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Comparative evaluation of dexmedetomidine, tramadol, and dexamethasone in prevention of post-spinal shivering in lower limb orthopedic surgeries

Loveleen Kour[1], Disha Dogra[2], Santosh Gupta[3], Tanvi Gupta[4]

[1]Assistant Professor, [2]Senior Resident, [3,4]Postgraduate Resident, Department of Anaesthesia and Intensive Care, Government Medical College, Jammu, Jammu and Kashmir, India

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ABSTRACT

Background: Shivering is a commonly encountered post-anesthesia event. Tramadol is an easily available drug that is often used to prevent shivering. However, its side effects like nausea have prompted the search for better dugs that could prevent shivering with minimal side effects. **Aims and Objectives**: Our study aimed at comparing the efficacy of tramadol, dexmedetomidine, and dexamethasone in preventing post-spinal shivering in lower limb orthopedic surgeries. **Materials and Methods**: A total of 90 patients were enrolled for this study and divided into three groups – group Dx-received 1 µg/kg of dexmedetomidine, group De-received 0.1 mg/kg of dexamethasone, and group T-received 0.5 mg/kg of tramadol. Incidence of shivering was the primary outcome. Secondary outcomes were-shivering score, sedation score, hemodynamic parameters, and adverse effects, if any. One-way analysis of variance was employed for comparing continuous variables and the Chi-square test for categorical variables. **Results:** Incidence of shivering and shivering score was the least in dexmedetomidine group, followed by tramadol and dexamethasone. Sedation score was higher with dexmedetomidine than tramadol and dexamethasone. **Conclusion**: Dexmedetomidine is most effective in preventing post-spinal shivering in patients. The sedation it caused added comfort to the patients for the duration of surgery and did not cause any significant adverse effect in post-operative period.

Key words: Dexmedetomidine; Dexamethasone; Tramadol; Post-spinal shivering

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INTRODUCTION

Shivering is defined as-Oscillatory, involuntary mechanical muscular activity and natural protective mechanism for the reduction of body temperature.[1] It is a fairly common occurrence, especially after spinal anesthesia with incidence as high as 85%.[2]

Various factors that have been proposed to cause perioperative shivering are –uninhibited spinal reflexes, post-operative pain, decreased sympathetic activity, pyrogen release, adrenal suppression, and respiratory alkalosis.[2] The high incidence of shivering after spinal anesthesia can be explained by the greater heat loss due to vasodilatation, rapid infusion of cold intravenous fluids and decreased shivering threshold caused by the intrathecal block.[2] Spinal anesthesia causes a 0.5° fall in body temperature.[3]

Shivering, apart from causing obvious discomfort to the patient, has a lot of detrimental effects. It nearly triples oxygen consumption and increases body heat production.[1] There is increased carbon dioxide production, increased minute ventilation, and increased risk of myocardial infarction, lactic acidosis, bleeding, raised intracranial, and

Address for Correspondence:
Dr. Loveleen Kour, Assistant Professor, Department of Anaesthesia and Intensive Care, Government Medical College, Jammu - 180 007, Jammu and Kashmir, India. **Mobile:** +91-7006678758. **E-mail:** loveeenkour@gmail.com

intraocular pressures.[4] Apart from these, shivering causes involuntary muscular activity causing an interference with monitoring techniques.[5]

Various modalities have been tried to prevent and treat post-anesthesia shivering. Tramadol is an opioid receptor agonist that also inhibits serotonin and nor adrenalin reuptake in the spinal cord. This facilitates 5 hydroxytryptamine release which influences thermoregulatory control. It is currently the most commonly used drug for the prevention and treatment of shivering. However, it causes nausea and vomiting which is very distressing for the patient. Hence, the need arose for better drugs with comparable efficacy yet free of side effects. Dexmedetomidine is a centrally acting alpha 2-adrenergic agonist. On the other hand, dexamethasone is a corticosteroid with analgesic, anti-inflammatory, and anti-emetic properties. In our study, we aimed at comparing tramadol with dexamethasone and dexmedetomidine to find the drug with maximum efficacy in preventing post-anesthesia shivering with minimal side effects.

Aims and objectives

Our study aimed at comparing the efficacy of tramadol, dexmedetomidine and dexamethasone in preventing post spinal shivering in lower limb orthopaedic surgeries. Primary objective of our study was to study the incidence of shivering with the study drugs. Secondary objectives were-to study shivering score, sedation score and adverse effects if any seen with either of study drugs.

MATERIALS AND METHODS

After obtaining approval of the institutional ethical committee, this study was conducted in the department of anesthesia between June 2021 and October 2022. This was a prospective, randomized, double-blind study.

Ninety American Society of anesthesiologist (ASA) Grade I and II patients aged-18–60 years of either sex, who were scheduled for lower limb orthopedic surgeries, were selected for the purpose of this study.

The inclusion criteria were:
1. Written informed consent from the patient
2. ASA Grade I and II
3. Patients aged 18–60 years of either sex
4. Patients scheduled for elective lower limb orthopedic surgeries.

The exclusion criteria were:
1. Patient refusal
2. Any contraindication to spinal anesthesia like patients with any neurological or bleeding disorder
3. Allergy to any of the study drugs
4. Infection at puncture site
5. Body mass index (BMI) >35 kg/m^2
6. Any comorbidities such as cardiovascular or cerebrovascular diseases, renal impairment, severe liver diseases, and hypo or hyperthyroidism
7. Convulsion or psychiatric disorders

Using GPOWER software version 3.0.10 (Heinrich Heine University Dusseldorf, Germany), it was estimated that the least number of patients required in each group with effect size of 0.25, 80% power, and 5% significance level is 30. Since we had to compare three groups in our study, we included 90 patients in our study.

The patients were randomly allocated into three groups of 30 each. Randomization was achieved with computer-generated random sequence and allocation concealment was done with the help of sequentially numbered, opaque, sealed envelope technique. Blinding was done by preparation of medication according to the assigned group by one anesthesiologist, whereas the performance of the block and administration of the drug was done by another anesthesiologist who was unaware of the group allocation. Data collection was done by the second anesthesiologist.

All the study participants underwent a pre-anesthetic visit during which their basic demographic characteristics (age, sex, BMI) were noted. The patients were kept fasting 8 h before surgery and given tablet alprazolam 0.25 mg night before surgery.

On the morning of surgery, an 18G cannula was secured and patients were pre-medicated with injection pantoprazole 40 mg IV. Upon being shifted to operation theatre, all routine monitoring, namely: Heart rate (HR), non-invasive blood pressure, pulse oximetry (SpO_2), and electrocardiogram was started. Intrathecal block was instituted with the patient in the sitting position with 3 mL of 0.5% heavy bupivacaine. This was immediately followed by prophylactic administration of the study drug according to the group allocated.

- Group Dx-received 1 μ/kg of dexmedetomidine
- Group De-received 0.1 mg/kg of dexamethasone
- Group T-received 0.5 mg/kg of tramadol.

The following parameters were recorded
1. Hemodynamic parameters (HR, systolic blood pressure, diastolic blood pressure, SpO_2, and respiratory rate) were recorded in every 2 min interval till 20 min and thereafter every 5 min interval till the completion of surgery
   Hypotension was defined as decrease in mean arterial pressure of more than 20% of baseline value and was treated with bolus IV injection of mephentermine (6 mg).

Bradycardia, a fall in HR below 50 beats/min was treated with IV atropine 0.6 mg.

2. Incidence and grade of shivering
   Shivering was graded based on Tsai and Chu 5 point score[6]
   - Score 0=No shivering
   - Score 1=Piloerection, peripheral vasoconstriction but no visible shivering
   - Score 2=Muscular activity of 1 muscle group
   - Score 3=Muscular activity of more than 1 Group of muscles but not generalized
   - Score 4=Shivering whole body.

   A rescue drug 1 mg/kg tramadol was administered if continuous shivering score of ≥3 was persisting for more than 10 min irrespective of the group.

3. Degree of sedation

The degree of sedation was graded on a 4-point scale as per Filos et al.,[7] where

- Grade 1=Awake and alert,
- Grade 2=Drowsy, responsive to verbal stimuli,
- Grade 3=Drowsy, arousable to physical stimuli, and
- Grade 4=Unarousable.

Over sedated/sedation score ≥3 with hypoxemia (SpO_2 <92%) was considered for intensive care unit admission.

4. Adverse effects-Nausea, vomiting, headache, allergy, pruritus, and any other undesired effects were noted and managed accordingly.

Incidence of shivering was the primary outcome of our study. Secondary outcomes were-shivering score, sedation score, hemodynamic parameters, and adverse effects, if any.

Statistical analysis

The recorded data were compiled and entered in a spreadsheet (Micro Excel) and then exported to the data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables (age, BMI) were expressed as mean±standard deviation and categorical variables (gender, ASA) were summarized as frequencies and percentages. One-way analysis of variance was employed for comparing continuous variables and The Chi-square test for categorical variables. P<0.05 was considered statistically significant. All P-values were two tailed.

RESULTS

A total of 90 patients who were scheduled for elective lower limb orthopedic surgeries were included in this study. Patients in all the groups were comparable with respect to all demographic characteristics-age, sex, weight, and ASA groups (Table 1).

Table 1: Comparison of baseline demographic variables between group dexmedetomidine, tramadol, and dexamethasone (n=30)

Parameter	Group Dx	Group T	Group De	P-value
Age (years)	44.80±6.67	43.20±5.98	43.80±6.02	0.802
Weight (kg)	66.70±4.87	65.82±7.75	67.02±2.02	0.628
Sex (F/M)	14/16	12/18	13/17	0.584
ASA status, n (%)				
ASA 1	17 (56)	18 (60)	16 (53.3)	0.312
ASA II	13 (43)	12 (40)	14 (46.6)	

The data are expressed as mean±SD and analyzed using one-way ANOVA test or as n (%) and analyzed using Chi-square test. ASA: American Society of Anesthesiologist, group Dx: Dexmedetomidine group, T: Tramadol group, group De: Dexamethasone group; SD: Standard deviation

Incidence of shivering was the least with dexmedetomidine (3 patients-10%); followed by tramadol (5 patients-16.6%). Dexamethasone, on the other hand, reported the highest incidence of shivering (10 patients-33.3%) (Table 2).

Shivering score was the least with dexmedetomidine with 2 out of 3 patients showing Grade 1 and 1 patient showing Grade 2. This was followed by the tramadol group with 2 patients showing Grade 1 and 3 patients showing Grade 2 shivering. Dexamethasone group reported 4 patients with Grade 1, 5 patients with Grade 2, and 1 patient with Grade 3 shivering score (Table 2).

Incidence of sedation was maximum with the dexmedetomidine group (26.6%) followed by tramadol (16.6%) with dexamethasone showing the least incidence (10%). The grade of sedation was Grade 3 in 3 patients (16.6%), Grade 2 in 5 patients (10%), and Grade 1(awake and alert) in the rest of 22 patients in the dexmedetomidine group. Tramadol group showed Grade 2 sedation in 3 patients (10%) and Grade 3 sedation in 2 patients (6.6%). Dexamethasone group showed Grade 2 sedation in 3 patients (10%) who exhibited sedation (Table 2).

Incidence of bradycardia and hypotension was comparable in dexmedetomidine and tramadol group followed by the dexamethasone group (Table 3). However, all episodes of bradycardia and hypotension were short-lived and easily managed with supportive measures.

Nausea and vomiting were noted in the tramadol group. There were no other significant adverse effects such as headache, allergy, and pruritus in any patient.

DISCUSSION

Shivering is a common occurrence in the perioperative period, especially in patients undergoing neuraxial

Table 2: Comparison of incidence of shivering, shivering score, and sedation score between group dexmedetomidine, tramadol, and dexamethasone (n=30)

Parameter	Group Dx	Group T	Group De	P-value
Shivering incidence (%)	10	16.6	33.3	<0.001*
Shivering score (score1/2/3)	2/1/0	2/3/0	4/5/1	<0.001*
Sedation incidence (%)	26.6	16.6	10	<0.001*
Sedation score (Grade 2/3/4)	5/3/0	3/2/0	3/0/0	<0.001*
Sedation score (%)	16.6/10/0	10/6.6/0	10/0/0	<0.001*

The data are expressed as n (%) and analyzed using Chi-square test. Group Dx-dexmedetomidine group, T: Tramadol group, De: Dexamethasone group, *Statistically significant

Table 3: Comparison of hemodynamic parameters between group dexmedetomidine, tramadol, and dexamethasone (n=30)

Parameter	Group Dx	Group T	Group De	P-value
Incidence of bradycardia (%)	5.25	4.62	1.52	<0.001*
Incidence of hypotension (%)	26.5	25	12	<0.001*

The data are expressed as n (%) and analyzed using Chi-square test. Group Dx: Dexmedetomidine group, T: Tramadol group, De: Dexamethasone group, *Statistically significant

anesthesia. Apart from the obvious discomfort to the patient, it has many detrimental effects which warrants the search of drugs which may prevent it.

Traditionally tramadol has been the conventional drug choice for treatment and prophylaxis of shivering. With the addition of new drugs to anesthetist's armamentarium, the scope of finding newer drugs that can prevent shivering has widened. Dexmedetomidine is a centrally acting alpha 2 agonist that has been shown to lower shivering threshold. Dexamethasone is a corticosteroid that has been shown to be effective in preventing shivering.

In our study, we compared these three drugs with regard to their efficacy in preventing shivering and any adverse effects which could limit their utility. We found dexmedetomidine to be the most effective and dexamethasone to be least effective in preventing shivering. The incidence of bradycardia and hypotension was comparable between tramadol and dexmedetomidine group, however, tramadol showed a higher incidence of nausea and vomiting.

The demographic data including age, weight, sex, and ASA grading were comparable in all three groups.

The doses of all study drugs used in our study were based on previous studies where dexmedetomidine in a dose of 1 μ/kg and dexamethasone 0.1 mg/kg had been found to be effective.[8,9] With regards to tramadol, earlier it was used in a dose of 1 mg/kg[10] but the incidence of nausea and vomiting was high. Thereafter, the dose was reduced to preserve the anti-shivering qualities but decrease side effects.[11] Accordingly, we used 0.5 mg/kg tramadol in our study.

Incidence of shivering was the least with dexmedetomidine (10%) followed by tramadol (16.6%) and dexamethasone (33%). The results of our study were similar to those seen by Shah and Ummu Habeeba[9] who studied the efficacy of prophylactic dexmedetomidine and dexamethasone for post-spinal shivering in lower segment cesarean section. They reported shivering incidence of 13.75% with dexmedetomidine as compared with 31.25% seen with dexamethasone. Bicer et al. observed a 15% incidence of shivering with dexmedetomidine and 55% with placebo.[12] Elvan et al.,[13] found that a loading dose of dexmedetomidine followed by maintenance infusion reduced the incidence of shivering to 17.5% as compared to 52.5% with placebos. These results were similar to the findings of our study. Zavareh et al.,[14] who studied the use of i.v dexamethasone in elective surgeries reported a shivering incidence of 31.1%. Usta et al.,[6] also got similar results of incidence of shivering of 10% after use of iv dexmedetomidine (1 mcg/kg). Botros et al.[3] noted 27.5% incidence of shivering following iv dexmedetomidine in patients undergoing elective nonobstetric procedures. This is higher than seen in our study. This could be due to the difference in the demographic profile compared to the current study.

El Bakry and Ibrahim[15] observed Grade 1 shivering in 16.6% and Grade 2 shivering in 3.33% following iv dexamethasone. These results are in line with this study. Tobi et al.,[11] while studying the effects of tramadol on perioperative shivering, reported a shivering incidence of 13.3% which was similar to that seen in our study. Tsai and Chu conducted a study on parturients who shivered after epidural anesthesia and found that 87% who received tramadol (0.5 mg/kg) stopped shivering within 15 min of treatment.[16] Saha et al. observed that tramadol administered at the time of wound closure decreased the incidence of shivering to 20% as compared to 60% in the control group.[17] This was similar to findings of this study. Mathews et al.[18]

observed a reduction in the incidence of shivering to 4% in the tramadol group as compared to 48% in the control group. Mohta et al.,[19] compared the efficacy of tramadol in different doses of 1, 2, and 3 mg/kg with pethidine (0.5 mg/kg) and observed a reduction in the incidence of shivering (9%, 6%, 3%, and 12%, respectively), compared to that in the control group (42%).

Shivering score was also minimal-grade 1 in majority of patients in the dexmedetomidine group while it was grade 2 in the tramadol and dexamethasone groups. One patient in the dexamethasone group showed grade 3 shivering. Ismaiel et al.[20] also noted a decrease in shivering intensity with both dexmedetomidine and dexamethasone, but intrathecal dexmedetomidine was more superior. Usta et al.[6] did not observe more than Grade 3 shivering after iv dexmedetomidine. El Bakry and Ibrahim[15] noted significantly lower intensity of shivering after iv dexamethasone and pethidine compared to the control group. They observed Grade 1 shivering in 16.6% and Grade 2 shivering in 3.33% following iv dexamethasone. These results are in line with the current study. Tobi et al.[11] reported Grade 1 shivering in all patients in the tramadol group. Similarly, Mohta et al.[19] while studying Tramadol in different doses also observed lower grade of shivering in these patients.

The anti-shivering effects of dexmedetomidine are mediated by binding to α^2-receptors that mediate vasoconstriction and the anti-shivering effect. In addition, it also has hypothalamic thermoregulatory effects. Dexmedetomidine reduces the vasoconstriction and shivering thresholds without altering the sweating threshold, suggesting its action on the central thermoregulatory system rather than peripheral actions. Dexmedetomidine has been shown to reduce the core temperature. Studies in healthy volunteers have demonstrated that dexmedetomidine controls shivering by reducing the shivering threshold.[21]

Tramadol is an opioid analgesic with its actions preferably mediated via μ receptor with minimal effect on κ and δ receptors. It has a modulatory effect on central monoaminergic pathways, and thus inhibits the neuronal uptake of noradrenaline/serotonin and encourages hydroxyl-tryptamine secretion which resets the body temperature regulation center.[18]

The anti-shivering effect of dexamethasone is thought to be mediated by the reduction of gradient between skin and body core temperature through it's anti-inflammatory action. It could also reduce shivering by regulating immune responses and inhibition of release of vasoconstrictors and pyrogenic cytokines.[22]

Incidence of sedation was highest with dexmedetomidine followed by tramadol and least with dexamethasone. However, the grade of sedation in dexmedetomidine was Grade 1 and 2 in most patients which was comparable to that with tramadol and dexamethasone. None of the patients had Grade 4 sedation in any group. These perioperative sedative properties of dexmedetomidine were found to be beneficial for patients and surgeons. Shah and Ummu Habeeba,[9] while studying the effects of prophylactic dexmedetomidine and dexamethasone in lower segment cesarean section also reported higher incidence of sedation with dexmedetomidine than dexamethasone. Ismaiel et al.,[20] noted Grade 1 sedation in 50%, Grade 2 in 43.33%, and Grade 3 in 6.66% of parturients after dexmedetomidine compared to Grade 1 sedation in just 20% of parturients after dexamethasone and none of the parturients had Grade 4 sedation in any of the groups. These findings were similar to those seen in our study.

Incidence of bradycardia and hypotension was comparable in dexmedetomidine and tramadol and least in dexamethasone. However, all these episodes were transient, seen immediately after administration of dexmedetomidine and got relieved with help of supportive measures. The higher incidence with dexmedetomidine could be due to it's inherent property to decrease HR due to post-synaptic activation of alpha 2 adrenoceptors in the central nervous system. Ismaiel et al.[20] reported 80% incidence of hypotension in the dexmedetomidine group and 83.3% in the dexamethasone group. They also had 10% and 6.6% of bradycardia incidences in dexmedetomidine group and dexamethasone group, respectively. Shah and Ummu Habeeba[9] reported bradycardia in 6.25% of patients with dexmedetomidine and none in the dexamethasone group. Kundra et al.,[8] while comparing efficacy of dexmedetomidine and tramadol on post-spinal anesthesia shivering, noted only one patient with bradycardia in the dexmedetomidine group and none in the tramadol group.

Post-operative nausea and vomiting (PONV) were a common side effect experienced with tramadol which remains a major delimitation to its use. Not only, is it extremely distressing for the patient but can also lead to serious complications sch as aspiration of gastric contents, suture dehiscence, esophageal rupture, subcutaneous emphysema, or pneumothorax.[8] PONV may delay discharge from PACUs and can be the leading cause of unexpected hospital admission after ambulatory anesthesia.[23]

Limitations of the study

1. Limited sample size.
2. This study included ASA 1 and 2 patients aged 18-60 years. Further studies should include ASA 3 and 4

patients over 60 years to improve the generalizibility of the findings of this study.

CONCLUSION

Both dexmedetomidine and tramadol were found to be more effective than dexamethasone in preventing shivering. However, dexmedetomidine was found to be superior to tramadol in terms of it's effect on incidence and severity of shivering. The sedation caused by dexmedetomidine was mild to moderate and observed to be beneficial to patients in perioperative period. The anti-shivering effects of tramadol were marred by it's propensity to cause nausea and vomiting.

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Authors' Contributions:
LK- Definition of intellectual content, literature survey, prepared first draft of manuscript, implementation of study protocol, data collection, data analysis, manuscript preparation and submission of article, concept, design, clinical protocol, manuscript preparation, editing, and manuscript revision, design of study, statistical analysis and interpretation; **DD**- Review manuscript; **SG**- Literature survey and preparation of figures; **TG**- Coordination and manuscript revision.

Work attributed to:
Government Medical College, Jammu and Kashmir, India.

Orcid ID:
Loveleen Kour - https://orcid.org/0000-0003-0559-359X
Disha Dogra - https://orcid.org/0009-0007-7522-5887
Santosh Gupta - https://orcid.org/0009-0002-4844-4543
Tanvi Gupta - https://orcid.org/0009-0001-0661-0681

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