

Comparison of The Efficacy of Dexmedetomidine Versus Tramadol on Post-Spinal Anesthesia Shivering at Abbasi Shaheed Hospital, Karachi

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Author's Contribution

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ABSTRACT

Objective: To compare the efficacy of dexmedetomidine versus tramadol on post-spinal anesthesia shivering at Abbasi Shaheed Hospital, Karachi.

Methodology: This Randomized control trial was conducted at Department of Anesthesia, Abbasi Shaheed Hospital, Karachi, from 05-06-21 till 05-12-21. Patients aged 20 to 60 years of either gender, classified as ASA \leq II, who developed post-spinal anesthesia shivering were included. Patients were randomly assigned to two groups: Group A received intravenous Dexmedetomidine (0.5 μ g/kg, 1 μ g/ml concentration) over 10 minutes after shivering began post-spinal block, while Group B received intravenous Tramadol (0.5 mg/kg, 1 mg/ml concentration) over the same period. Outcomes assessed as shivering resolution within 15 minutes, absence of recurrence (grade \geq 3), and time taken for shivering to stop after drug administration.

Results: In the dexmedetomidine group, the mean age was 48.21 ± 6.24 years, mean time to disappearance of shivering was 12.54 ± 1.78 seconds, and mean time to recurrence of shivering was 37.4 ± 10.54 minutes. Similarly, in the tramadol group ($n = 77$), the mean age was 49.48 ± 8.41 years, time to disappearance of shivering was 14.52 ± 8.56 seconds, and time to recurrence was 32.8 ± 11.89 minutes. Efficacy was observed in 73 patients (94.8%) in the dexmedetomidine group and in 60 patients (77.9%) in the tramadol group, with a statistically significant difference ($p = 0.01$).

Conclusion: Dexmedetomidine was observed to be a useful alternative to tramadol for the management of post-spinal anesthesia shivering, offering faster relief with fewer incidences of nausea and vomiting.

Keywords: Anesthesia, Dexmedetomidine, Tramadol, Shivering, effectiveness

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Introduction

Anesthesia has evolved over time, allowing straightforward and economical approaches to achieve effective analgesia.¹ Spinal anesthesia is one of these uncomplicated and cost-effective approaches that involves the administration of local anesthesia drugs, injected through lumbar vertebrae into subarachnoid space. Local anesthesia reversibly blocks ventral-dorsal spinal nerve roots, root ganglia, and other spinal cord segments, leading to loss of motor, sensory and visceral nervous system functions.^{2,3} Spinal anesthesia is widely

recognized for its non-invasive preventive management of airway, better pain control, increased postoperative analgesia and quick recovery from analgesia.⁴

Shivering, a biological response to hypothermia, is attributed to a secondary mechanism of heat preservation through non-thermoregulatory process. It has been reported among around 40-70% of cases under spinal anesthesia.^{5,6} Shivering after spinal anesthesia is linked to increased production of CO₂, higher oxygen consumption, poor healing of wound, bleeding, and poor

patient-related outcomes.^{4,7} However, choice of anti-shivering drug mostly relies on availability or preference of clinician.⁸

Pharmacological interventional studies suggest that intravenous administration of dexmedetomidine (sedative), and Tramadol (opioid) are effective against shivering after spinal anesthesia, with quicker onset, quicker control over shivering, lower chances of shivering recurrence and better sedation. Tramadol is frequently administered to control shivering in medical settings, but it often causes unpleasant symptoms like nausea and vomiting, which can be highly uncomfortable for patients. Hence, identifying an alternative medication with minimal adverse effects is important.⁹ Dexmedetomidine, an alpha-2 adrenergic receptor stimulant, has shown effectiveness in both managing and preventing shivering during different surgical procedures by lowering the body's threshold for shivering.^{9,10} However, dexmedetomidine administration was linked with a few side effects including bradycardia and hypotension.¹¹⁻¹³

Available research studies show a very limited number of comparative clinical trials on intravenous administration of dexmedetomidine and tramadol in reducing shivering after spinal anesthesia. Therefore, we conducted a comparative randomized controlled trial on efficacy of intravenous dexmedetomidine and tramadol in minimizing shivering effect of spinal anesthesia.

Methodology

This study was designed as a randomized controlled trial and conducted at the Department of Anesthesia, Abbasi Shaheed Hospital, Karachi. The study duration was six months, commencing after approval Ref no CPSP/REU/ANS-2018-174-1856, from June 5, 2021, to December 5, 2021. A total of 154 patients were included in the study, with 77 patients allocated to each group. The sample size was calculated using WHO software, considering a test power ($1-\beta$) of 80%, a confidence interval of 95%, and a prevalence of prevention of recurrence estimated at 96% versus 84%. A non-probability consecutive sampling technique was used for participant selection.

Inclusion criteria included patients aged 20 to 60 years of either gender, classified as ASA \leq II, who developed post-spinal anesthesia shivering. Exclusion criteria comprised patients with contraindications to spinal anesthesia (e.g., refusal, bleeding diathesis), a history of receiving vasoconstrictors or adrenergic agonists, those

undergoing emergency surgeries, individuals with spinal deformities, hypersensitivity to study drugs, a history of convulsions, those who received massive blood transfusions (≥ 3 units or blood loss $>50\%$ of total blood volume intraoperatively), patients with a body temperature below 36.5°C at extubation, and pregnant women (confirmed by history and dating scan). Post-Spinal Anesthesia Shivering was defined as shivering occurring in patients undergoing spinal anesthesia, with a shivering grade of ≥ 3 , characterized by readily detectable tremors of the face, jaw, head, trunk, and extremities lasting longer than 15 seconds.

Approval for the study was obtained from the College of Physicians and Surgeons Pakistan, and informed consent was taken from all participants. After fulfilling the inclusion criteria, patients visiting the Department of Anesthesia were enrolled. They were randomly allocated into two groups using sealed opaque envelopes: Group A received intravenous Dexmedetomidine (0.5 mg/kg in a concentration of 1 mcg/ml) over 10 minutes upon the onset of shivering post-subarachnoid block, while Group B received intravenous Tramadol (0.5 mg/kg in a concentration of 1 mg/ml) over the same duration.

Standard IV access was established using an 18G cannula, and patients were preloaded with 15 ml/kg Lactated Ringer's solution 30 minutes before anesthesia. All equipment, including emergency drugs, was prepared in advance. Under strict aseptic conditions and with the patient in the left lateral position, subarachnoid block was performed using 0.5% bupivacaine at the L2-3 or L3-4 interspace. No active warming methods were used, and all fluids were administered at room temperature. The ambient temperature across the operation theater, pharmacy, and recovery areas was maintained between 21–24°C.

Vital signs, including non-invasive blood pressure (NIBP), pulse rate, SpO₂, and axillary temperature, were recorded at the beginning of surgery, at the onset and cessation of shivering, and subsequently every 10 minutes until the end of the study. The anesthesiologist and the researcher jointly evaluated shivering, and the respective study drugs were administered accordingly. The cessation and recurrence of shivering were documented as per operational definitions. In cases of recurrence, a second dose of the respective drug was administered. Efficacy was recorded based on the operational definition. Additionally, each participant's height (in meters) was measured using a wall-mounted scale, and weight (to the nearest kilogram) was recorded

using a calibrated weighing machine. Body mass index (BMI) was calculated upon admission. Efficacy in both the dexmedetomidine and tramadol groups was evaluated based on three primary criteria. First, cessation of post-spinal anesthesia shivering was defined as the complete resolution of shivering within 15 minutes of treatment, achieving a shivering grade of 0. Second, prevention of recurrence was assessed by observing the absence of shivering recurrence, specifically a shivering grade of ≥ 3 , following the initial treatment episode. Lastly, time to disappearance of shivering was measured as the interval, in seconds, from the administration of the respective study drug to the complete cessation of shivering. Data were entered into a structured proforma attached as an annexure. All collected data were entered and analyzed using SPSS Version 20.

Results

According to the demographic characteristics the 154 patients showed a relatively balanced age range between 20–60 years across both dexmedetomidine and tramadol groups. Males were more predominant in the tramadol group (63.6%) compared to dexmedetomidine (50.6%). Both urban and rural residents were evenly represented, with a slight urban majority in the dexmedetomidine group. Type II diabetes mellitus was more common in the dexmedetomidine group (46.8%), while hypertension rates were similar in both groups. Smoking was more prevalent in the dexmedetomidine group (28.6%). BMI distribution indicated that most patients were either overweight or belonged to obesity class I in both groups, as shown in table I.

Dexmedetomidine demonstrated significantly higher efficacy (94.8%) in managing post-spinal anesthesia shivering compared to tramadol (77.9%), with the difference being statistically significant ($p = 0.01$). (Table II)

Dexmedetomidine and tramadol treatments were highly effective in relatively younger age patients (20-40 years) as compared to older age group (41-60 years), male gender, urban residents, unemployed individuals, those with monthly family income ≤ 25000 or ≥ 50001 , type-II diabetes patients, and BMI values below 18.5 and above 30 Kg/m^2 , with statistically significant differences ($p < 0.05$), while hypertension and smoking did not show significant association with treatment efficacy. (Table III)

Table I: Demographic distribution of treatment groups. (n=154)

Demographic Variables	Treatment groups	
	Dexmedetomidine	Tramadol
Age		
20-40 YEARS	36(46.8%)	38(49.4%)
41-60 YEARS	41(53.2%)	39(50.6%)
Gender		
MALE	39(50.6%)	49(63.6%)
FEMALE	38(49.4%)	28(36.4%)
Residence Status		
URBAN	42(54.5%)	37(48.1%)
RURAL	35(45.5%)	40(51.9%)
Occupational Status		
Employed	39(50.6%)	48(62.3%)
Unemployed	38(49.4%)	29(37.7%)
Family Monthly Income Status		
≤ 25000	15(19.5%)	15(19.5%)
25001-50000	54(70.1%)	48(62.3%)
≥ 50001	08(10.4%)	14(18.2%)
Diabetes Mellitus Type II		
YES	36(46.8%)	18(23.4%)
NO	41(53.2%)	59(76.6%)
Hypertension		
YES	34(27.3%)	21(27.3%)
NO	43(55.8%)	56(72.7%)
Smoking Status		
YES	22(28.6%)	16(20.8%)
NO	55(71.4%)	61(79.2%)
BMI Status Kg/m²		
≤ 18.5 (underweight)	05(6.5%)	03(3.9%)
18.5-24.9 (normal)	24(31.2%)	23(29.9%)
25-29.9 (overweight)	19(24.7%)	22(28.6%)
30-34.9 (Obesity class-I)	21(27.3%)	20(26%)
35-39.9 (Obesity class-II)	06(7.8%)	07(9.1%)
>40 (Obesity class-III)	02(2.6%)	02(2.6%)

Table II: Efficacy comparison of treatment. (n=154)

Treatment Groups	Efficacy		P-Value
	Yes	No	
Dexmedetomidine(n=77)	73(94.8%)	04(5.2%)	0.01
Tramadol(n=77)	60(77.9%)	17(22.1%)	

Discussion

Shivering is frequently observed during the perioperative period. A variety of pharmacologic agents have been investigated for its management; however, despite the availability of several treatment options, none have demonstrated complete efficacy without associated side effects. This study was conducted to compare the efficacy of dexmedetomidine versus tramadol in controlling post-spinal anesthesia (post-SA) shivering. In our findings, the mean age of patients in the dexmedetomidine group was 48.21 ± 6.24 years, slightly lower than that in the tramadol group, which was 49.48 ± 8.41 years. These findings are somewhat comparable to the study by Nihar A. et al¹⁴ where the mean age was 40.7 ± 12.0 years in the

Table III: Efficacy distribution of treatment with demographic variables. (n=154)

Demographic Variables	Efficacy				P-Value
	Dexmedetomidine (n=77)		Tramadol (n=77)		
	Yes	No	Yes	No	
Age					
20-40 YEARS	36 (100%)	00 (00%)	29 (76.3%)	09 (2.37%)	0.01
41-60 YEARS	37 (90.2%)	04 (9.8%)	31 (79.5%)	08 (20.5%)	0.17
Gender					
MALE	39 (100%)	00 (00%)	37 (75.5%)	12 (24.5%)	0.01
FEMALE	34 (89.5%)	04 (10.5%)	23 (82.1%)	05 (17.9%)	0.39
Residence Status					
URBAN	42 (100%)	00 (00%)	27 (73%)	10 (27%)	0.01
RURAL	31 (89.6%)	04 (11.4%)	33 (82.5%)	07 (17.5%)	0.45
Occupational Status					
Employed	35 (89.7%)	04 (10.3%)	36 (75%)	12 (25%)	0.07
Unemployed	38 (100%)	00 (00%)	24 (82.8%)	05 (17.2%)	0.01
Family Monthly Income Status					
≤25000	15 (100%)	00 (00%)	04 (73.3%)	04 (26.7%)	0.01
25001-50000	50 (92.6%)	04 (7.4%)	39 (81.2%)	09 (18.8%)	0.08
≥50001	08 (100%)	00 (00%)	10 (71.4%)	04 (28.6%)	0.01
Diabetes Mellitus Type II					
YES	36 (100%)	00 (00%)	13 (72.2%)	05 (27.8%)	0.01
NO	37 (90.2%)	04 (9.8%)	47 (79.7%)	12 (20.3%)	0.15
Hypertension					
YES	30 (88.2%)	04 (11.8%)	17 (81%)	04 (19%)	0.45
NO	43 (100%)	00 (00%)	43 (76.8%)	13 (23.2%)	0.01
Smoking Status					
YES	21 (95.5%)	01 (4.5%)	13 (81.2%)	03 (18.8%)	0.15
NO	52 (94.5%)	03 (5.5%)	47 (77%)	14 (23%)	0.01
BMI Status Kg/m²					
≤18.5	05 (100%)	00 (00%)	02 (66.7%)	01 (33.3%)	0.01
18.5-24.9	21 (87.5%)	03 (12.5%)	18 (78.3%)	05 (21.7%)	0.39
25-29.9	18 (94.7%)	01 (5.3%)	18 (81.8%)	04 (18.2%)	0.20
30-34.9	21 (100%)	00 (00%)	14 (70%)	06 (30%)	0.01
35-39.9	06 (100%)	00 (00%)	06 (85.7%)	01 (14.3%)	0.01
>40	02 (100%)	00 (00%)	02 (77.9%)	00 (00%)	0.01

dexmedetomidine group and 37.6 ± 12.8 years in the tramadol group. Similarly, Ganjoo S. et al¹⁵ also reported mean ages of 36.4 years for dexmedetomidine and 38.44 years for tramadol. The slight variation in mean age between our study and the cited literature may be attributed to differences in sample size, patient

demographics, or the inclusion criteria used across studies. However, all studies consistently included adult patients within a similar age range, justifying the comparison and supporting the generalizability of our findings.

In this study, the Dexmedetomidine group demonstrated a significantly faster onset of action for shivering control, with a mean time to disappearance of 12.54 ± 1.78 seconds compared to 14.52 ± 8.56 seconds in the Tramadol group. This suggests that Dexmedetomidine has a quicker effect in halting shivering. Furthermore, the time to recurrence of shivering was longer in the Dexmedetomidine group (37.4 ± 10.54 minutes) than in the Tramadol group (32.8 ± 11.89 minutes), indicating that Dexmedetomidine provides a more sustained shivering control. These findings align with Kumar D et al¹⁶ who noted a slight difference in the onset of shivering between the groups, with the Tramadol group experiencing onset at 73 minutes and the Dexmedetomidine group at 72.4 minutes.

Moreover, Kumar D et al¹⁶ reported a marked difference in the duration for complete resolution of shivering, with Dexmedetomidine taking 178 seconds and Tramadol taking 275 seconds, which was statistically significant. In comparison, Singla A et al¹⁷ also observed that the average time to achieve shivering control was significantly shorter in the Dexmedetomidine group (8.74 ± 5.54 minutes) versus the Tramadol group (14.08 ± 11.83 minutes, $p = 0.002$). Additionally they found that sedation levels were higher in the Dexmedetomidine group ($p < 0.001$), a result that aligns with our study.

In this study, comparison of treatment efficacy of dexmedetomidine and tramadol showed that dexmedetomidine (94.8%) was more effective than tramadol (77.9%) in minimizing the post-spinal anesthesia shivering, with statistically significant difference ($p=0.01$). Consistently Wang et al¹⁰ also reported that the Dexmedetomidine showed a significantly higher effectiveness rate of 94.8% compared to tramadol, $p=0.001$, followed by significantly shorter time to control shivering, decreased rate of the recurrences and lower incidence of nausea and vomiting ($p < 0.001$), while hypotension, sedation, and bradycardia were significantly more frequently with dexmedetomidine.¹⁰ Consistent findings were noted in the study of Mahor et al¹⁸ who revealed higher efficacy of dexmedetomidine in comparison to tramadol against shivering after spinal anesthesia, where shivering was

significantly less common in dexmedetomidine group ($p<0.01$). In another study by Emampour BF et al² reported that the Group A had a significantly longer motor block duration (115.23 ± 42.71 minutes) than group B (63.35 ± 24.5 minutes, $p < 0.001$), whereas group B experienced a longer duration of analgesia (148 ± 27 minutes vs. 90 ± 34 minutes) and lower VAS scores ($p < 0.001$), with no notable differences in complications like nausea, vomiting, shivering, or itching.² Consistent with the findings of this study, several other investigations have also highlighted dexmedetomidine as a superior option for preventing shivering in patients undergoing surgeries with regional anesthesia, offering the added benefits of dependable sedation and a lower frequency of nausea and vomiting compared to tramadol.^{11,19-21}

Present study, while providing valuable insights into the comparative efficacy of dexmedetomidine and tramadol for post-spinal anesthesia shivering, has certain limitations like sample size was relatively small, limited to a single center, the study did not include long-term follow-up to assess delayed side effects or patient satisfaction. Additionally the sedation levels were noted but not graded with standardized scales and external factors were not controlled, which may have influenced the shivering response. Therefore future research, larger multi-center randomized controlled trials are recommended to validate the findings, exploration of optimal dosing and combination therapies, and assess cost-effectiveness and patient-reported outcomes for better clinical application.

Conclusion

As per the study conclusion, dexmedetomidine proves to be an effective and preferable alternative to tramadol for the management of post-spinal anesthesia shivering, with a significantly faster onset of action and fewer adverse effects. While both medications are beneficial in controlling shivering, dexmedetomidine offers improved tolerability with minimal side effects compared to the higher incidence of nausea and vomiting seen with tramadol. Due to the several limitations future larger multi-center randomized controlled trials are recommended to validate the findings.

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