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Original Article

Anaesthesia Section

Efficacy of Dexmedetomidine for Prevention of Postspinal Anaesthesia Shivering in Orthopaedic Surgeries: A Double-blinded Randomised Controlled Study

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ABSTRACT

Introduction: Post-spinal Anaesthesia Shivering (PSAS) refers to involuntary, repetitive skeletal muscle contractions triggered by a fall in core body temperature that generate heat but can cause significant discomfort, increase intracranial and intraocular pressures and raise oxygen demand with potential clinical consequences.

Aim: To assess the efficacy of two intravenous (i.v.) doses of dexmedetomidine, administered prior to spinal anaesthesia, in preventing PSAS in patients undergoing lower limb orthopaedic procedures.

Materials and Methods: This double-blinded, randomised controlled study was conducted at Department of Anaesthesia, King George's Medical University, Lucknow, Uttar Pradesh, India in collaboration with the Department of Orthopaedics, for a period of 12 months, from October 2022 to September 2023. A total of 75, American Society of Anaesthesiologists (ASA) physical status grade I/II patients were scheduled for elective lower limb orthopaedic surgeries after ethical approval. Participants were randomly assigned to three groups (n=25 each) via a computer-generated sequence: Group I received 100 mL of normal saline; Group II received dexmedetomidine 0.25 µg/kg diluted in 100 mL saline; and Group III received dexmedetomidine 0.5 µg/kg in 100 mL saline. Infusions were administered over 10 minutes. Blinding was maintained for both the administering and observing anaesthesiologists. Categorical data (gender, ASA grade, incidence of shivering, consumption of tramadol) was analysed using Chi-square tests and continuous data {age, height, weight, Body Mass Index (BMI), duration of surgery and spinal anaesthesia, onset of shivering after spinal anaesthesia, temperature, Ramsay sedation score, Heart Rate, (HR) Systolic Blood Pressure (SBP)} was analysed using Analysis of Variance (ANOVA) tests, with level of significance (p-value<0.01) considered as statistically significant.

Results: Demographic variables (age, gender, weight, height, BMI, ASA status and duration of surgery) were comparable across the three groups, in terms of their p-value. The mean onset time of shivering, tramadol consumption and post-spinal temperature fall were not statistically significant. The mean Ramsay sedation score at 10 minutes was highest in group III (3.8±0.98), followed by group II (2.4±0.82) and group I (1.8±0.69), showing a highly significant difference (p-value<0.0001). HR and SBP declined after spinal anaesthesia and rose again at the time of shivering in all groups, with statistically significant differences observed between groups. The duration of spinal anaesthesia increased progressively from group I (153.12±2.84 min) to group II (168.32±3.24 min) and group III (171.44±3.98 min) (p-value<0.0001), while the incidence of adverse events was infrequent.

Conclusion: Preoperative i.v. dexmedetomidine effectively reduces the incidence of shivering following spinal anaesthesia. A lower dose (0.25 µg/kg) is associated with fewer sedative and cardiovascular effects and may be preferable for routine use.

Keywords: Adrenergic alpha-2 receptor agonist, Lower extremity, Tramadol

INTRODUCTION

Shivering after spinal anaesthesia is a common physiological reaction involving repetitive skeletal muscle movements due to hypothermia-induced thermoregulatory responses [1]. It affects approximately 40-70% of patients undergoing such procedures. Although shivering is a physiological attempt to restore thermal homeostasis, its clinical implications extend far beyond discomfort. PSAS elevates oxygen demand, carbon dioxide production, catecholamine release and cardiac output, complicating intraoperative monitoring and patient stability [2]. Shivering can increase patient discomfort, elevate intraocular and intracranial pressures and potentially exacerbate conditions in those with compromised respiratory or cardiac function. The pathophysiology of PSAS is multifactorial. Spinal blockade induces sympathetic vasodilation, leading to redistribution of core heat to the periphery, contributing to a rapid decline in core temperature. Additionally, the impairment of thermoregulatory vasoconstriction below the level of the block, infusion of cold i.v. fluids and impaired thermoregulatory responses despite intact hypothalamic regulation, collectively precipitate a mismatch between heat production and heat loss [3].

Due to these clinical concerns, both pharmacological and non pharmacological strategies have been explored to prevent and treat shivering. Non pharmacological methods, such as forced-air warming, warmed i.v. fluids, circulating-water mattresses and pre-warming can reduce heat loss, but are often insufficient when used alone, particularly in prolonged surgeries or colder operating rooms. Consequently, various pharmacologic agents with anti-shivering properties, targeting various receptors (opioid, alpha-2 adrenergic, serotonergic, anticholinergic) have been utilised. Agents like tramadol, clonidine, fentanyl, meperidine, ketamine and serotonergic antagonists have been used with varying efficacy, but their use may be limited by nausea, vomiting, respiratory depression, excessive sedation, or hallucinations. These limitations have generated interest in alternative agents, such as dexmedetomidine, with more favourable haemodynamic and safety profiles [4-6].

Given the limitations of physical warming techniques, pharmacologic approaches, particularly dexmedetomidine, offer a promising alternative. Dexmedetomidine, a selective alpha-2 adrenoceptor agonist commonly used for its sedative properties, has been found to decrease the shivering threshold and exert anti-shivering effects, thus, making it a versatile adjunct in the perioperative period [7]. Its anti-shivering effect is mediated through central thermoregulatory inhibition, reduction of the shivering threshold and attenuation of sympathetic overactivity [8].

Several studies have been done comparing the efficacy of dexmedetomidine with other drugs such as ketamine, tramadol, meperidine in reducing PSAS, particularly in caesarean section [3,4]. However, there were only a few studies describing the effect of dexmedetomidine in lower limb orthopaedic surgeries, where prolonged surgical duration and larger dermatomal block height may predispose patients to a higher risk of shivering [9,10].

Furthermore, although dexmedetomidine has been studied at various doses, only a small number of trials have compared different i.v. dosing regimens to determine the optimal dose that balances efficacy with haemodynamic stability [11,12]. This creates a knowledge gap regarding the most effective minimal dose that provides adequate anti-shivering protection while maintaining safety, especially in orthopaedic populations who may already be at risk of autonomic fluctuations.

The present study was novel in that it specifically evaluated the comparative efficacy of two i.v. dexmedetomidine doses in preventing PSAS in orthopaedic patients undergoing lower limb surgeries. Unlike previous research, which primarily compared dexmedetomidine with other agents or focused on dose-related effects on sedation and analgesia [11,12] the current study uniquely investigated its prophylactic role against PSAS. The primary objective was to estimate the incidence of PSAS in each group and the secondary objectives were to compare the need of tramadol as a rescue drug for treatment of shivering, to compare the sedation score and body temperature changes, to compare the haemodynamic parameters and to compare the side-effects and complications, if any, among the groups.

MATERIALS AND METHODS

This double-blind, randomised controlled study was conducted at Department of Anaesthesia, King George's Medical University, Lucknow, Uttar Pradesh, India, in collaboration with the Department of Orthopaedics, for a period of 12 months, from October 2022 to September 2023, following Institutional Ethics Committee approval (Ref. code: XI-PGTSC-IIA/P1) and written informed consent.

Sample size calculation: The sample size was calculated (using the following formula) based on the expected difference in shivering incidence (dexmedetomidine group with controls) reported by Usta B et al., assuming α=0.05 and β=0.1, resulting in 25 patients in each group [13]. At the start of the study, 89 patients were assessed for eligibility out of which, 14 patients were excluded from the study and the remaining 75 patients were included in the study.

$$N_1 = \left\{ z1 - \frac{\alpha}{2} * \sqrt{p} * q * \left(1 + \frac{1}{k}\right) + z1 - \beta * \sqrt{p1} * q1 + \left(\frac{p2q2}{k}\right) \right\} 2/\Delta 2$$

{p1, p2=proportion (incidence) of groups #1 and #2 , Δ=|p2-p1|=absolute difference between two proportions, n1=sample size for group #1, n2=sample size for group #2, α=probability of type I error (usually 0.05), β=probability of type II error (usually 0.2), z=critical Z value for a given α or β, K=ratio of sample size for group #2 to group #1}

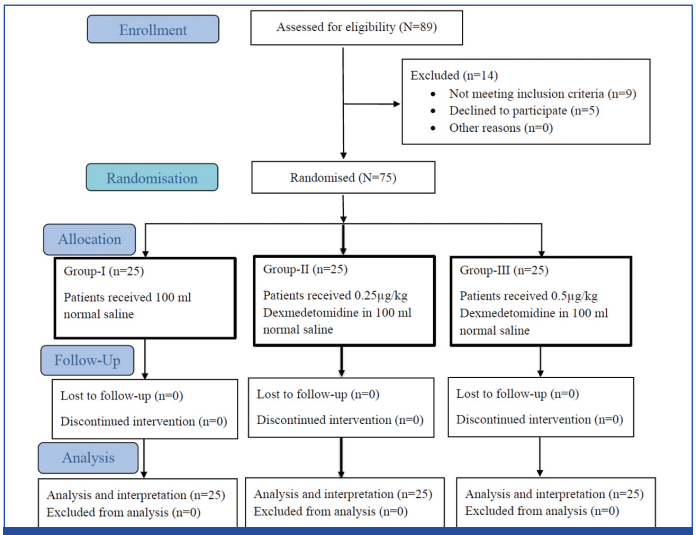
Inclusion criteria: Patients aged 18-60 years, ASA physical status I or II and patients scheduled for lower limb orthopaedic surgeries.

Exclusion criteria: Refusal to participate, allergies to study drugs, contraindications to spinal anaesthesia, significant co-morbidities (neurological, respiratory, endocrine, cardiac, hepatic, renal), bradycardia, heart block, pregnancy, or lactation.

Study Procedure

Participants were randomly allocated into three groups (n=25 each) via a computer-generated random number table [Table/Fig-1]. Random allocation sequence was computer-generated, done by a statistician. The participants were enrolled and assigned to the intervention by a junior resident of the Anaesthesiology department, who was not a part of the data collection process.

- Group I: 100 mL of normal saline (control group),
- Group II: Dexmedetomidine 0.25 µg/kg in 100 mL saline,
- Group III: Dexmedetomidine 0.5 µg/kg in 100 ml saline.



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) diagram showing random allocation of patients into three groups.

The dose of dexmedetomidine was decided based on previous studies [11,12]. Infusions were administered over 10 minutes. The patient and the anaesthesiologist (conducting the case and recording data) were unaware about drug administered or group allocation. Patients were monitored using standard anaesthesia protocols, including HR, Non-invasive Blood Pressure (NIBP), Oxygen Saturation (SpO_2), Electrocardiogram (ECG) and axillary temperature. Preloading with 500 mL of room temperature Ringer's lactate was done before spinal anaesthesia.

Sedation was assessed using Filos four-point scale [14]-

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

Spinal Anaesthesia (SA) was administered at the L3-4 level by 25G Quincke's spinal needle under aseptic conditions in sitting position, using 15 mg of 0.5% heavy bupivacaine with 25 µg fentanyl. All operation theatres were maintained at an ambient temperature of around 24°C-25°C. HR and NIBP were recorded at baseline, five minutes after infusion, five minutes after spinal anaesthesia, 10 minutes after spinal anaesthesia, at the time of shivering and 10 minutes after onset of shivering, along with continuous ECG and SpO_2 monitoring. The attending anaesthesiologist recorded the time of shivering onset after spinal anaesthesia, its severity, duration of surgery and axillary body temperature at 15, 30, 45, 60, 90 and 120 minutes post-spinal anaesthesia.

Shivering was graded using Wrench's four-point scale [15]-

- Grade 0: No shivering,
- Grade 1: One or more of the following: piloerection, peripheral vasoconstriction, peripheral cyanosis, but without visible muscle activity,

- Grade 2: Visible muscle activity confined to one muscle group,
- Grade 3: Visible muscle activity in more than one muscle group and Grade 4: Gross muscle activity involving the whole body.

Tramadol 25 mg i.v. was administered as rescue therapy for shivering grades ≥2. Adverse events like nausea, bradycardia (HR <50 bpm), hypotension (SBP <90 mmHg), or respiratory depression (SpO_2 <92%) were treated with injection Ondansetron 4 mg i.v., injection Atropine 0.6 mg i.v., injection Mephenteramine i.v. in incremental doses of 6 mg and supplemental oxygen at 4 L/min via Hudson face mask, respectively.

STATISTICAL ANALYSIS

Data were analysed using Statistical Package for Social Sciences (SPSS) version 26.0. Continuous variables were presented as mean±SD and analysed using ANOVA; categorical variables were compared using the Chi-square test. Level of significance (p-value<0.05 or 0.001) was considered statistically significant.

RESULTS

Baseline characteristics (age, gender, weight, BMI, ASA grade and duration of surgery) were comparable across all groups except for height, which was significantly higher in group II [Table/Fig-2].

Demographics	Group I (n=25) (Mean±SD)	Group II (n=25) (Mean±SD)	Group III (n=25) (Mean±SD)	p-value
Age	57.00±9.36	60.30±11.2	58.60±7.53	F=0.75 p=0.47
Gender n (%)				
Males	15 (60.00%)	13 (52.00%)	12 (48.00%)	χ^2=0.75 p=0.68
Female	10 (40.00%)	12 (48.00%)	13 (52.00%)	
Weight (kg)	66.93±7.30	69.28±9.40	68.52±6.20	F=0.59 p=0.55
Height (cm)	168.28±10.4	170.67±6.8	169.38±4.2	F=0.62 p=0.54
BMI (kg/m^2)	21.51±2.14	22.51±2.78	22.15±2.24	F=1.11 p=0.33
ASA grade n (%)				
I	3 (12.00%)	5 (20.00%)	6 (24.00%)	χ^2=1.23 p=0.54
II	22 (88.00%)	20 (80.00%)	19 (76.00%)	
Duration of surgery (min)	118.62±25.54	116.42±28.94	112.00±38.00	F=0.29 p=0.74

[Table/Fig-2]: Demographic distribution of patients .
*p-values for age, weight, height, BMI, duration of surgery calculated by ANOVA test and for gender, ASA grade by Chi-square test.

Shivering incidence was highest in the placebo group (24%) and lower in the dexmedetomidine groups (12% each). The onset of shivering after spinal anaesthesia and consumption of tramadol was statistically non significant among the three groups [Table/Fig-3].

Mean temperature dropped in all groups, without significant intergroup differences [Table/Fig-4].

Ramsay sedation scores at 10 minutes post-infusion were highest in group III, followed by group II and lowest in group I, with p-value<0.0001 [Table/Fig-5].

The significant differences in HR were observed among the groups at five minutes after infusion, five minutes after spinal anaesthesia, 10 minutes after spinal anaesthesia, at time of shivering and 10 minutes after the onset of shivering (p-value<0.0001) [Table/Fig-6].

The significant differences in SBP were observed among the groups at five minutes after infusion (p-value=0.0436), 10 minutes after spinal anaesthesia (p-value=0.0008), at the time of shivering (p-value=0.0015) and 10 minutes after onset of shivering (p-value=0.0324) [Table/Fig-7].

Incidence of shivering	Group I (n=25) n (%)	Group II (n=25) n (%)	Group III (n=25) n (%)	p-value
0	19 (76.00)	22 (88.00)	22 (88.00)	
1	0	1 (4.00)	2 (8.00)	
2	2 (8.00)	2 (8.00)	1 (4.00)	
3	4 (16.00)	0	0	
4	0	0	0	
Total	6 (24.00)	3 (12.00)	3 (12.00)	χ^2=1.786 p=0.41
Consumption of tramadol (mg)	6 (24.00)	2 (8.00)	1 (4.00)	χ^2=5.303 p=0.07
Onset of shivering after spinal anaesthesia (min)	37.46±4.85	38.67±3.98	36.32±3.24	F=2.07 p=0.13

[Table/Fig-3]: Incidence of shivering, consumption of tramadol and onset of shivering after spinal anaesthesia.
*p-values for incidence of shivering, consumption of tramadol calculated by Chi-square test and for onset of shivering after spinal anaesthesia by ANOVA test.

Temperature (°celsius)	Group I (n=25) (Mean±SD)	Group II (n=25) (Mean ±SD)	Group III (n=25) (Mean ±SD)	p-value
Baseline	36.72±0.23	36.76±0.27	36.73±0.25	F=0.17 p=0.84
15 min after spinal anaesthesia	35.93±0.26	35.94±0.22	35.93±0.24	F=0.01 p=0.98
30 min after spinal anaesthesia	35.72±0.21	35.73±0.36	35.72±0.32	F=0.01 p=0.99
45 min after spinal anaesthesia	35.65±0.25	35.64±0.42	35.66±0.35	F=0.02 p=0.97
60 min after spinal anaesthesia	35.51±0.34	35.52±0.29	35.52±0.31	F=0.01 p=0.99
90 min after spinal anaesthesia	35.46±0.41	35.47±0.44	35.46±0.39	F=0.01 p=0.99
120 min after spinal anaesthesia	35.41±0.49	35.42±0.47	35.43±0.43	F=0.01 p=0.98

[Table/Fig-4]: Mean temperature of enrolled patients.
*p-values for temperature calculated by ANOVA test (F value)

Ramsay sedation score (10 min after infusion)	Group I (n=25) (Mean±SD)	Group II (n=25) (Mean±SD)	Group III (n=25) (Mean±SD)	p-value
	1.8±0.69	2.4±0.82	3.8±0.98	F=37.46 p<0.0001*

[Table/Fig-5]: Ramsay sedation score of enrolled patients (10 min after infusion).
*p-values for Ramsay sedation score calculated by ANOVA test

Heart Rate (HR)	Group I (n=25) (Mean±SD)	Group II (n=25) (Mean±SD)	Group III (n=25) (Mean±SD)	p-value
Baseline	88.4±4.63	87.3±4.82	85.3±4.62	F=2.80 p=0.06
5 min after infusion	86.3±5.73	80.5±4.87	72.5±5.73	F=40.29 p<0.0001*
5 min after spinal anaesthesia	87.5±4.55	81.6±4.24	73.2±5.63	F=55.04 p<0.0001*
10 min after spinal anaesthesia	86.8±5.53	82.2±5.73	73.8±4.52	F=38.37 p<0.0001*
At time of shivering	92.8±4.88	86.3±5.83	74.1±5.55	F=76.29 p<0.0001*
10 min after onset of shivering	91.6±4.73	85.4±5.77	73.9±4.37	F=80.92 p<0.0001*

[Table/Fig-6]: Mean Heart Rate (HR) of enrolled patients.
*p-values for Heart Rate (HR) calculated by ANOVA test

SBP (mmHg)	Group I (n=25) (Mean±SD)	Group II (n=25) (Mean±SD)	Group III (n=25) (Mean±SD)	p-value
Baseline	123.8±6.35	125.9±7.56	123.9±6.54	F=0.75 p=0.47
5 min after infusion	121.6±6.73	121.8±6.67	117.3±7.64	F=3.2 p=0.04*

5 min after spinal anaesthesia	112.4±7.75	111.2±7.86	109.5±6.75	F=0.95 p=0.39
10 min after spinal anaesthesia	108.5±6.53	107.8±6.35	101.6±7.43	F=7.82 p=0.0008*
At time of shivering	117.3±6.78	113.5±7.75	109.8±6.53	F=7.09 p=0.0015*
10 min after onset of shivering	116.9±6.87	114.6±7.53	111.4±7.43	F=3.59 p=0.03*

[Table/Fig-7]: Mean Systolic Blood Pressure (SBP) of enrolled patients.
*p-values for Systolic Blood Pressure (SBP) calculated by ANOVA test

The duration of spinal anaesthesia increased progressively from group I (153.12±2.84 min) to group II (168.32±3.24 min) and group III (171.44±3.98 min), which was statistically significant (p-value<0.0001) [Table/Fig-8].

	Group I (n=25) (Mean±SD)	Group II (n=25) (Mean±SD)	Group III (n=25) (Mean±SD)	p-value
Duration of spinal anaesthesia (min) (sensory block)	153.12±2.84	168.32±3.24	171.44±3.98	F=202.7 p<0.0001*

[Table/Fig-8]: Duration of spinal anaesthesia (sensory block) of enrolled patients.
* p-values for duration of spinal anaesthesia calculated by ANOVA test

Nausea and vomiting were seen in only one patient of group I, while none of the patients of the dexmedetomidine groups experienced it. Bradycardia occurred in only one patient in group II and two patients in group III, while hypotension was observed in just one patient in group III.

DISCUSSION

The SA, widely regarded as a reliable technique for lower limb orthopaedic procedures, frequently results in hypothermia and shivering by impairing thermoregulation, inhibiting tonic vasoconstriction and promoting redistribution of core body heat to the periphery [16,17]. Shivering adversely affects intraoperative stability and postoperative recovery. Effective shivering prevention has become a necessity for boosting perioperative patient comfort and reducing problems linked with shivering. Different clinical trials have evaluated various drugs such as meperidine [4,7], ketamine and tramadol [3,18] that act on these receptors to prevent or treat shivering following SA. These drugs have produced different degrees of efficacy, along with side-effects such as haemodynamic instability, respiratory depression, nausea and vomiting. Pharmacologic prevention using dexmedetomidine, an alpha-2 adrenergic agonist, offers benefits in both anti-shivering and sedative effects [19].

In the current study, higher shivering incidence was observed in the placebo group, which confirms that dexmedetomidine infusion was able to reduce shivering incidence as compared to the placebo group, in which only normal saline was given. Similar findings have been reported in other studies, including those by Kour L et al. and Mohammed S et al., who demonstrated superior anti-shivering efficacy of dexmedetomidine over other agents [18,20].

Notably, the present study found a reduced need for rescue tramadol in dexmedetomidine groups (4-8%) compared to the placebo group (24%). It was consistent with a meta-analysis done by Ferrea G et al., who compared four intravenous agents- dexmedetomidine, tramadol, nalbuphine and meperidine- for managing shivering during caesarean delivery under neuraxial anaesthesia and concluded that dexmedetomidine was the most effective [21]. Donatiello V et al., further demonstrated that its continuous infusion during orthopaedic procedures under locoregional anaesthesia enhanced the analgesic action of local anaesthetics and reduced postoperative opioid needs [22].

In the current study, Ramsay sedation score, measured at 10 minutes post-infusion, was higher in dexmedetomidine groups as compared to placebo groups. These findings aligned with those of Patel R et al., who found both 0.3 µg/kg/hr and 0.5 µg/kg/hr dexmedetomidine infusions provided effective sedation [23].

The present study's findings of a consistent intraoperative decline in axillary skin temperature- most prominent within the first 30 minutes after spinal anaesthesia- corroborate earlier studies that have not only highlighted such thermal drops but also explored underlying causes and effective strategies for managing perioperative hypothermia [24,25].

Bradycardia and hypotension were more common with the higher dexmedetomidine dose, consistent with Liu F et al. and Hung TY et al., who identified cardiovascular side-effects requiring attention [26,27]. However, no respiratory depression occurred, confirming dexmedetomidine's safety in this regard.

In minimal dose of 0.25 µg/kg, dexmedetomidine effectively prevents PSAS and due to its favourable safety profile, such as analgesia, conscious sedation and absence of respiratory compromise, it is safe to use even in settings with limited anaesthesia expertise.

Limitation(s)

Limitations include a single-centre design and variability in surgical team expertise. Results may not generalise to patients with comorbidities or undergoing non orthopaedic procedures.

CONCLUSION(S)

Intravenous dexmedetomidine administered prior to spinal anaesthesia was effective in reducing both the incidence and severity of shivering in patients undergoing lower limb orthopaedic surgery. Within the dose range of 0.25-0.5 µg/kg used in the present study, it not only attenuated post-spinal shivering but also provided favourable haemodynamic stability with fewer side-effects. A minimal dose of 0.25 µg/kg dexmedetomidine is sufficient to prevent PSAS, along with its favourable safety profile, providing analgesia and conscious sedation, with no respiratory compromise and fewer cardiovascular effects, supporting its potential for safe use even in settings with limited anaesthesia expertise. The associated sedative effect contributed to improved intraoperative comfort without causing excessive sedation. Dexmedetomidine also appeared to augment the analgesic action of local anaesthetics and lowered postoperative opioid requirements. Furthermore, it demonstrated a wide safety margin, with preservation of respiratory function and no increase in postoperative complications.

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