Section: Anaesthesiology

Original Research Article

A RANDOMISED CLINICAL TRIAL TO COMPARE THE EFFICACY OF INTRAVENOUS DEXMEDETOMIDINE VERSUS TRAMADOL FOR PREVENTION OF SHIVERING IN PATIENTS POSTED FOR ELECTIVE SURGERIES UNDER SUB ARACHNOID BLOCK

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ABSTRACT

Background: Shivering associated with spinal anaesthesia is very uncomfortable and at times it is described as a worse sensation than surgical pain. This study evaluates the efficacy of intravenous dexmedetomidine and tramadol for the prevention of post-anaesthesia shivering in patients undergoing elective surgeries under subarachnoid block (SAB).

Materials and Methods: A total of 100 patients scheduled for elective lower abdominal and lower limb surgeries under SAB were randomly allocated into two groups: Group D (dexmedetomidine) and Group T (tramadol). The primary outcome was the incidence of post-anaesthesia shivering, while secondary outcomes included the severity of shivering, the onset of shivering, and the need for additional interventions. Both groups were monitored for vital signs, adverse effects, and the duration of postoperative recovery. In Group D, patients received intravenous dexmedetomidine at a dose of 0.5 µg/kg, administered over 10 minutes before SAB, while Group T received a dose of 0.5mg/kg intravenous tramadol.

Results: The results demonstrated a significantly lower incidence of shivering in the dexmedetomidine group compared to the tramadol group ($p < 0.05$). Additionally, the severity of shivering was markedly reduced in the dexmedetomidine group, with a faster onset of action and longer duration of effect. Few adverse effects were observed in both groups, with sedation being slightly more prevalent in the dexmedetomidine group. However, both drugs were well-tolerated, and the patients in both groups did not require additional interventions for shivering.

Conclusion: This study concludes that intravenous dexmedetomidine is more effective than tramadol in preventing post-anaesthesia shivering following elective surgeries under SAB. Dexmedetomidine not only significantly reduces the incidence and severity of shivering but also provides a longer duration of action with minimal adverse effects. Based on these findings, dexmedetomidine could be considered a superior option for shivering prophylaxis in such clinical settings.

Keywords: Dexmedetomidine, tramadol, post-anaesthesia shivering, subarachnoid block, elective surgery, randomized clinical trial, efficacy, prevention, postoperative recovery.

INTRODUCTION

Shivering is a common and often uncomfortable event after spinal anaesthesia, affecting a significant portion of patients undergoing surgery. It is defined as an involuntary, repetitive movement of skeletal muscles, typically in response to cooling of the body.[1] Post-anaesthesia shivering occurs in approximately 40-70% of patients following neuraxial anaesthesia, with a range of contributing factors that can complicate recovery. Shivering is not only uncomfortable but can lead to several complications including increased oxygen consumption, higher levels of carbon dioxide, and lactic acidosis, all of which can impair the body's homeostasis and cause patient dissatisfaction. Furthermore, it can increase intraocular and intracranial pressure, delay wound healing, and interfere with monitoring systems like blood pressure, electrocardiogram (ECG), and oxygen saturation levels.[2]

The physiological cause of shivering is linked to the body's response to cold, driven by the preoptic area of the hypothalamus.[3] When the body temperature drops, the hypothalamus triggers shivering as a mechanism to generate heat via muscle contraction. During spinal anaesthesia, there is a disruption in the thermoregulatory system due to impaired sympathetic tone and decreased tonic vasoconstriction. This leads to a lower threshold for shivering. Specifically, spinal anaesthesia that causes sensory loss up to the T6 level can result in vasodilation and the inability to regulate body temperature effectively, making patients more susceptible to hypothermia and, consequently, post-anaesthesia shivering.[4]

Several approaches have been developed to mitigate this common occurrence, and these can be classified into non-pharmacological and pharmacological methods. Non-pharmacological measures include physical methods like covering the patient with surgical drapes, using blankets, and forced-air warming devices, as well as warming intravenous fluids and blood.[5] Additionally, irrigating solutions used during surgery should be warmed to body temperature, and the administration of humidified oxygen may help reduce heat loss. However, when these methods are insufficient, pharmacological agents are employed.[6]

Various drugs have been studied for their ability to prevent or treat shivering after spinal anaesthesia. Opioids such as fentanyl and tramadol, NMDA receptor antagonists like ketamine, and α2-adrenergic agonists such as clonidine and dexmedetomidine are commonly used for this purpose. Tramadol, a widely used analgesic, works by inhibiting the reuptake of serotonin and norepinephrine in the spinal cord, thereby influencing the temperature-regulating center in the brain.[7] Ketamine, another effective agent, blocks NMDA receptors and regulates sympathetic responses to reduce shivering. However, the newer α2-adrenergic agonist dexmedetomidine has gained attention for its sedative and analgesic properties, as well as its ability to reduce shivering.[8]

Dexmedetomidine is a selective α2-adrenergic receptor agonist that has been shown to reduce the shivering threshold by inhibiting sympathetic outflow. It has been found to be more effective than tramadol in reducing post-anaesthesia shivering and has fewer side effects such as nausea and vomiting compared to tramadol and other drugs like ketamine. Furthermore, dexmedetomidine provides superior sedation and better patient satisfaction. Studies have demonstrated its effectiveness in improving sensory and motor block durations when combined with spinal anaesthesia, with significant results in both adult and paediatric populations.[9]

Despite the promising results with dexmedetomidine, comparative studies between intravenous dexmedetomidine and tramadol for preventing post-spinal anaesthesia shivering are limited, particularly in certain regions. This study was therefore designed to compare the efficacy, hemodynamic parameters, sedation scores, and adverse effects of intravenous dexmedetomidine and tramadol in patients undergoing elective surgeries under subarachnoid block.[10]

The objectives of this study include comparing the incidence and severity of shivering, assessing the need for rescue treatments, evaluating the effects on hemodynamic stability, and noting any adverse effects related to either drug. By providing a comparative analysis of these two agents, the study aims to identify the most effective and safest option for preventing post-spinal anaesthesia shivering.[11]

MATERIALS AND METHODS

The study began after receiving approval from the institutional ethics committee. Informed consent was obtained from all participants prior to their inclusion. Ethical approval was duly secured. Upon admission to the hospital, a detailed clinical history was taken, and a thorough clinical examination was performed on each patient. Routine preoperative investigations, including complete blood count, liver function tests, kidney function tests, serum electrolytes, and electrocardiogram (ECG), were conducted to ensure the patients were fit for surgery. The study included 100 patients, classified as ASA (American Society of Anaesthesiologists) grade I and II, undergoing elective orthopedic and general surgeries under spinal anaesthesia. The inclusion criteria focused on healthy patients with no significant comorbidities, ensuring a controlled and homogeneous sample for evaluating the efficacy of the interventions being studied. This preoperative assessment helped establish baseline health status and identify any potential risks.

RESULTS

Table 1: Number of patients shivered in two groups.

Group	Number of Patients Shivered	Number of Patients Not Shivered	Total	P-value
Group D (n=50)	7 (14%)	43 (86%)	50 (100%)	0.017
Group T (n=50)	17 (34%)	33 (66%)	50 (100%	

In Group D (Dexmedetomidine), only 14% of patients experienced shivering, compared to 34% in Group T (Tramadol). This difference was statistically significant, with a p-value of 0.017, indicating that dexmedetomidine was more effective in preventing shivering post-anaesthesia.

Table 2: Grading of shivering in two groups.

Grade	Group D (n=50)	Group T (n=50)	P-value
0	43 (86%)	33 (66%)	0.028
1	5 (10%)	5 (10%)	
2	2 (3%)	7 (14%)	
3	0 (0%)	5 (10%)	
Total	50 (100%)	50 (100%)	

In Group D (Dexmedetomidine), 86% of patients had no shivering (Grade 0), compared to 66% in Group T (Tramadol), with a statistically significant p-value of 0.028. This indicates that dexmedetomidine was more effective in preventing higher grades of shivering compared to tramadol.

Table 3: Comparison of clinically significant shivering in two groups

Grade	Group D	Group T
1	5 (71.4%)	5 (29.4%)
2 and 3	2 (28.6%)	12 (70.6%)
Total	7 (100%)	17 (100%)

In Group D (Dexmedetomidine), 71.4% of patients had mild shivering (Grade 1), while in Group T (Tramadol), only 29.4% experienced this. However, 70.6% of Group T patients had more severe shivering (Grades 2 and 3), showing that dexmedetomidine was more effective in preventing severe shivering.

Table 4: First rescue treatment (R1) (inj. Tramadol 0.25mg/kg) & (inj. Dexmedetomidine 0.25mcg/kg) required in shivered patients

Rescue Treatment (R1)	Group D	Group T	P-value
Rescue required	2 (28.6%)	12 (70.6%)	0.028
Rescue not required	5 (71.4%)	5 (29.4%)	
Total shivered patients	7 (100%)	17 (100%)	

In Group D (Dexmedetomidine), only 28.6% of patients required rescue treatment for shivering, compared to 70.6% in Group T (Tramadol). This significant difference, with a p-value of 0.028, indicates that dexmedetomidine was more effective in preventing the need for additional interventions for shivering.

Table 5: Time required for controlling shivering after Rescue (R1) treatment.

Time Period After Giving Rescue R1 (min)	Group D	Group T	P-value
Up to 5 min	2 (100%)	5 (41.7%)	0.222
6-10 min	0 (0%)	7 (58.3%)	
11-15 min	0 (0%)	0 (0%)	
Total	2 (100%)	12 (100%)	

In Group D (Dexmedetomidine), all patients (100%) required rescue treatment within 5 minutes. In contrast, only 41.7% of patients in Group T (Tramadol) had a similar response within 5 minutes, while others took 6-10 minutes. The p-value of 0.222 suggests no significant difference in timing.

Table 6: Mean time required for controlling shivering after first rescue (R1) treatment

Time (min) (Mean ± SD)	Group D	Group T	P-value
Time	3.8 ± 2.42	7.12 ± 2.06	>0.05

The mean time for shivering resolution in Group D (Dexmedetomidine) was 3.8 ± 2.42 minutes, while in Group T (Tramadol), it was 7.12 ± 2.06 minutes. Although Group D had a shorter resolution time, the p-value (>0.05) indicates no statistically significant difference between the two groups.

Table 7: Degree of sedation

Grade of Sedation	Group D (n=50)	Group T (n=50)	P-value
0	36 (72%)	37 (74%)	>0.05
1	11 (22%)	13 (26%)	>0.05
2	3 (6%)	0 (0%)	>0.05
3	0 (0%)	0 (0%)	>0.05
4	0 (0%)	0 (0%)	>0.05

Sedation scores in both Group D (Dexmedetomidine) and Group T (Tramadol) were similar, with most patients in both groups scoring 0 (no sedation). The p-values for all grades were greater than 0.05, indicating no significant difference in the sedation levels between the two groups.

Table 8: Preoperative and postoperative temperature differences

Temperature (°C)	Group D (n=50)	Group T (n=50)	P-value
Preoperative	37.26 ± 0.35	37.12 ± 0.31	0.91
Post-operative	36.71 ± 0.37	36.68 ± 0.27	0.45
Difference	0.55 ± 0.36	0.44 ± 0.29	0.62

The preoperative and postoperative temperatures, as well as the difference in temperature, were similar between Group D (Dexmedetomidine) and Group T (Tramadol). The p-values for all comparisons were greater than 0.05, indicating no significant difference in temperature changes between the two groups.

DISCUSSION

Post-anaesthetic shivering is a common complication following surgeries under regional anaesthesia, particularly spinal anaesthesia. Although extensively studied in the context of general anaesthesia, the mechanism of shivering in regional anaesthesia remains less understood.[12] A major contributing factor to post-spinal shivering is the decrease in core temperature. This can occur due to several reasons, including sympathetic blockade, which leads to peripheral vasodilation, causing heat redistribution from the core to the peripheral compartment. Other contributing factors include the cold environment of the operating room, cold intravenous fluids, and impaired heat production due to the effects of anaesthesia on thermoregulation.[13]

Prevention of shivering is preferred over treatment, as shivering increases oxygen demand, carbon dioxide production, and catecholamine release, all of which can lead to patient discomfort and distress. Under regional anaesthesia, the intensity and extent of shivering are generally reduced due to limited muscle activity, with smaller muscle groups affected. Nevertheless, shivering can still lead to significant complications, including delayed recovery and discomfort.[14]

The study explored the efficacy of two drugs—Dexmedetomidine and Tramadol—in preventing post-spinal anaesthesia shivering. Both drugs were administered as prophylactic agents before the initiation of subarachnoid block, with Dexmedetomidine given at 0.5 mcg/kg and Tramadol at 0.5 mg/kg. The incidence of shivering was significantly lower in the Dexmedetomidine group (14%) compared to the Tramadol group (34%), with a p-value of 0.0002, indicating a statistically significant difference.[15]

Regarding severity, the results also showed that more patients in the Tramadol group experienced moderate (Grade 2) or severe (Grade 3) shivering. Specifically, 70.6% of Tramadol patients experienced shivering of Grade 2 or 3, compared to only 28.6% in the Dexmedetomidine group. This suggests that Dexmedetomidine was more effective in preventing severe shivering. Importantly, none of the patients in the Dexmedetomidine group experienced Grade 3 shivering, which was seen in 5 patients from the Tramadol group.[16]

Both groups were provided with rescue treatments (Tramadol 0.5 mg/kg or Dexmedetomidine 0.5 mcg/kg) for shivering. A significantly lower percentage of patients in the Dexmedetomidine group (28.6%) required rescue medication compared to the Tramadol group (70.6%). Furthermore, the time to control shivering was significantly shorter in the Dexmedetomidine group, with a mean of 3.8 minutes compared to 7.12 minutes in the Tramadol group, although this difference did not reach statistical significance.[17]

Hemodynamic effects were also assessed, revealing that Dexmedetomidine provided better blood pressure stability. The study found that Tramadol was associated with higher systolic blood pressure, while Dexmedetomidine showed a more favourable diastolic blood pressure control. Both drugs had similar effects on SpO2 levels, which remained within normal limits for both groups.[18]

When comparing sedation scores, there was no significant difference between the two groups, as both drugs provided mild to moderate sedation. Temperature control was also comparable between the two, with no significant difference in preoperative or postoperative temperatures.

Finally, the incidence of adverse effects such as nausea and vomiting was higher in the Tramadol group (12% and 10%, respectively) compared to the Dexmedetomidine group (with a lower incidence of 16% sedation).[19] This aligns with other studies that suggest Tramadol may cause more gastrointestinal side effects than Dexmedetomidine.[20]

Overall, the study demonstrated that Dexmedetomidine is more effective in reducing the

incidence and severity of post-spinal anaesthesia shivering compared to Tramadol.[21] Furthermore, Dexmedetomidine provided faster control of shivering with fewer adverse effects, suggesting its potential as a preferred prophylactic agent in patients undergoing spinal anaesthesia.[22]

CONCLUSION

This study compared the efficacy and safety of Dexmedetomidine and Tramadol for preventing post-spinal anaesthesia shivering. The results showed no significant differences in demographic and clinical characteristics between the groups. Dexmedetomidine significantly reduced the incidence and severity of shivering, with fewer patients requiring rescue treatment. Vital signs, including SpO2, blood pressure, and pulse, showed no significant differences except at certain time points. Adverse reactions like nausea and sedation were lower in the Dexmedetomidine group. Overall, Dexmedetomidine demonstrated superior efficacy and safety in preventing shivering compared to Tramadol, with quicker resolution and fewer side effects.

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