ASIAN JOURNAL OF PHARMACEUTICAL AND CLINICAL RESEARCH

INNOVARE ACADEMIC SCIENCES
Knowledge to Innovation

Vol 16, Issue 9, 2023

Online - 2455-3891
Print - 0974-2441

Research Article

DEXMEDETOMIDINE AND TRAMADOL FOR MANAGEMENT OF POST-SPINAL ANESTHESIA SHIVERING: A COMPARATIVE STUDY

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Received: 02 August 2023, Revised and Accepted: 14 September 2023

ABSTRACT

Objectives: The aim of the study was to compare the efficacy of dexmedetomidine and tramadol in the management of post-spinal anesthesia shivering (PSAS) as well as to compare their side-effect profile.

Methods: This was a comparative study conducted in the department of anaesthesiology in FH Medical College, Etmadpur, Agra. Sixty patients undergoing surgeries under spinal anesthesia were included in this study on the basis of predefined inclusion and exclusion criteria. Patients were given either dexmedetomidine or tramadol depending on the group they belonged to. Efficacy of both the drugs in controlling PSAS, hemodynamic and side effect profile was compared.

Results: The mean age of cases in Group D and Group T was found to be 32.78±8.12 and 35.74±7.92 years, respectively. Mean age and weight as well as gender distribution and American Society of Anesthesiology grades were found to be comparable in both the groups. The mean time for the disappearance of shivering after administration of drug in Group D and Group T was found to be 3.12±1.12 and 5.80±1.20 min, respectively. Meantime for disappearance of shivering was less in Group D as compared to Group T and the difference was found to be statistically "highly significant" ($p<0.0001$). In Group D, bradycardia was seen in 2 (6.66%) patients whereas hypotension and itching were seen in 1 (3.33%) patient each. In Group T, 6 (20%) patients developed post-operative nausea and vomiting.

Conclusion: Dexmedetomidine is a better alternative to tramadol for the management of PSAS.

Keywords: Dexmedetomidine, Tramadol, Post-spinal anesthesia shivering, Hemodynamic.

 DOI: http://dx.doi.org/10.22159/ajpcr.2023v16i10.49364. Journal homepage: https://innovareacademics.in/journals/index.php/ajpcr

INTRODUCTION

Spinal anesthesia is a widely used technique in modern anesthesia practice. It offers several advantages such as rapid onset of anesthesia and effective analgesia as well as ease of administration. However, one common and distressing complication that can occur after spinal anesthesia is shivering. Post-spinal anesthesia shivering (PSAS) can lead to discomfort, increased oxygen consumption, and potential complications, making its management a critical aspect of perioperative care [1].

PSAS is a common physiological response to spinal anesthesia. It occurs in up to 40–70% of patients undergoing lower abdominal and lower limb surgeries. This involuntary muscle contraction results from the disruption of the normal thermoregulatory mechanisms by spinal anesthesia [2]. Shivering not only causes discomfort but also poses several potential risks. It increases oxygen consumption, leading to a higher demand for oxygen, which is particularly concerning in patients with compromised cardiorespiratory function [3]. In addition, it can disrupt the surgical field, making it difficult for the surgical team to perform procedures accurately. Moreover, shivering can lead to increase in blood pressure, heart rate (HR), and intraocular pressure, which is undesirable in certain patient populations, such as those with cardiovascular disease or open eye surgeries. Therefore, effective prevention and management of PSAS are critical to ensure patient comfort, safety, and optimal surgical conditions [4]. The management of PSAS primarily revolves around preventive and therapeutic measures. Preventive strategies include maintaining an appropriate operating room temperature, using warm intravenous (IV) fluids, and actively warming patients before and during surgery. However, despite these measures, PSAS can still occur, necessitating the use of pharmacological interventions for its treatment [5].

Various pharmacological agents have been explored for the prevention and treatment of PSAS. Both dexmedetomidine and tramadol have shown promise in preventing PSAS. Among the pharmacological agents used for the management of PSAS, tramadol and dexmedetomidine have emerged as potential candidates due to their diverse mechanisms of action and favorable side effect profiles [6]. Dexmedetomidine is a highly selective α2-adrenergic agonist with sedative, analgesic, and sympatholytic properties. Its use in the perioperative period has expanded beyond its primary role as a sedative and analgesic agent. Dexmedetomidine has been investigated for its ability to mitigate PSAS through its central sympatholytic effect and modulation of the thermoregulatory center in the hypothalamus [7].

Recent studies have shown promising results regarding the efficacy of dexmedetomidine in controlling PSAS. Its ability to provide sedation and analgesia, coupled with its anti-shivering properties, positions it as an attractive option for the management of this complication. However, the optimal dose and administration route of dexmedetomidine for PSAS prevention and treatment are still under investigation. Tramadol is a synthetic opioid analgesic with a unique dual mechanism of action. It acts as a weak μ-opioid receptor agonist and inhibits the reuptake of serotonin and norepinephrine. Its role in controlling PSAS stems from its ability to increase the pain threshold, modulate neurotransmitter levels, and decrease shivering thresholds in the hypothalamus [8].

Given the potential of both dexmedetomidine and tramadol in controlling PSAS, it is essential to conduct a comparative study to determine which agent offers superior efficacy and safety. This research aims to address this gap by comparing the effectiveness of dexmedetomidine and tramadol in preventing and treating PSAS in patients undergoing spinal anesthesia.

AIMS AND OBJECTIVES

The aim of the study was to compare the efficacy of dexmedetomidine and tramadol in the management of PSAS as well as to compare their side-effect profile.

METHODS

This was a comparative study conducted in the Department of anaesthesiology, FH Medical College, Etmadpur, Agra. A total of 60 patients belonging to American Society of Anesthesiology (ASA) Grade I and ASA Grade II, undergoing various surgeries under spinal anesthesia were included in this study on the basis of predefined inclusion and exclusion criteria. The duration of study was 1 year extending from January 2021 to December 2021. An informed and written consent was obtained from all the patients. The sample size was calculated on the basis of pilot studies done on the topic of post-spinal anesthesia complications assuming 90% power and 95% confidence interval, the sample size required was 25 patients per arm (total 50). Based on the central limit theorem, the sample size was determined to be enough if it was more than 25 thus, 30 patients were included in each group. Computer-based randomization was used for randomization and anesthetists as well as surgeons were blind to allocation information.

Before the surgery, a comprehensive pre-anesthetic evaluation was performed. Baseline vital signs, including HR, non-invasive blood pressure (NIBP), respiratory rate (RR), electrocardiogram, oxygen saturation (SpO_2), and body temperature, were recorded on entry into the operating room. An 18 G IV line was established, and preloading with Ringer lactate at a dose of 10 mL/kg was done over a 15-min period. Ambient temperature was maintained between 24°C and 26°C, and all drugs and fluids were administered at room temperature. The specified drug as per the random allocation patient was prepared and given.

- Group D: Received 0.5 μg/kg dexmedetomidine diluted using normal saline to 20 mL and given IV slowly, over 10 min at a rate of 2 mL/min through an infusion pump on the appearance of shivering
- Group T: Received 0.5 mg/kg tramadol diluted using normal saline to 20 mL and given IV slowly, over 10 min at a rate of 2 mL/min through an infusion pump on the appearance of shivering.

Spinal anesthesia was administered at L2–L3 or L3–L4 interspace using a 25 G Quincke's needle, in the lateral decubitus position. After confirming the free flow of 0.5% bupivacaine, heavy (3.5 mL) was administered at a rate of 0.2 mL/s. Supplemental oxygen was delivered at a rate of 4 L/min through a face mask, and surgery commenced. Continuous monitoring of intraoperative vital signs was conducted, and fluid management was tailored to the patient's specific surgical procedure and body weight.

Assessment and recording of the hemodynamic parameters were done at 2-min interval for 10 min, then at 10-min interval for 1 h, and after that every half hourly till 3 h. Time taken for cessation of shivering was noted. The level of sedation was also assessed, graded, and recorded simultaneously. Grading was done using the Ramsay sedation scale [9]. Adverse effects such as itching, bradycardia, hypotension, post-operative nausea, and vomiting were also compared in both groups. Time of onset of shivering was noted and recorded as 0 h. The grade of shivering along with vital parameters such as HR, RR, blood pressure (NIBP), SpO_2, and core body temperature was also recorded. The grade of shivering was determined as per Crossley and Mahajan grading of intraoperative shivering [10].

- Grade 0: No shivering
- Grade 1: One or more of the following: Piloerection, peripheral vasoconstriction, and peripheral cyanosis without other cause, 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
- Grade 4: Gross muscle activity involving the whole body.

Statistical analysis was done using SPSS version 21.0 software. Quantitative data were presented as mean and standard deviation. Qualitative data were presented with incidence and percentage tables. For quantitative data, unpaired t-test was applied and for qualitative data, Chi-square test was used. $p<0.05$ was taken as statistically significant.

Inclusion criteria

The following criteria were included in the study:

1. Patients undergoing elective surgeries under spinal anesthesia in whom any grade of shivering was noted
2. Age >18 years
3. Those who gave informed and written consent to be part of the study
4. ASA Grade I/II.

Exclusion criteria

The following criteria were excluded from the study:

1. Those who refused consent
2. Age <18 years
3. ASA Grade III or above
4. Patients allergic to any of the drug used.

RESULTS

The groups were compared for mean age, gender distribution, weight, and ASA Grades. The mean age of cases in Group D and Group T was found to be 32.78±8.12 and 35.74±7.92 years, respectively. The mean weight of patients in Group D and T was found to be 69.64±11.12 kg and 66.34±9.38 kg, respectively. In Group D as well as Group T, majority of patients belonged to ASA I. The mean age and weight as well as gender distribution and ASA grades were found to be comparable in both groups with no statistically significant difference in any of these parameters in both groups ($p>0.05$) (Table 1).

The analysis of the patients on the basis of surgeries performed showed that the most common surgery performed in the studied cases was unilateral inguinal hernia surgery which was done in 20 (33.33%) patients followed by hysterectomy which was done in 13 (21.67%) patients. Other surgeries included trans-urethral resection of prostate (18.33%), lower limb orthopedic surgeries (15%), and lower segment cesarean section (11.67%) (Fig. 1).

Table 1: Comparison of mean age, weight, gender, ASA, and Mallampati classification grades in patients

Demographics and ASA grades	Group D	Group T	p-value
Mean age	32.78±8.12	35.74±7.92	p=0.1583 Not significant
Gender distribution (%)			
Males	18 (60.00)	19 (63.33)	1.0000
Females	12 (40.00)	11 (36.67)	Not significant
Weight	69.64±11.12	66.34±9.38	0.2191 Not significant
ASA grade (%)			
Grade I	21 (70.00)	23 (76.67)	0.7710
Grade II	9 (30.00)	7 (23.33)	Not significant

ASA: American Society of Anesthesiology

Table 2: Mean duration of surgery and spinal anesthesia in both groups

Mean duration of surgery and spinal anesthesia	Group D	Group T	p-value
Mean duration of surgery	58.64±11.24	64.36±13.46	p=0.0792 (Not significant)
Mean duration of spinal anesthesia	120.12±16.12	126.44±18.22	p=0.1601 Not Significant

Table 3: Meantime, grade, and recurrence of shivering in both groups

Shivering Grade and Duration	Group D	Group T	p-value
Grades of shivering			
Grade 1	9	7	>0.05
Grade 2	11	15	Not significant
Grade 3	7	6	
Grade 4	3	2	
Meantime for disappearance of shivering	3.12±1.12	5.80±1.20	<0.0001 Highly significant
Recurrence of shivering			
Yes	2	4	0.6706
No	28	26	Not significant

Table 4: Mean sedation score in both groups

Time	Group D	Group T	p-value
2 min	2±0.0	2±0.0	-
4 min	2±0.0	2±0.0	-
6 min	2±0.0	2±0.0	-
8 min	2.09±0.24	2.10±0.14	p=0.8444
10 min	2.42±0.64	2.12±0.16	p=0.0156
20 min	2.54±0.76	2.24±0.18	p=0.0397
30 min	2.38±0.70	2.10±0.14	p=0.0359
40 min	2.22±0.62	2.04±0.12	p=0.1239
50 min	2.12±0.18	2.08±0.10	p=0.2917
60 min	2±0.0	2±0.0	-
90 min	2±0.0	2±0.0	-
120 min	2±0.0	2±0.0	-

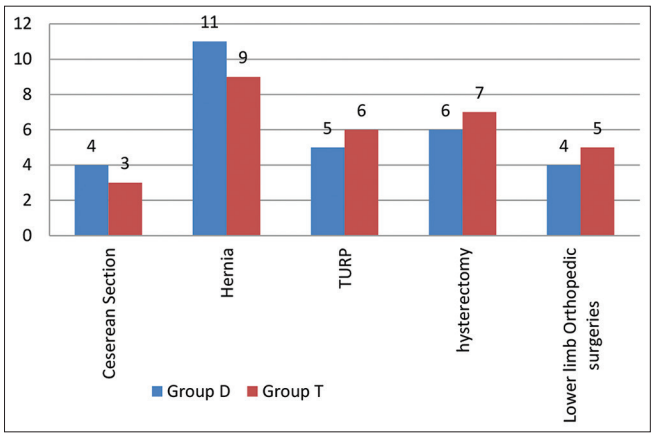

Figure 1: Types of surgeries in studied cases

The comparison of both groups was done for the mean duration of surgery as well as the mean duration of spinal anesthesia. The mean duration of surgery in Group D and Group T was found to be 58.64±11.24 min and 64.36±13.46 min, respectively. The mean duration of spinal anesthesia in Group D and Group T was found to be 120.12±16.12 and 126.44±18.22 min, respectively (Table 2).

The patients were compared for grade of shivering, meantime for disappearance of shivering, and incidence of recurrence of shivering. Both the groups were found to be comparable for grades of shivering. The mean time for the disappearance of shivering after administration of drug in Group D and Group T was found to be 3.12±1.12 and 5.80±1.20 min, respectively. Mean time for disappearance of shivering was less in Group D as compared to Group T and the difference was found to be statistically "highly significant" ($p<0.0001$). Although the incidence of recurrence of shivering was more in Group T as compared to Group D, the difference was statistically "not significant" ($p=0.6706$) (Table 3).

Comparison of hemodynamic parameters such as HR and systolic as well as diastolic blood pressures and SPO_2 showed that these parameters were comparable in both the groups with no statistically significant difference at any time from administration of drug till after 3 h ($p>0.05$) (Figs. 2-5).

Mean sedation scores of both groups were compared. Mean sedation scores of patients in both groups were comparable up to 6 min and after 40 min after administration of the respective drug. Between 10 min and 40 min, the sedation score was more Group D as compared to Group T and the difference was statistically significant ($p<0.05$) (Table 4).

Finally, both the groups were compared for incidence of complications such as bradycardia, hypotension, itching, and post-operative nausea and vomiting. In Group D, bradycardia was seen in 2 (6.66%) patients whereas hypotension and itching were seen in 1 (3.33%) patient each. In Group T, 6 (20%) patients developed post-operative nausea and vomiting (Fig. 6).

DISCUSSION

Post-operative shivering remains a common complication following surgery under spinal anesthesia, necessitating effective management strategies. Dexmedetomidine, an alpha-2 adrenergic agonist, exerts its anti-shivering effect through central thermoregulatory control and reduction of sympathetic outflow [11]. This mechanism has been well-established in numerous studies. On the other hand, tramadol, primarily an opioid analgesic, has been proposed to have less direct influence on shivering control [12].

In our study, the mean time for the disappearance of shivering after administration of drug in Group D and Group T was found to be 3.12±1.12 and 5.80±1.20 min, respectively. Meantime for the disappearance of shivering was less in Group D as compared to Group T

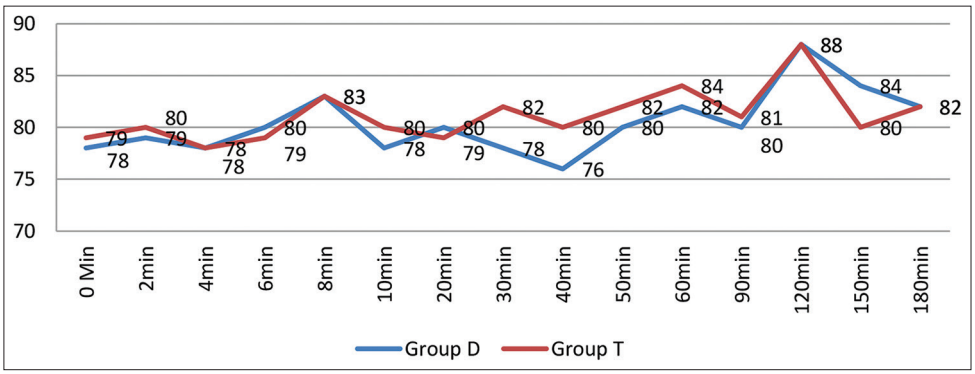

Figure 2: Comparison of heart rate in both groups

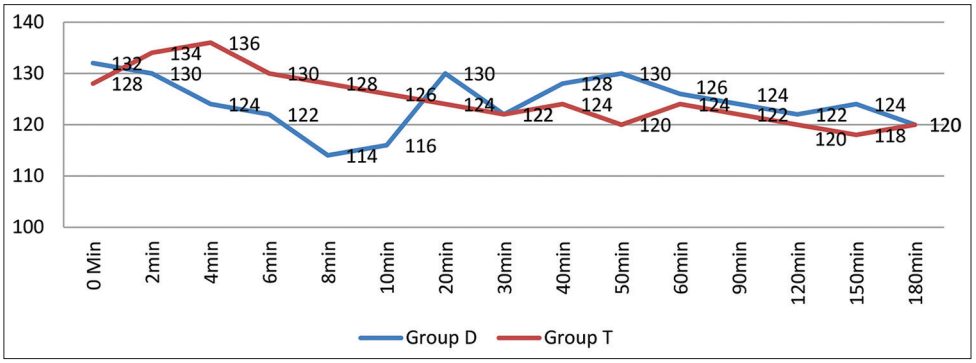

Figure 3: Comparison of systolic blood pressures in both groups

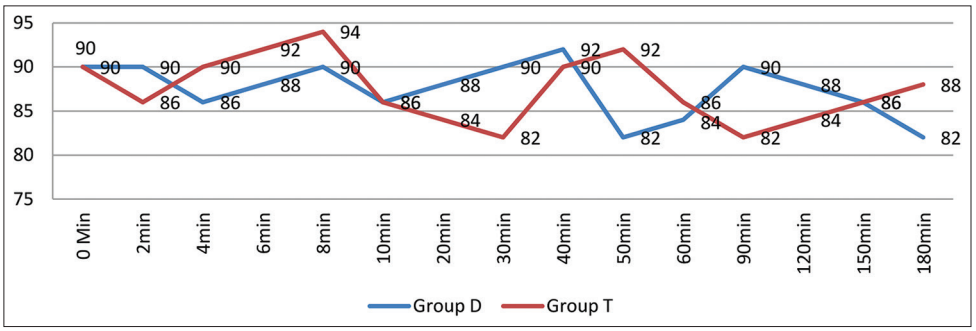

Figure 4: Comparison of diastolic blood pressures in both groups

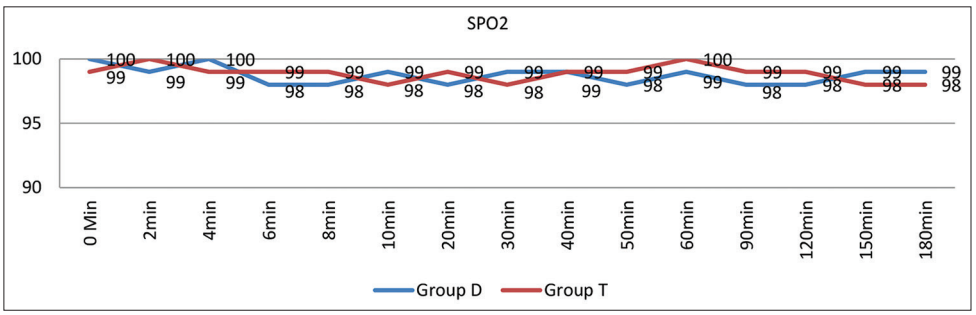

Figure 5: Comparison of oxygen saturation in both groups

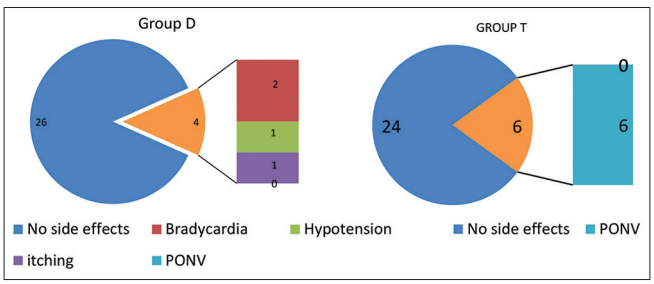

Figure 6: Adverse effects in both groups

and the difference was found to be statistically "highly significant" ($p<0.0001$). Similar to our study, several studies support the superior efficacy of dexmedetomidine over tramadol in controlling post-operative shivering. A randomized and controlled trial by Wang *et al*. found that dexmedetomidine significantly reduced the incidence and severity of shivering compared to tramadol in patients undergoing spinal anesthesia for orthopedic surgeries [13]. Similarly, a meta-analysis conducted by Wang *et al*. (2020) encompassing multiple studies reported a higher success rate of shivering control with dexmedetomidine as compared to tramadol. This corroborates the notion that dexmedetomidine may offer more effective shivering management. Similar superior efficacy of dexmedetomidine over tramadol was also reported by the authors such as Kundra *et al*. [14].

In our study between 10 min and 40 min, the sedation score was more Group D as compared to Group T and the difference was statistically significant. It is noteworthy to discuss the differential effects on sedation observed in our patient cohorts. Dexmedetomidine, due to its selective alpha-2 adrenergic agonist properties, exhibited a desirable sedative effect characterized by a calm and cooperative state in patients without causing excessive drowsiness. This moderate level of sedation facilitated an easier transition from surgery to post-anesthetic recovery. Similar sedative profile of dexmedetomidine and tramadol was also reported by the authors such as Zhang *et al*. [15] and Mittal *et al*. [16].

Another crucial aspect is the safety profile of these drugs. In Group D, bradycardia was seen in 2 (6.66%) patients whereas hypotension and itching was seen in 1 (3.33%) patient each. In Group T, 6 (20%) patients developed post-operative nausea and vomiting. In our study, patients who received tramadol had significantly more incidence of post-operative nausea and vomiting. Dexmedetomidine's dosing and administration also provide an advantage. It can be administered as a single bolus or through continuous infusion, allowing for tailored

management of shivering [17]. Tramadol, while effective, may require higher doses and is typically administered parenterally, potentially increasing the risk of side effects. Furthermore, studies have indicated that patients receiving dexmedetomidine may experience improved overall satisfaction and a smoother recovery process due to its favorable side effect profile [18]. Dexmedetomidine, often used in anesthesia, has a favorable safety profile with minimal respiratory depression and hemodynamic stability [19]. However, dexmedetomidine is found to be associated with bradycardia and hypotension in our study. In contrast, tramadol is associated with opioid-related side effects, such as respiratory depression, nausea, and vomiting [20].

Limitation of study

One of the important limitations of our study was almost all of the patients who were included in this study had undergone short-duration surgeries so recurrence of shivering during surgery could not be properly assessed. A similar study on longer surgeries would be needed to properly assess recurrence rates of shivering during surgery.

CONCLUSION

Dexmedetomidine is a better alternative to tramadol for the management of PSAS. It is associated with significantly reduced mean time for the disappearance of shivering as compared to tramadol. Moreover, no significant adverse effects were associated with its administration.

ACKNOWLEDGMENT

The authors would like to acknowledge the support extended by faculty and staff of Department of Anaesthesiology, FH Medical College, Etmadpur, Agra, India, for undertaking this study.

AUTHORS CONTRIBUTION

AZ- Concept and design of the study; interpreted the results, prepared first draft of manuscript, and critical revision of the manuscript; SK- Statistically analyzed and interpreted and reviewed the literature and manuscript preparation; US and VB- Design of the study, statistically analyzed and interpreted, preparation of manuscript, and revision of the manuscript; and PS- Overall coordination of the study.

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