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ORIGINAL RESEARCH

A Comparative Evaluation of Dexmedetomidine, Ketamine, and Tramadol in Preventing Perioperative Shivering in Patients Undergoing Spinal Anaesthesia: A Randomized Controlled Trial

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ABSTRACT

Background: Shivering, which commonly occurs after spinal anaesthesia, is characterized by involuntary and repetitive movements of skeletal muscles. The present study compared efficacy of Dexmedetomidine, Ketamine and Tramadol for prevention of perioperative shivering under Spinal Anaesthesia.

Materials & Methods:80 patients of 18-65 years, of American Society of Anaesthesiologists (ASA) I and II, undergoing surgery under spinal anesthesia of both genderswere divided into 4 groups of 20 each. Group I received Tramadol 0.5 mg/kg, group II received Dexmedetomidine 0.5 µg/kg, group III received Ketamine 0.25 mg/kg and group IV received normal saline 5 mL. Each study drug was diluted to 5 mL using normal saline and administered as a slow intravenous (i.v.) bolus injection five minutes before spinal anaesthesia. Patients were monitored for shivering (using a four-point scale), level of consciousness, heart rate, SpO2, respiratory rate, non-invasive blood pressureat five-minute intervals.

Results:T h e mean age was 37.4 years in group I, 38.1 years in group II, 37.5 years in group III and 38.16 years in group IV. The mean weight was 62.5 kgs, 62.25 kgs, 60.97 kgs and 62.21 kgs in group I, II, III and IV respectively. ASA I/II was 11:9, 12:8, 9:11 and 13:7 in group I, II, III and IV respectively. The difference was non- significant (P> 0.05). Grade 0 was seen in 13, 20, 18 and 12, grade 1 in 3, 0, 1 and 4, grade 2 in 1, 0, 0, and 3, grade 3 in 2, 0, 1 and 1 and grade 4 in 1, 0, 0 and 0 in group I, II, III and IV respectively. The difference was significant (P< 0.05). There was non- significant difference in HR, SBP, DBP, SPO_2 and RR in all groups (P> 0.05).Heart Rate (HR) was lower in the Dexmedetomidine group (80.0 ± 6.8 bpm) and the Control group (76.2 ± 6.6 bpm) compared to the Tramadol and Ketamine groups.Systolic Blood Pressure (SBP) was notably higher in the Ketamine group (140.2 ± 11.2 mmHg).Respiratory Rate (RR) was highest in the Tramadol group (20.2 ± 2.0) and lowest in the Control group (15.6 ± 1.4), though this variation was statistically insignificant (p > 0.05).

Conclusion: In the prevention of shivering post-spinal anaesthesia, dexmedetomidine outperforms ketamine and tramadol (p=0.027). Dexmedetomidine has the benefit of keeping haemodynamics, respiratory rate and consciousness stable.

Keywords: Dexmedetomidine, Shivering, tramadol

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INTRODUCTION

Shivering, which commonly occurs after spinal anaesthesia, is characterized by involuntary and repetitive movements of skeletal muscles. After neuraxial anaesthesia, the incidence of perioperative shivering is relatively high, with estimates ranging from about 40% to 70%.[1]It raises the consumption of oxygen and production of carbon dioxide, leads to lactic acidosis, and results in dissatisfaction and discomfort for the patient. Shivering can also lead to an increase in intraocular and intracranial pressure, exacerbate wound pain, hinder the healing process of wounds, and prolong the duration of postanaesthetic care before discharge. Another drawback is that it hampers the monitoring of blood pressure, electrocardiogram, and oxygen saturation.[2]

A physiological response to cooling of the hypothalamic preoptic area is shivering, which serves to increase metabolic heat production via muscle contraction. The causes of intra/postoperative shivering are diverse and encompass factors such as loss of temperature, heightened sympathetic tone, pain, and the systemic release of pyrogens.[3] Spinal anaesthesia diminishes tonic vasoconstriction, which contributes to thermoregulatory system impairment and a lowered shivering threshold. Sympathetic paralysis leading to extensive vasodilatation may occur with spinal anaesthesia when sensory loss extends up to the T6 level. Shivering can be managed through both non-pharmacological and pharmacological approaches.[4]

Tramadol is a preferred and widely used medication for shivering after spinal anaesthesia. It prevents the uptake of serotonin and noradrenaline in the spinal cord while promoting the release of hydroxyltryptamine, thereby modulating the human temperature regulation centre. Another agent, ketamine, has become popular over the past ten years.[5]The recent sedative dexmedetomidine lowers the shivering threshold by diminishing vasoconstriction. Compared to tramadol, dexmedetomidine has a lower incidence of nausea and vomiting, and it offers superior sedation compared to ketamine.[6]

AIM AND OBJECTIVES

The present study compared efficacy of Dexmedetomidine, Ketamine and Tramadol for prevention of perioperative shivering under Spinal Anaesthesia.

MATERIALS AND METHODS

Study Design: Prospective, randomized, double-blind, controlled clinical study.

Study Population

- Total Number of Participants: 80 patients.
- Age Group: 18–65 years.
- Gender: Both male and female.
- ASA Physical Status Classification: Grade I and II.
- Type of Surgery: Elective surgeries under spinal anaesthesia.

Study Place: The study was conducted in theDepartment of Anaesthesia, Lord Buddha Koshi Medical College & Hospital, Saharsa, Bihar, India in collaboration with Department of Anaesthesia, Nalanda Medical College and Hospital, Patna, Bihar, India

Study Duration: The study was carried out over a period of 18 months from June 2023 to December 2024.

Inclusion Criteria

- Patients aged 18 to 65 years.
- ASA physical status I and II.
- Scheduled for elective surgeries under spinal anaesthesia.
- Provided written informed consent.

Exclusion Criteria

- Known hypersensitivity to Tramadol, Ketamine, or Dexmedetomidine.
- History of psychiatric illness or chronic analgesic/sedative use.
- Patients with cardiovascular, respiratory, hepatic, or renal dysfunction.
- Pregnant or lactating women.
- Patients with contraindications to spinal anaesthesia.

Ethical Considerations

- Ethical clearance was obtained from the institutional ethics committee.
- Informed written consent was taken from all patients after explaining the procedure, risks, and benefits of participation.

Study Procedure

- Randomization: 80 Patients were randomly allocated into four groups (Group I–IV) with 20 patients each using a computer-generated random number table.
- Blinding: Double-blind – neither the patient nor the observer knew the group allocation.

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Group Allocation and Drug Administration:

- Group I (Tramadol): 0.5 mg/kg IV diluted to 5 mL with normal saline.
- Group II (Dexmedetomidine): 0.5 μg/kg IV diluted to 5 mL.
- Group III (Ketamine): 0.25 mg/kg IV diluted to 5 mL.
- Group IV (Control): 5 mL of normal saline.
- All drugs were administered slowly over 1–2 minutes, 5 minutes before spinal anaesthesia.

Surgical Technique

- Spinal anaesthesia was performed in a sitting position at L3–L4 or L4–L5 interspace using 0.5% hyperbaric bupivacaine 15 mg.
- Patients were placed in a supine position after the block.
- Standard intraoperative care and temperature maintenance protocols were followed.

Outcome Measures

Primary Outcome:

Incidence and severity of perioperative shivering as measured by a 4-point grading scale. Grades of Shivering:

- Grade 0: No shivering.
- Grade 1: Mild fasciculations of the face/neck.
- Grade 2: Visible tremors involving more than one muscle group.
- Grade 3: Gross muscle activity involving the whole body.
- Grade 4: Severe whole-body muscle activity.

Secondary Outcomes:

- Hemodynamic parameters: Heart rate, non-invasive blood pressure.
- Respiratory parameters: SpO_2, respiratory rate.
- Level of consciousness.
- Incidence of nausea and vomiting.

Monitoring Schedule:

- Every 5 minutes for the first 30 minutes post spinal anaesthesia.
- Every 15 minutes thereafter for the remainder of the perioperative period.

Statistical Analysis

- Data were compiled and analyzed using appropriate statistical software (e.g., SPSS, version 25.0).
- Continuous variables were expressed as mean ± standard deviation (SD).
- Categorical variables were expressed as percentages.
- Comparative analysis was done using:

ANOVA for continuous variables.

Chi-square test/Fisher's exact test for categorical variables.

- A P value < 0.05 was considered statistically significant.

RESULTS

The present study included 80 patients of 18-65 years, both genders were divided into 4 groups of 20 each.

Table 1: Baseline demographic characteristics of study participants

Parameter	Group I (Tramadol), n=20	Group II (Dexmedetomidine), n=20	Group III (Ketamine), n=20	Group IV (Control), n=20	P value
Age (years)	37.42 ± 1.99	38.10 ± 1.56	37.5 ± 2.04	38.16 ± 1.69	0.94
Weight (kg)	62.5 ± 3.47	62.25 ± 2.50	60.97 ± 1.90	62.21 ± 3.19	0.90
ASA I/II	11 / 9	12 / 8	9 / 11	13 / 7	0.57

Table 1 shows that mean age was 37.4 years in group I, 38.1 years in group II, 37.5 years in group III and 38.16 years in group IV. The mean weight was 62.5 kgs, 62.25 kgs, 60.97 kgs and 62.21 kgs in group I, II, III and IV respectively. ASA I/II was 11:9, 12:8, 9:11 and 13:7 in group I, II, III and IV respectively. The difference was non- significant (P> 0.05).

Table 2: Grades of Shivering

Grade	Group I (Tramadol)	Group II (Dexmedetomidine)	Group III (Ketamine)	Group IV (Control)	P value
Grade 0	13	20	18	12	0.05
Grade 1	3	0	1	4	
Grade 2	1	0	0	3	
Grade 3	2	0	1	1	
Grade 4	1	0	0	0	

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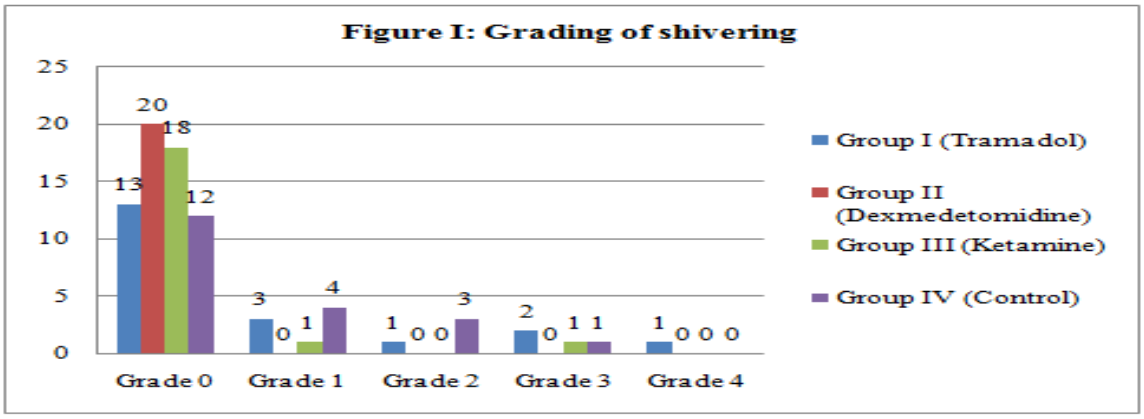

Table 2, figure I shows that in Group I (Tramadol), the highest number of patients (13) had Grade 0 (no shivering).3 patients were assigned to Grade 1, 1 patient to Grade 2, 2 patients to Grade 3, and 1 patient to Grade 4.In Group II (Dexmedetomidine), Grade 0 was seen in all 20 patients, showing no shivering in this group.No patients experienced Grade 1, Grade 2, Grade 3, or Grade 4.In Group III (Ketamine), 18 patients were in Grade 0 (no shivering).1 patient was in Grade 1, 0 patients in Grade 2, 1 patient in Grade 3, and 0 patients in Grade 4.In Group IV (Control), 12 patients experienced Grade 0 (no shivering).4 patients had Grade 1, 3 patients had Grade 2, 1 patient had Grade 3, and no patients had Grade 4.The P value is 0.05, which indicates that the differences observed in the distribution of shivering grades across the four groups are statistically significant at the 5% significance level. This suggests that the type of medication used (Tramadol, Dexmedetomidine, Ketamine, or Control) has a notable impact on the incidence and severity of perioperative shivering.

Table 3: Assessment of Haemodynamic and Respiratory Parameters (Mean ± SD)

Parameter	Group I (Tramadol)	Group II (Dexmedetomidine)	Group III (Ketamine)	Group IV (Control)	P value
HR (beats/min)	91.2 ± 7.4	80.0 ± 6.8	91.0 ± 7.0	76.2 ± 6.6	0.42
SBP (mmHg)	120.2 ± 10.5	118.6 ± 9.8	140.2 ± 11.2	119.4 ± 10.0	0.23
DBP (mmHg)	80.2 ± 6.2	72.4 ± 5.8	76.4 ± 6.0	78.0 ± 6.6	0.58
SpO_2 (%)	99.2 ± 0.6	98.6 ± 0.5	99.0 ± 0.4	98.2 ± 0.8	0.17
RR (breaths/min)	20.2 ± 2.0	17.4 ± 1.8	17.2 ± 1.6	15.6 ± 1.4	0.64

Table 3 show that Heart Rate (HR) was lower in the Dexmedetomidine group (80.0 ± 6.8 bpm) and the Control group (76.2 ± 6.6 bpm) compared to the Tramadol and Ketamine groups.Systolic Blood Pressure (SBP) was notably higher in the Ketamine group (140.2 ± 11.2 mmHg), likely due to its sympathomimetic effects.Diastolic Blood Pressure (DBP) showed minimal variation across groups.SpO_2 levels remained within normal range in all groups, indicating no significant respiratory depression.Respiratory Rate (RR) was highest in the Tramadol group (20.2 ± 2.0) and lowest in the Control group (15.6 ± 1.4), though this variation was statistically insignificant ($p > 0.05$). No statistically significant difference was observed in any of the parameters across groups ($p > 0.05$), suggesting stable haemodynamic and respiratory profiles in all interventions.

DISCUSSION

Dexmedetomidine, a recent sedative agent, lowers the shivering threshold by decreasing vasoconstriction. Dexmedetomidine results in less nausea and vomiting than tramadol, and it offers superior sedation compared to ketamine.[7] Due to the potential harm caused by perioperative shivering, it is essential to prioritize prevention over treatment. A number of investigations have been carried out regarding tramadol and ketamine.[8] However, there are only a limited number of trials involving the recent

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drugdexmedetomidine in comparison to either tramadol or ketamine.[9] Tramadol is associated with greater nausea than dexmedetomidine, which is more effective in controlling shivering. Compared to ketamine, dexmedetomidine provides greater sedation while shivering is reduced.[10]

The present study compared efficacy of Dexmedetomidine, Ketamine and Tramadol for prevention of perioperative shivering under Spinal Anaesthesia.

We found that mean age was 37.4 years in group I, 38.1 years in group II, 37.5 years in group III and 38.16 years in group IV. The mean weight was 62.5 kgs, 62.25 kgs, 60.97 kgs and 62.21 kgs in group I, II, III and IV respectively. ASA I/II was 11:9, 12:8, 9:11 and 13:7 in group I, II, III and IV respectively. In the present study, all four groups were comparable in terms of baseline demographic characteristics such as age, weight, and ASA physical status, with no statistically significant differences observed ($P > 0.05$). Similar baseline comparability was reported in a study by Kose et al., where patients undergoing spinal anaesthesia were randomly allocated to receive different anti-shivering agents, including tramadol and ketamine, and no significant demographic differences were found among groups.[11] Another randomized trial by Usta et al. comparing intravenous dexmedetomidine and tramadol for shivering prevention also reported comparable age, weight, and ASA status among study groups, supporting the reliability of random allocation in clinical trials.[12]

Khan et al.[13]compared the efficacy, effect on haemodynamics, and any adverse effects of tramadol, ketamine and dexmedetomidine when used prophylactically to prevent perioperative shivering after spinal anaesthesia. A total of 120 patients were assigned to four groups: T, D, K, and N, to receive Tramadol 0.5 mg/kg or Dexmedetomidine 0.5 µg/kg or Ketamine 0.25 mg/kg or normal saline 5 mL, respectively. Each study drug was diluted to 5 mL using normal saline and administered as a slow intravenous (i.v.) bolus injection five minutes before spinal anaesthesia. Patients received subarachnoid block in L3-4 or L4-5 space in sitting position with 0.5% hyperbaric bupivacaine 15 mg. Patients were monitored for shivering, (using a four-point scale), level of consciousness, heart rate, SpO2, respiratory rate, non- invasive blood pressure, nausea and vomiting, at intervals of every five minutes for the first 30 minutes and every 15 minutes for the remaining observation period. Dexmedetomidine (n=0) offered lower incidence of shivering prevention after spinal anaesthesia than ketamine (n=2, 6.6%), tramadol (n=10,33%) and normal saline groups (n=11, 36.6%). Dexmedetomidine also provided the advantages of maintaining haemodynamics, respiratory rate, and consciousness, similar to ketamine or tramadol (p-value >0.05).

The incidence and severity of perioperative shivering were significantly lower in the Dexmedetomidine group compared to the other groups, with **100% of patients in Group II (Dexmedetomidine) showing no shivering (Grade 0)**, as opposed to 65% in the Tramadol group, 90% in the Ketamine group, and only 60% in the Control group. The overall **p value was 0.05**, indicating a statistically significant difference among the groups.Shivering is a common complication under spinal anaesthesia, with a reported incidence ranging from 40% to 60% in the absence of prophylactic treatment.[14] It not only causes discomfort but also increases metabolic demand and oxygen consumption, which can be detrimental in patients with limited cardiopulmonary reserves.[15]

The findings in the Dexmedetomidine group are consistent with previous studies. **Bajwa et al. (2012)** reported that Dexmedetomidine at a dose of 0.5 µg/kg effectively prevented shivering without significant sedation or haemodynamic instability.[16] Dexmedetomidine, an α2-adrenergic agonist, acts centrally to reduce the shivering threshold, thereby providing effective prophylaxis.

In the **Tramadol group**, 65% of patients did not experience shivering, which aligns with findings from **Sharma et al. (2011)**, who observed that Tramadol was effective in reducing the severity of shivering due to its opioid and serotonergic activity.[17] However, its use can be limited by side effects such as nausea and vomiting, which may affect patient comfort.

Ketamine, an NMDA receptor antagonist, also showed efficacy in preventing shivering with 90% of patients in the Ketamine group (Group III) being shivering-free. **Wang et al. (2017)** concluded that low-dose ketamine was effective in reducing the incidence of shivering and was associated with minimal psychomimetic effects at subanesthetic doses.[18]

Sahi S et al.[19], conducted a trial between dexmedetomidine (1 µg/kg), clonidine (2 µg/kg), tramadol (1 mg/kg) along with normal saline. All three drugs prevented postspinal shivering, but

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tramadol had significantly less nausea and shivering.

The study found **no statistically significant differences** in heart rate, blood pressure, SpO_2, or respiratory rate between the intervention and control groups, indicating that all drugs were **haemodynamically stable and safe** in the administered doses.

Dexmedetomidine, an α2-adrenergic agonist, is known for its sympatholytic properties, which can lead to **bradycardia and hypotension**.[20] In our study, although the HR and DBP were lower in the Dexmedetomidine group, the differences were not statistically significant. This aligns with findings by Talke et al., who observed dose-dependent haemodynamic changes with Dexmedetomidine but found it generally safe in low doses.[21]

Ketamine, a dissociative anesthetic, demonstrated a mild increase in systolic BP, which may be attributed to its sympathomimetic activity, consistent with previous literature.[22]Despite the elevation, no adverse haemodynamic events were recorded.

Tramadol maintained relatively stable parameters, reflecting its minimal cardiovascular impact, as also reported by De Witte and Sessler.[23]

SpO_2 and respiratory rate remained within normal limits in all groups, with no cases of respiratory depression. These findings further affirm that low-dose administration of these drugs does not compromise **respiratory function**, making them suitable adjuvants in spinal anaesthesia.[12]

Hidayah et al.[24] studied 150 ASA classification I and II patients between 18 and 70 years old scheduled for any elective surgery performed under spinal anaesthesia. Patients were randomly allocated to receive either prophylactic IV ketamine 0.5 mg/kg (Group K), IV tramadol 0.5 mg/kg (Group T) or normal saline as control (Group P) after intrathecal injection of 0.5% hyperbaric bupivacaine 12.5 mg (2.5 ml) and 25 mcg fentanyl. The frequency and degree of shivering, haemodynamic parameters, core body temperature and side effects of the studied drugs were recorded for the first 30 minutes. The incidence of shivering was 8% in Group K, 16% in Group T and 24% in Group P. This result was statistically significant between Groups K and P. Patients from Group K also exhibited significantly higher mean arterial blood pressure and heart rate at 5 and 15 minutes post intrathecal injection while their mean core temperature was also significantly higher. Side effects such as nausea, vomiting, hallucination, agitation and sweating were comparable between all three groups. Patients from Group K however, had significant higher incidence of behavioural changes (blunted affect or catatonic state) and nystagmus.

LIMITATIONS OF THE STUDY

- Small sample size may limit generalizability of the results.
- The study excluded patients with comorbidities, which limits its application in high-risk groups.
- Single-centre study – results may not be applicable in different settings.
- Ambient temperature control was not explicitly standardized, which could influence shivering.
- Short duration of observation – late-onset shivering and side effects may have been missed.
- Subjective assessment of shivering scale – potential observer bias despite blinding.

CONCLUSION

Authors found that in the prevention of shivering post-spinal anaesthesia, dexmedetomidine outperforms ketamine and tramadol. Dexmedetomidine has the benefit of keeping haemodynamics, respiratory rate and consciousness stable.The baseline demographic characteristics, including age, weight, and ASA physical status, were comparable across all four groups, with no statistically significant differences ($p > 0.05$), ensuring the homogeneity of study populations.Dexmedetomidine emerged as the most effective agent for the prevention of perioperative shivering, without compromising haemodynamic or respiratory stability, followed by Ketamine and Tramadol. Its use may be recommended in clinical settings where effective thermoregulation and patient comfort are critical.

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