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A Randomized Controlled Trial Comparing Three Different Doses of Dexmedetomidine as an Effective Modality for Prevention of Post-Spinal Anaesthesia Shivering at Tertiary Care Centre

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ABSTRACT

Background: Shivering is a common and distressing complication after spinal anaesthesia, leading to increased oxygen consumption, carbon dioxide production, and patient discomfort. Dexmedetomidine, an α2-adrenergic agonist, has shown potential in preventing post-anaesthetic shivering. However, the optimal prophylactic dose remains uncertain.

Methods: This randomized controlled trial included 120 patients scheduled for elective lower abdominal, lower limb, and perineal surgeries under spinal anaesthesia. Patients were randomly allocated into four groups (n=30 each): Group A received 0.2 µg/kg dexmedetomidine, Group B received 0.3 µg/kg dexmedetomidine, Group C received 0.5 µg/kg dexmedetomidine, and Group D (control) received normal saline. Study drugs were administered intravenously over 10 minutes immediately after spinal anaesthesia. Incidence and severity of shivering, sedation levels, recurrence of shivering and haemodynamic parameters were recorded and analyzed.

Results: Shivering occurred in 53.3% of patients in the control group compared with 23.3%, 13.3%, and 10% in Groups A, B, and C, respectively ($p < 0.05$). Dexmedetomidine significantly reduced both the incidence and severity of shivering. Group C (0.5 µg/kg) provided an optimal balance between efficacy and safety, with adequate sedation and minimal haemodynamic fluctuations. In contrast, Group A (0.2 µg/kg) & B (0.3 µg/kg), though effective, were associated with recurrence of shivering.

Conclusion: Prophylactic intravenous dexmedetomidine effectively prevents shivering following spinal anaesthesia. A dose of 0.5 µg/kg offers the best compromise between efficacy and safety, making it the preferred option for clinical use. Further multicenter studies are recommended to validate these findings and establish standardized dosing protocols.

Keywords*: Dexmedetomidine, Spinal anaesthesia, Shivering, Prophylaxis, Randomized controlled trial.*

INTRODUCTION

Post-spinal anaesthesia shivering is a frequent and distressing complication encountered in patients undergoing surgery under neuraxial blockade. The incidence of shivering following spinal anaesthesia has been reported to range between **40% and 70%**, depending on patient characteristics and perioperative conditions [1]. Shivering not only causes discomfort but also leads to increased oxygen consumption, carbon dioxide production, lactic acidosis, raised intraocular and intracranial pressure, and interference with haemodynamic monitoring [2,3]. Hence, its prevention has important clinical implications. The exact mechanism of post-spinal anaesthesia shivering is multifactorial. Spinal anaesthesia impairs thermoregulatory vasoconstriction below the level of the block, leading to increased heat loss and redistribution of core heat to the periphery

[4]. Non-thermoregulatory factors, including unopposed sympathetic activity, pain, and reflex muscle activity, have also been implicated [5].

Various pharmacological agents such as meperidine, clonidine, ketamine, tramadol, and ondansetron have been used for the prevention and treatment of shivering, but none is devoid of limitations, including side effects like nausea, vomiting, respiratory depression, or delayed recovery [6,7].

Dexmedetomidine, a highly selective **α_2-adrenergic receptor agonist**, has emerged as a promising alternative due to its sedative, analgesic, anxiolytic, and sympatholytic properties [8]. It has been shown to reduce the shivering threshold and modulate central thermoregulatory control without significant respiratory depression [9]. However, the optimal dose of dexmedetomidine for preventing post-spinal shivering while minimizing haemodynamic instability remains unclear.

Therefore, the present randomized controlled trial was designed to compare the efficacy and safety of **three different intravenous doses of dexmedetomidine (0.2, 0.3, and 0.5 µg/kg)** in preventing shivering following spinal anaesthesia in patients undergoing lower abdominal, perineal, and lower limb surgeries.

MATERIALS AND METHODS

Study Design and Setting

This prospective, randomized, controlled study was conducted after obtaining approval from the Institutional Ethical Committee and written informed consent from all participants. A total of 120 adult patients, aged 18–60 years and belonging to the American Society of Anaesthesiologists (ASA) physical status grades I or II, scheduled for lower abdominal, lower limb, or perineal surgeries under spinal anaesthesia, were included.

Inclusion Criteria

- Age between 18 and 60 years
- Male or female patients
- Glasgow Coma Scale score: 15/15
- Normal higher mental functions
- ASA physical status grade I or II
- Written informed and valid consent obtained
- Expected surgical duration between 1–3 hours

Exclusion Criteria

- Refusal to participate in the study
- Age <18 years or >60 years
- History of cardiac disease, chronic kidney disease, hepatic disease, or malignancy
- Contraindication to spinal anaesthesia
- Known allergy to local anaesthetics or dexmedetomidine
- Patient height <140 cm

Preoperative Evaluation

All patients underwent detailed history taking (including comorbidities, allergies, and addictions), general physical examination, and systemic examination of cardiovascular, respiratory, abdominal, and central nervous systems. Airway and spine evaluation were performed. Routine laboratory investigations included complete blood count, coagulation profile, liver and renal function tests, and random blood sugar. A 12-lead electrocardiogram was performed in all cases.

On the day of surgery, nil per oral (NPO) status was confirmed. Baseline body temperature was measured (36.5–37.5 ^{0}C). In the operating theatre, temperature was kept constant at 18^{0}C. Monitoring included ECG, non-invasive blood pressure (NIBP), and pulse oximetry (SpO_2). An intravenous line was secured using an 18-G or 20-G cannula, and patients were preloaded with 8–10 ml/kg Ringer's lactate or normal saline before induction of anaesthesia.

Randomization and Grouping

Patients were randomly allocated into four groups (A, B, C, D) on an alternate basis:

- **Group A**: Spinal anaesthesia with 15 mg 0.5% hyperbaric bupivacaine followed by intravenous dexmedetomidine 0.2 µg/kg diluted to 10 ml in normal saline, infused over 10 minutes.
- **Group B**: Intravenous dexmedetomidine 0.3 µg/kg diluted to 10 ml in normal saline, infused over 10 minutes.
- **Group C**: Intravenous dexmedetomidine 0.5 µg/kg diluted to 10 ml in normal saline, infused over 10 minutes.
- **Group D (Control group)**: Spinal anaesthesia with 15 mg 0.5% hyperbaric bupivacaine followed by 10 ml normal saline infusion over 10 minutes.

Spinal anaesthesia was administered under aseptic precautions in the sitting position at the L3–L4 interspace using a 25G Quincke needle. Free flow of CSF was confirmed before injecting bupivacaine.

Outcome Measures

Haemodynamic parameters, level of sensory block (assessed by the pinprick method), incidence and severity of shivering, sedation score, and complications (hypotension, bradycardia, nausea, vomiting) were recorded intraoperatively and during the immediate postoperative period (30 minutes).

- **Sedation** was assessed using the Modified Ramsay Sedation Scale (score 1–6).
- **Shivering** was graded according to Wrench's scale (grade 0–4).

Management of Adverse Events

- Hypotension was treated with intravenous inj. Mephentermine.
- Bradycardia was treated with intravenous inj. Glycopyrrolate.
- Oxygen supplementation, warm fluids, warmer and patient covering were used as supportive measures against shivering.
- Persistent shivering was treated with intravenous inj. Dexamethasone or inj. Tramadol as a second-line treatment with standard doses applicable.

RESULTS AND OBSERVATIONS

Table 1: COMPARISON OF AGE DISTRIBUTION IN STUDY GROUPS

Group	Mean	SD	p-value
A	35.13	11.52	0.525
B	38.33	12.49	
C	38.20	11.21	
D	39.37	10.95	

In our study test was applied for comparison of age between the two study groups. In Group A the mean age was 35.13 +/- 11 years, in Group B the mean age was 38.33 +/- 12 years, in group C mean age was 38.20 +/- 11 years and in group D mean age was 39+/- 10 years. There was no statistical difference between the groups with respect to age as their p value (p = 0.525) was >0.05

Table 2: COMPARISON OF GENDER DISTRIBUTION IN STUDY GROUPS

Group		Female	Male	p-value
Group A	**N**	12	18	0.97
	%	40%	60%	
Group B	**N**	13	17	
	%	43.33%	56.66%	
Group C	**N**	12	18	
	%	40.00%	60.00%	
Group D	**N**	11	19	
	%	36.70%	63.30%	

In our study, the Chi square test was used to compare gender distribution between four study groups. The number of males and females in group A was 18 and 12, group B was 17 and 13, group C was 18 and 12, group D 19 and 11. There was a non-significant difference between gender distribution in all four groups (p=0.97)

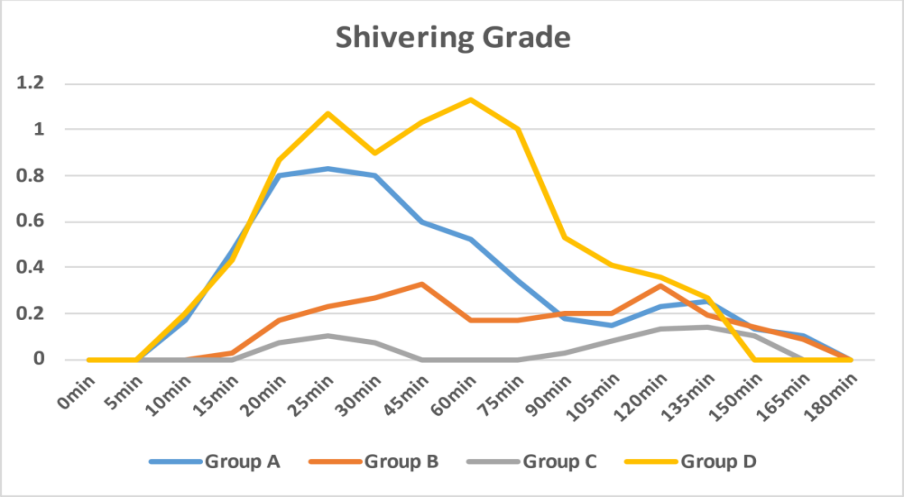

Figure 1: Comparison of Shivering Grade

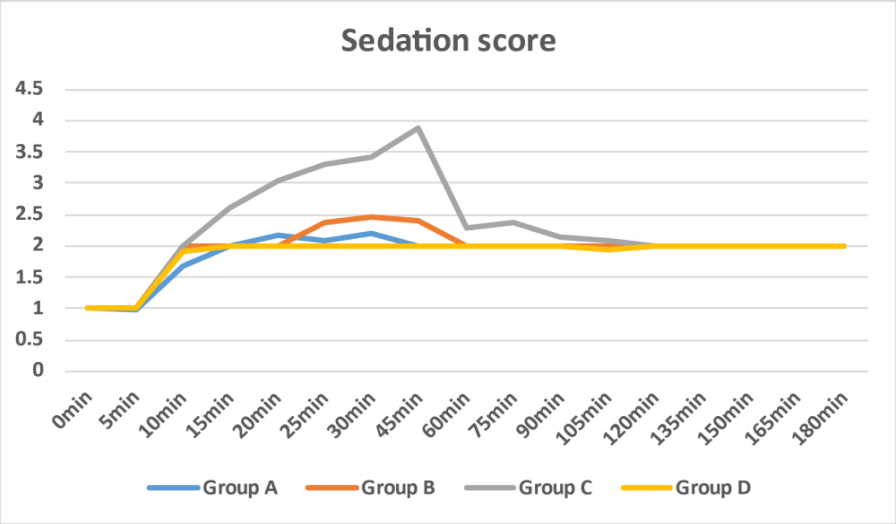

Figure 2: Comparison of Sedation Score in study groups

Table 3: COMPARISON OF SENSORY BLOCKADE ACHIEVED

Group		T2	T4	T6	T8	T10	p-value
Group A	**n**	0	10	10	9	1	
	%	0.00%	33.30%	33.30%	30.00%	3.30%	
Group B	**n**	0	19	10	1	0	
	%	0.00%	63.30%	33.30%	3.30%	0.00%	
Group C	**n**	0	15	14	1	0	
	%	0.00%	50.00%	46.70%	3.30%	0.00%	0.015*
Group D	**n**	1	19	8	2	0	
	%	3.30%	63.30%	26.70%	6.70%	0.00%	

This table compares the maximum sensory blockade achieved in all four groups. In this chi square test was used to compare the sensory blockade achieved in different groups. The maximum level achieved in group A, B, C was T4 while in 1 patient in group D achieved T2 level.

Table 4: COMPARISON OF MEAN SYSTOLIC BLOOD PRESSURE (SBP) IN STUDY GROUPS:

Interval	Group A		Group B		Group C		Group D		p-value
	Mean	**SD**	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	
0min	129.53	9.66	128.93	9.03	130.43	10.16	130.93	8.59	0.844
5min	116.33	10.24	115.60	10.91	116.57	7.49	117.87	8.39	0.821
10min	107.50	8.61	106.83	10.27	104.50	8.28	111.57	7.77	0.021*
15min	100.53	7.01	99.80	8.64	97.43	9.44	102.90	10.90	0.145
20min	96.70	8.34	95.03	7.70	93.87	5.44	98.10	14.10	0.328
25min	98.43	9.28	97.07	5.69	95.93	4.23	100.40	12.72	0.222
30min	101.27	7.78	99.63	5.77	97.73	5.66	103.30	12.88	0.080
45min	103.33	9.79	101.20	6.69	99.73	5.36	105.13	7.10	0.031*
60min	106.03	8.79	104.63	6.21	102.67	7.78	107.87	8.39	0.076
75min	107.00	6.89	105.80	6.90	103.57	10.28	108.70	11.60	0.180
90min	108.28	5.63	107.07	5.46	104.67	8.05	110.17	8.98	0.032*
105min	110.23	6.62	109.29	5.01	105.67	9.62	112.19	7.67	0.015*
120min	110.05	6.84	110.91	6.54	102.10	9.49	111.86	4.47	<0.001*
135min	114.58	5.53	113.73	6.05	102.58	8.85	115.30	6.48	<0.001*
150min	115.50	11.08	114.80	11.71	105.29	7.65	116.86	5.87	0.121
165min	116.70	11.54	116.67	15.06	109.67	9.71	120.00	0.00	0.783
180min	108.50	9.19	115.67	13.65	102.00	0.00	122.00	0.00	0.670

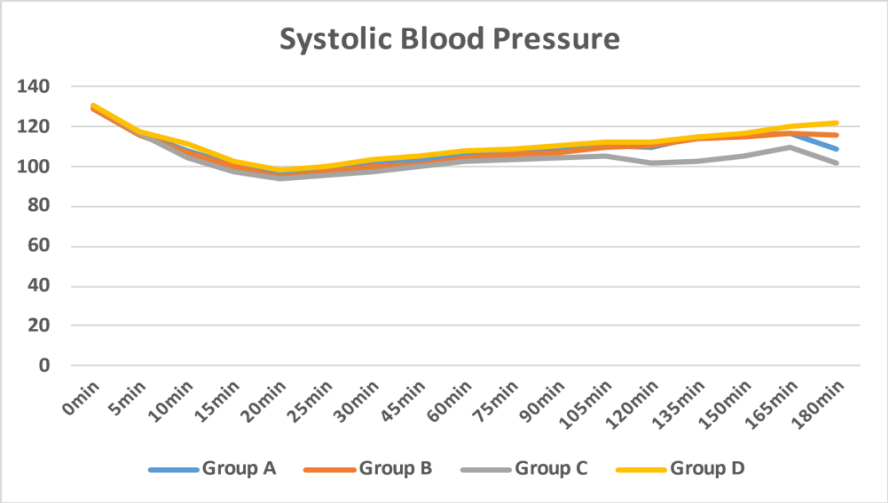

Figure 3: Comparison of Systolic Blood Pressure

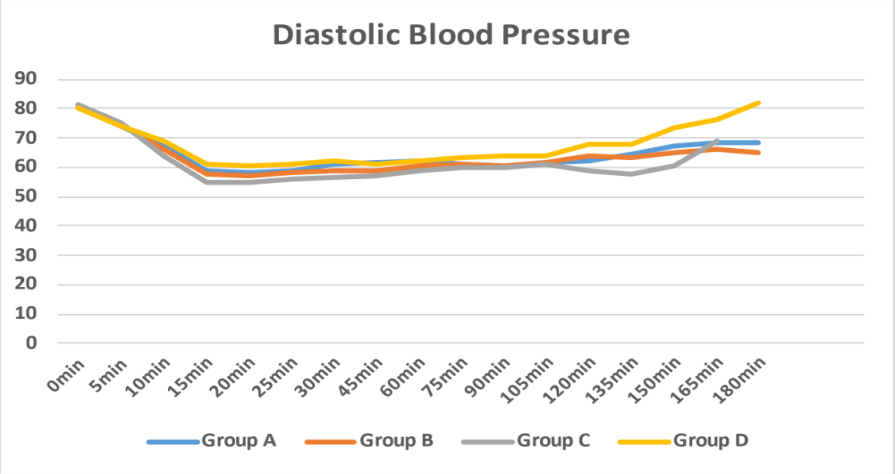

Figure 4: Comparison of Diastolic Blood Pressure

Table 5: COMPARISON OF MEAN ARTERIAL PRESSURE

Interval	Group A		Group B		Group C		Group D		p-value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	
0min	96.38	6.98	97.27	6.50	97.93	4.97	97.11	6.91	0.830
5min	87.38	7.03	88.29	7.24	89.03	4.09	88.73	5.91	0.748
10min	80.34	6.72	79.72	7.38	77.66	7.42	83.02	4.49	0.022*
15min	72.64	6.32	71.67	7.46	68.92	8.45	75.08	7.80	0.020*
20min	71.13	9.55	69.90	7.46	68.00	4.56	73.72	7.61	0.031*
25min	71.69	7.88	71.13	4.80	69.11	4.58	73.96	8.52	0.0501*
30min	74.06	6.57	72.32	5.51	70.44	6.28	76.33	9.45	0.013*
45min	75.37	6.85	73.11	4.55	71.18	5.02	75.73	5.97	0.007*
60min	75.84	7.64	75.01	3.81	73.40	5.71	76.68	7.46	0.230
75min	72.68	14.41	75.93	3.76	74.63	6.88	77.99	6.24	0.127
90min	73.34	14.52	76.13	3.33	74.87	6.79	76.39	15.28	0.707
105min	66.80	26.81	72.49	20.00	67.08	24.92	73.39	22.18	0.583
120min	54.17	36.25	62.30	32.59	46.20	33.56	35.23	40.62	0.031*
135min	51.18	39.76	42.91	39.41	27.83	35.74	31.57	40.69	0.091
150min	38.79	42.49	27.18	39.28	18.24	33.29	24.57	38.39	0.229

Table 6: COMPARISON OF COMPLICATIONS

Group		None	Bradycardia	Hypotension & Bradycardia	Nausea	Vomiting
Gr A	**N**	26	0	0	3	1
	%	86.70%	0.00%	0.00%	10.00%	3.30%
Gr B	**N**	28	0	0	2	0
	%	93.30%	0.00%	0.00%	6.70%	0.00%

Gr C	**N**	28	1	1	0	0
	%	93.30%	3.30%	3.30%	0.00%	0.00%
Gr D	**N**	25	0	0	3	2
	%	83.30%	0.00%	0.00%	10.00%	6.70%

Table 7: DETAILS OF RESCUE MEDICATIONS

Group		**None**	**Inj. Dexamethasone**	**Inj. Glycopyrrolate**	**Inj. Tramadol**
Gr A	**N**	19	11	0	0
	%	63.30%	36.70%	0.00%	0.00%
Gr B	**N**	23	7	0	0
	%	76.70%	23.30%	0.00%	0.00%
Gr C	**N**	27	1	2	0
	%	90.00%	3.30%	6.70%	0.00%
Gr D	**N**	14	10	0	6
	%	46.70%	33.30%	0.00%	20.00%

DISCUSSION

Post-spinal anaesthesia shivering remains a significant challenge in the perioperative period. The present randomized controlled trial compared three different intravenous doses of dexmedetomidine (0.2, 0.3, and 0.5 µg/kg) with placebo for the prevention of shivering in patients undergoing surgeries under spinal anaesthesia. Our findings demonstrate that dexmedetomidine, at all three doses, significantly reduced the incidence and severity of shivering compared with control, with the highest efficacy noted at 0.5 µg/kg.

The incidence of shivering in the control group in our study was consistent with earlier reports, which documented shivering in **40–70%** of patients after neuraxial blockade [1,2]. Dexmedetomidine's efficacy in preventing shivering can be explained by its central α_2-adrenergic receptor agonism, which decreases central thermoregulatory thresholds for vasoconstriction and shivering [3]. Additionally, its sedative and anxiolytic effects may further contribute to better patient tolerance during hypothermic stress [4].

Our results align with the findings of Elvan et al. [5], who reported that dexmedetomidine significantly reduced postoperative shivering in patients undergoing abdominal hysterectomy. Similarly, Bajwa et al. [6] demonstrated that prophylactic dexmedetomidine infusion was effective in reducing the incidence of post-spinal shivering and also provided stable haemodynamics.

In terms of dosing, we observed that **0.5 µg/kg** was most effective in preventing shivering with stable haemodynamics and optimal sedative effect but was associated with a transient bradycardia and hypotension in few patients, consistent with the dose-dependent sympatholytic action of dexmedetomidine [7]. The **0.3 µg/kg dose** provided a favorable balance between shivering control with minimal haemodynamic compromise, however recurrence of shivering intra and postoperatively was observed. This is in agreement with Usta et al. [8], who suggested that lower doses of dexmedetomidine can prevent shivering without major cardiovascular side effects.

Sedation scores in our study were higher in dexmedetomidine groups compared with control, which is consistent with its known sedative properties mediated via locus coeruleus suppression [9]. Importantly, no case of respiratory depression was observed, reaffirming dexmedetomidine's safety profile compared with opioids like meperidine or tramadol [10].

Regarding haemodynamic effects, transient hypotension and bradycardia were noted, particularly at higher doses, but were manageable with standard interventions. Similar haemodynamic alterations have been described in earlier trials [11]. Thus, clinicians should carefully titrate doses, especially in patients with borderline cardiovascular reserve.

Overall, our findings suggest that dexmedetomidine is an effective pharmacologic option for the prevention of post-spinal shivering. Among the studied doses, 0.5 µg/kg may represent the optimal dose, balancing efficacy with haemodynamic safety. Future large-scale multicentric studies are needed to further validate these results and assess long-term outcomes.

CONCLUSION

Dexmedetomidine is an effective agent for the prevention of post-spinal anaesthesia shivering. In this randomized controlled trial, all three studied doses (0.2, 0.3, and 0.5 µg/kg) significantly reduced the incidence and severity of shivering compared with placebo. Among them, **0.5 µg/kg provided the best balance of efficacy and safety**, with minimal haemodynamic compromise and adequate sedation, whereas the 0.3µg/kg and 0.2µg/kg dose, though effective, were associated with recurrence of shivering.

Thus, prophylactic administration of intravenous dexmedetomidine at 0.5 µg/kg appears to be an optimal strategy for preventing shivering following spinal anaesthesia in patients undergoing lower abdominal, lower limb, and perineal

surgeries. Further large-scale studies are recommended to validate these findings and establish standardized dosing guidelines.

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