedetomidine group (9 ± 1.17 min) than in the tramadol group (6 ± 2.32 min) ($p < 0.0001$). Although slower in onset, the effect was more sustained: duration of shivering was significantly shorter in the dexmedetomidine group (5 ± 2.22 min) vs tramadol (8 ± 3.43 min, $p = 0.0002$), indicating more efficient control.These results align with the pharmacological profile of dexmedetomidine and with pediatric studies such as that by Easley et al. [20], which demonstrated similar effects under general anaesthesia, though extrapolation should be done cautiously due to population and procedural differences.In terms of central nervous system (CNS) effects, mild sedation was observed more frequently in the dexmedetomidine group (13.33%) compared to the tramadol group (6.67%), although this difference was not statistically significant. All patients maintained sedation levels at or below Grade 4 on the Ramsay Sedation Scale, and oxygen saturation remained stable throughout the study. The mild sedative effect associated with dexmedetomidine is well-established in literature, including the findings by Botros et al. [8], and may enhance patient comfort without compromising safety. Regarding gastrointestinal (GI) effects, nausea and vomiting were significantly more common in the tramadol group (33.33%) than in the dexmedetomidine group (6.67%), with a statistically significant difference ($p = 0.0211$). This increased incidence is attributed to the μ-opioid and serotonergic activity of tramadol and is consistent with earlier findings by Kelsaka et al. [14] and Shakya et al. [15], thereby reinforcing the superior GI tolerability of dexmedetomidine. In terms of cardiovascular effects, bradycardia was observed in 10% of patients receiving dexmedetomidine, while none of the patients in the tramadol group experienced this event ($p = 0.2373$). As a central α2-agonist, dexmedetomidine is known to cause bradycardia, a finding supported by Belleville et al. [23]; however, in this study, the bradycardia was hemodynamically insignificant and required no intervention. Importantly, no episodes of hypotension were recorded in either group, indicating that both dexmedetomidine and tramadol are hemodynamically safe within the administered dosage and clinical context.

V. Conclusion

Dexmedetomidine demonstrated superior efficacy, longer duration of action and fewer adverse effects compared to tramadol in managing post-spinal anaesthesia shivering. While tramadol has a faster onset, dexmedetomidine provides better patient comfort with added benefits of mild sedation, lower recurrence, and better tolerability—making it a clinically advantageous alternative in neuraxial anaesthesia settings.

VI. Limitations

One limitation of this study is the inability to monitor core body temperature, which is a critical factor in thermoregulation and shivering response. Further, larger multicentric trials could help establish more definitive conclusions, especially regarding recurrence and rare side effects.

Financial support and sponsorship- Nil.
Conflicts of interest-There are no conflicts of interest.

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