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Dr. Dhrubajyoti Biswa
Junior Resident, Department of Anesthesiology, MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India

Dr. Akansha Sharma
Senior Resident, Department of Anesthesiology, MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India

Dr. RL Gogna
Professor and Head of Department of Anesthesiology, MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India

Corresponding Author:
Dr. Dhrubajyoti Biswa
Junior Resident, Department of Anesthesiology, MGM Institute of Health Sciences, Navi Mumbai, Maharashtra, India

Comparative assessment of clonidine and tramadol on post-spinal anaesthesia shivering among patients with lower abdominal and lower limb surgeries

Dr. Dhrubajyoti Biswa, Dr. Akansha Sharma and Dr. RL Gogna

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Abstract
Background: Shivering is a potentially serious complication, resulting in increased metabolic rate; increased oxygen consumption (up to 100-600%) along with raised carbon dioxide (CO2) production; ventilation and cardiac output; adverse postoperative outcomes, such as wound infection; increased surgical bleeding; and morbid cardiac events. It causes arterial hypoxemia, lactic acidosis, increased intraocular pressure (IOP), increased intracranial pressure (ICP); and interferes with pulse rate, blood pressure (BP) And electrocardiographic (ECG) monitoring.
Materials and Methods: The present study was conducted in the Department of Anesthesia of the MGM medical College, Navi Mumbai. The present study was a randomized controlled trial which was conducted after obtaining institutional ethics committee approval. It was conducted among 100 patients aged between 18 to 70 years, who were scheduled for abdominal and lower limb surgeries and who developed shivering following spinal anaesthesia. These 100 patients of ASA grade I and II which were selected randomly after taking informed and written consent from their relatives.
Results: Out of 50 patients in Group C, shivering subsided in 48 patients. While in group T, shivering subsided in 44 patients out of 50. There was significant difference in both groups for control of shivering which proved that the rate of success after clonidine was more than that of tramadol.
Conclusion: Both clonidine (75 µg) and tramadol (0.5 mg/kg) can effectively treat patients with post-spinal anaesthesia shivering, but tramadol took longer time for complete cessation of shivering than clonidine. Both clonidine (75 µg) and tramadol (0.5 mg/ kg) can effectively treat patients with post-spinal anaesthesia shivering, but tramadol took longer time for complete cessation of shivering than clonidine.

Keywords: Clonidine, tramadol, post-spinal anaesthesia shivering, randomized controlled trial

Introduction
Regional anaesthesia (spinal anaesthesia) is widely used as a safe anaesthetic technique for both elective and emergency operations. Shivering is known to be a frequent complication, reported in 40 to 70% of patients undergoing surgery under regional anaesthesia [1, 2]. Shivering is a potentially serious complication, resulting in increased metabolic rate; increased oxygen consumption (up to 100-600%) along with raised carbon dioxide (CO2) production; ventilation and cardiac output; adverse postoperative outcomes, such as wound infection; increased surgical bleeding; and morbid cardiac events. It causes arterial hypoxemia, lactic acidosis, increased intraocular pressure (IOP), increased intracranial pressure (ICP); and interferes with pulse rate, blood pressure (BP) And electrocardiographic (ECG) monitoring [3]. Different drugs like pethidine, clonidine, doxapram, kentaserine, tramadol and nefopam [4] have been evaluated for the prevention and treatment of peri-operative shivering. They are simple, cost effective and readily available. Among the various drugs for controlling shivering, pethidine has been shown to be effective with a minimum dose of 0.35mg/kg [5]. It has thus been the gold standard drug for the control of post-anaesthetic shivering; however, it is associated with many undesirable side effects including post-operative nausea and vomiting and respiratory depression. Tramadol on the other hand at a dose of 1mg/kg had also been shown to be effective in the treatment of post-anaesthetic shivering but the incidence of nausea and vomiting was high [6]. Hence, the aim of the present study was to compare the efficacy of clonidine, and α2-agonist with that of tramadol, a non-opioid analgesic for control of shivering after spinal anaesthesia in patients undergoing lower abdominal and lower limb surgeries.

Materials and methods

The present study was conducted in the Department of Anesthesia of the MGM medical College, Navi Mumbai. The ethical clearance for the study was approved from the ethical committee of the hospital. The present study was a randomized controlled trial which was conducted after obtaining institutional ethics committee approval. It was conducted among 100 patients aged between 18 to 70 years, who were scheduled for abdominal and lower limb surgeries and who developed shivering following spinal anaesthesia. These 100 patients of ASA grade I and II which were selected randomly after taking informed and written consent from their relatives. Once patient developed shivering, they were randomly allocated into two groups. In the process of randomization, patients were divided into two groups named as Group C and Group T. Group-C (Control): Received Inj. clonidine 75µg slow I.V injection diluted in 10ml NS intra-operatively. Group-T (Treatment): Received Inj. tramadol 1 mg/kg slow I.V injection diluted in 10ml NS intra-operatively. Patients were monitored by non-invasive arterial blood pressure (BP), ECG, heart rate (HR) and SpO2. All patients received 4 L/min of O2 by simple face mask with the patient in the sitting position; spinal analgesia was performed at the level of L3-L4 or L2- L3 through a midline approach using a 23-gauge Quincke spinal needle with the hole pointing upwards.

The statistical analysis of the data was done using SPSS version 11.0 for windows. Chi-square and Student's t-test were used for checking the significance of the data. A p-value of 0.05 and lesser was defined to be statistically significant.

Results

In the present study, it was found that the present study was conducted among 100 ASA grade I or II patients, aged 18-70 years which were scheduled for abdominal and lower limb surgery. Table 1 shows comparison between the spinal drug and sensory block level among the study subjects. There was no significance difference regarding dose of drug given for spinal anesthesia (0.5% bupivacaine) and sensory level achieved by it. Table 2 shows the comparison between the shivering grades among the study subjects. There was no significant difference between both the groups regarding shivering grade. Table 3 shows the comparison of the control of shivering among the study subjects. Out of 50 patients in Group C, shivering subsided in 48 patients. While in group T, shivering subsided in 44 patients out of 50. There was significant difference in both groups for control of shivering which proved that the rate of success after clonidine was more than that of tramadol.

Discussion

The present study was designed to measure and compare effectiveness of tramadol and clonidine for control of shivering that occurs following spinal anesthesia. A large number of studies have been done to assess the role of prophylactic pharmacological intervention for post-spinal anesthesia shivering. Vyas V *et al*. [7] compared efficacy and safety of clonidine versus tramadol in postspinal anesthesia shivering. A total of 60 American Society of Anesthesiologists physical status Class l and II adult patients (age 18–65 years) undergoing surgery under spinal anesthesia and developed shivering received either clonidine 1 µg/kg or tramadol 1 mg/kg intravenously. The time required for cessation of shivering, control and recurrence rate of shivering, effect on hemodynamics and side effects were compared between two groups. Time for cessation of shivering was less in clonidine group than tramadol group (02.51 vs. 04.82 min; $P < 0.001$). Complete control of shivering was achieved in 80% of patients in clonidine group versus 70% in tramadol group. There was no significant difference for control ($P = 0.5$) and rate of recurrence of shivering between clonidine and tramadol group (06.7% vs. 16.7%; $P = 0.42$). Pulse rate and systolic blood pressure were significantly lower in clonidine group at 5 and 15 min as compared with tramadol. Significantly more number of patients experienced nausea and dizziness (36.7% vs. 0%; $P < 0.001$ and 20% vs. 0%; $P = 0.01$) with tramadol while bradycardia and hypotension were numerically more common in patients receiving clonidine (6.7% vs. 0% and 13.3% vs. 0%). They concluded that Clonidine provides early relief from shivering than tramadol with fewer side effects in patients undergoing surgery under spinal anesthesia. Guha Banerjee S [8] evaluated the relative efficacy of prophylactic intravenous (IV) clonidine and tramadol for control of intraoperative shivering following spinal anesthesia. After institutional ethical clearance, 142 patients were chosen from either gender, aged 20–60 years, physical status American Society of Anesthesiology Class I and II scheduled for elective infraumbilical surgery under spinal anesthesia. Patients were randomized into two groups: Group C ($n = 71$) received injection clonidine 50 µg) IV in 100 ml normal saline (NS) over 10 min and Group T ($n = 71$) received injection tramadol 50 mg IV. In 100 ml NS over 10 min after spinal anesthesia. Incidence of shivering was not significant when compared between the two groups ($P > 0.05$). The axillary temperatures fell significantly in Group C from the baseline and remained at a significantly lower level up to 60 min after rescue drug was administered in patients who shivered. There was a similar fall in axillary temperature in Group T in patients having shivering, but the difference was not significant. When compared between the two groups among patients who shivered, the difference in fall of temperature was not significant. Side effects such as hypotension, bradycardia, and sedation were significantly more common in clonidine group, whereas nausea was significantly more common patients of tramadol group. They concluded that prophylactic administration of both tramadol and clonidine is effective for controlling shivering under spinal anesthesia. However, tramadol is better because of higher response rate, less sedation, and lesser hemodynamic alterations.

Mittal G *et al*. [9] evaluated and compared the efficacy, haemodynamic and adverse effects of dexmedetomidine with those of tramadol, when used for control of post-spinal anaesthesia shivering. A prospective, randomised, and double-blind study was conducted in 50 American Society of Anaesthesiologists Grade I and II patients of either gender, aged between 18 and 65 years, scheduled for various surgical procedures under spinal anaesthesia. The patients were randomised in two groups of 25 patients each to receive either dexmedetomidine 0.5 µg/kg or tramadol 0.5 mg/kg as a slow intravenous bolus. Grade of shivering, onset of shivering, time for cessation of shivering, recurrence, response rate, and adverse effects were observed at scheduled intervals. Unpaired *t*-test was used for analysing the data. Time taken for cessation of shivering was significantly less with dexmedetomidine when

compared to tramadol. Nausea and vomiting was observed only in tramadol group (28% and; 20% respectively). There was not much difference in the sedation profile of both the drugs. They concluded that although both drugs are effective, the time taken for cessation of shivering is less with dexmedetomidine when compared to tramadol. Moreover, dexmedetomidine has negligible adverse effects, whereas tramadol is associated with significant nausea and vomiting. Wang J *et al*. [10] performed a meta-analysis of randomized controlled trials to compare dexmedetomidine with tramadol on the treatment of post-spinal anesthesia shivering. Dexmedetomidine had higher effective rate of shivering control, shorter time to cease shivering, lower recurrent rate of shivering, lower incidences of nausea, and vomiting, higher incidence of sedation, hypotension and bradycardia, compared with tramadol. They concluded that Dexmedetomidine is superior to tramadol for shivering treatment, due to higher effective rate of shivering control, earlier onset of action and lesser recurrence of shivering with higher incidence of sedation and lower incidences of nausea and vomiting. However, dexmedetomidine is also associated with higher incidences of hypotension and bradycardia than tramadol.

Table 1: Comparison between the spinal drug and sensory block level among the study subjects

Parameters		Group C	Group T	p-value
Spinal drug (ml, 0.5 % Bupivacaine)		3.460	3.463	0.25
Sensory block	T4	2	0	0.39
	T6	9	8	0.28
	T8	7	9	0.45
	T10	10	9	0.33
	T12	5	4	0.29

Table 2: Shows the comparison between the shivering grades among the study subjects

Shivering grade	Group C	Group T	p-value
3	28	27	0.28
4	22	23	0.33

Table 3: Shows the comparison of the control of shivering among the study subjects

Control of Shivering	Group C	Group T
Yes	48	44
No	2	6

Conclusion:

Within the limitations of the present study, it can be concluded that both Clonidine (75 µg) and Tramadol (0.5 mg/kg) can effectively treat patients with post-spinal anaesthesia shivering, but Tramadol took longer time for complete cessation of shivering than clonidine. Clonidine offers better thermodynamics than tramadol, with fewer side effects.

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