

A comparative study of intravenous tramadol versus butorphanol for control of shivering in patients undergoing spinal anesthesia

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ABSTRACT

Background: Shivering in patients following spinal anesthesia is a common problem which is cumbersome for the operating room personnel as well as the patient. Various methods, both pharmacological and non-pharmacological, have been tried to control shivering. This study aimed to evaluate the relative efficacy of intravenously administered butorphanol 20 µg/kg and tramadol 1 mg/kg in controlling shivering following spinal anesthesia in the intraoperative period.

Materials and Methods: A prospective, randomized comparative study was conducted in patients who received spinal anesthesia and developed shivering were randomly allotted to one of the two groups, namely butorphanol group who received i.v. 20 µg/kg butorphanol and tramadol group who received i.v. 1 mg/kg tramadol. Vital parameters of the patients such as heart rate, blood pressure, SpO₂, and temperature were monitored at regular intervals as per protocol. Events such as failure to stop shivering, recurrence of shivering, and side effects such as nausea and vomiting were also noted. Statistical tests such as Chi-square test and Student's *t*-test (unpaired and paired) were applied to the data collected.

Results: Of the 76 patients who developed shivering following spinal anesthesia during the period of study 38 patients received i.v. tramadol and other 38 patients received i.v. butorphanol. The mean temperature at which patients developed shivering was 36.22°C and the mean duration for shivering to occur following spinal anesthesia was 28.82 min. Butorphanol controlled shivering in mean time of 190.53 s while tramadol controlled shivering in mean time of 205.47 s. There was no statistically significant difference between the two groups in terms of time required to control shivering. Butorphanol failed to control shivering in two patient and had recurrence of shivering in seven patients while tramadol which had no failures and no recurrence of shivering.

Conclusion: Our study concludes that intravenously administered tramadol 1 mg/kg was more effective in controlling shivering than butorphanol 20 µg/kg following spinal anesthesia. Further, the incidence of nausea and vomiting was more in patients treated with i.v. tramadol in comparison to i.v. butorphanol.

Key words: Butorphanol, shivering, spinal anesthesia, tramadol

INTRODUCTION

Spinal anesthesia is a popular and safe anesthesia technique for various surgeries. Shivering following spinal anesthesia is a common problem and may occur in 19–33% of patients receiving spinal anesthesia.^[1,2] Shivering is unpleasant for the patient, anesthesiologist and the surgeon besides being physiologically stressful for the patient.

Shivering can occur in patients receiving regional anesthesia as well as in those patients recovering from general anesthesia. It causes several undesirable physiologic consequences including increase in oxygen consumption, carbon dioxide, and minute

ventilation. It may induce hypoxemia, lactic acidosis, increased intraocular pressure and intracranial pressure, and interfere with patient monitoring such as electrocardiographic, NIBP, and SpO₂. Shivering may damage dental prosthesis and poor-quality teeth. It may negate orthopedic procedures such as fractures and dislocations and can be detrimental to patients with low cardiopulmonary reserve.^[3,4]

Spinal anesthesia is known to decrease the vasoconstriction and shivering thresholds. There is core to periphery redistribution of heat due to spinal-induced vasodilatation and shivering is preceded by core hypothermia and vasoconstriction above the level of block.^[2,5] Interestingly, core hypothermia following spinal

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Received: 02-05-2018

Revised: 19-05-2018

Accepted: 14-06-2018

anesthesia may not trigger sensation of cold as the cutaneous vasodilatation resulting from sympathetic blockade increases skin temperature, leading to a sensation of warmth although accompanied by thermoregulatory shivering.^[6]

Various methods are available for the control of shivering; these may be non-pharmacological or pharmacological. Intraoperative hypothermia can be minimized by any technique that limits cutaneous heat loss to the environment such as those due to cold operating room, evaporation from surgical incisions, and conductive cooling produced by administration of cold intravenous fluids.^[2] Fluid warmers,^[7] ambient O.R temperature, space blankets,^[8] surgical drapes, and active circulating water mattress have been used. Pharmacological methods using variety of drugs such as pethidine, morphine, tramadol,^[9,10] clonidine, doxapram, ketanserin, neofam, neostigmine, and magnesium sulfate^[11] have been tried. These drugs are easily available and cost-effective. In the quest for more safe and efficacious drug, in our study, we compared two easily available and safe drugs butorphanol and tramadol, intravenously administered for treating shivering in patients who received spinal anesthesia for various surgical procedures.

To compare the relative efficacy and safety of intravenously administered 20 µg/kg butorphanol against 1 mg/kg tramadol to control perioperative shivering in patients who receive spinal anesthesia for various surgical procedures.

MATERIALS AND METHODS

Source of Data

Patients admitted to Navodaya Medical College and Research Center, Raichur, during the period 01-06-2011–03-08-2012 were the source of data. Those patients who developed intraoperative shivering following spinal anesthesia for various surgical procedures were included in the study.

Inclusion Criteria

The following criteria are included in the study:

- Patients of either gender aged between 18 and 45 years.
- ASA grade of I –II.
- Patients who develop shivering following spinal anesthesia.
- Elective surgeries.

Exclusion Criteria

The following criteria are excluded from the study:

- Age <18 or more than 45 years.
- ASA Grade III and IV.
- Patients receiving blood transfusion.
- Patients on drugs affecting autonomic nervous system.
- History of allergy to any of the study drugs.
- Surgeries lasting more than 4 h.
- Any major systemic illness, fetal compromise.
- Active disease of CNS such as meningitis, poliomyelitis, intracranial hemorrhage, and such acute combined degeneration of spinal cord.
- Spinal stenosis and active disease (spondylosis, tuberculosis, and tumors).
- Cardiogenic or hypovolemic shock.
- Coagulation disorders.

We conducted a prospective, randomized comparative study at Navodaya Medical College Hospital, Raichur, after obtaining approval from the ethical committee and written informed consent from the patients. All patients who were included in the study were pre-medicated with tablet diazepam 5 mg on the night before the surgery and tablet diazepam 10 mg on the morning of the surgery, administered orally with sips of water 2 h before the planned surgery. Baseline temperature was recorded using a mercury thermometer in the axilla placed in the vicinity of the axillary artery. Operation theater temperature was maintained at 22–25°C. All patients in our study received spinal anesthesia in the left lateral position using 25G Quincke needles through midline approach in the L3-L4 intervertebral space under strict aseptic precautions under local anesthesia to the skin. Following free flow of CSF, 0.5% hyperbaric bupivacaine 3–4 ml was injected depending on the requirement of surgery. All patients were administered 4 L of oxygen by Hudson transparent face mask and were adequately covered with surgical drapes.

Patients who developed shivering after administering spinal anesthesia were included in the study and data were recorded from patients who continued to shiver for at least 2 min. Shivering of Grades 2 and 3 as proposed by Crossley and Mahajan Scale of shivering was considered to require treatment. When patients developed shivering of above-mentioned grades for a minimum of 2 min, they were randomly allotted to one of the two study groups -

- Group B (*n* = 38) - received 20 µg/kg butorphanol i.v.
- Group T (*n* = 38) - received 1 mg/kg Tramadol i.v.

The study drug was then administered slow i.v. as per the allotted group. The time from drug administration till the patient stopped shivering was accurately noted in seconds (using a stop clock in cell phone). Patients were monitored at intervals of 1 min for the first 5 min and thereafter 10, 20, and 30 min till end of surgery. Patients were closely monitored for failure of the drug, recurrence of shivering, and side effects such as nausea and vomiting.

In patients who developed nausea and vomiting, injection ondansetron 4 mg was administered i.v. Treatment that stopped shivering was considered to have been successful. In patients who had recurrence of shivering, injection pethidine 25 mg was administered intravenously, and the test drug was considered unsuccessful. All the observations and the particulars of the patients were recorded in a pro forma, a copy of which is enclosed. Statistical methods such as Chi-square test and Student's *t*-test (unpaired and paired) were used to find the significance of homogeneity of study characteristics between the two groups of patients.

RESULTS

The present study was conducted on 76 adult patients among whom 38 patients were female and 38 were male [Table 1].

The present study included 19 males and 19 females in tramadol group, and in butorphanol group, it was 19 males and 19 females. This was statistically not significant (*P* = 0.819). The mean age distribution in butorphanol group was 36.76 ± 9.82 years, whereas it was 32.45 ± 8.56 years in tramadol group (*P* = 0.545), and it was statistically not significant. Mean weight in

butorphanol group was 61.63 ± 12.78 kg and 59.74 ± 11.71 kg in tramadol group which was not significant ($P = 0.52$) [Table 1]. In butorphanol group, 32 patients were ASA-I and six patients were ASA-II, whereas in tramadol group 35 patients were ASA-I and three patients were ASA-II which was statistically not significant ($P = 0.293$) [Figure 1].

In butorphanol group, 13, 16, and 9 patients underwent abdominal, lower limb, and urological surgeries, respectively, and in tramadol group, 12, 20, and 6 patients underwent abdominal, lower limb, and urological surgeries, respectively [Table 2]. Among the study group, patients' minimum temperature recorded was 36.2°C and maximum was 37.6°C . The mean temperature of patients before administration of spinal anesthesia was 37.12°C .

Patients in the butorphanol group 31 (81%) had Grade 2 shivering and 7 (18%) patients had Grade 3 shivering in comparison to patients in the tramadol group in whom 29 (76%) had Grade 2 shivering while 9 (23%) patients had Grade 3 shivering [Table 3].

Intergroup comparison between the groups reveals the difference in mean temperature before spinal anesthesia and during shivering, and mean time for onset and control of shivering was not significant [Table 4].

There is no statistically significant difference between the two groups regarding mean heart rate, systolic blood pressure, diastolic blood pressure, SpO_2 , and temperature during shivering [Table 5].

In patients who received either of the drugs for the treatment of shivering, there was highly significant increase in the SpO_2 after

control of shivering as compared to its values during shivering ($P < 0.001$) [Table 6]. Although clinically five patients had nausea/vomiting with tramadol while none of the patients who received butorphanol had these side effects, there was statistically significant difference between the two groups.

In butorphanol group, shivering was effectively controlled in 81% of patients, while it was 86% in tramadol group. None of the patients in butorphanol group developed nausea/vomiting, whereas 13% of patients developed the same in tramadol group [Table 7 and Figure 2].

DISCUSSION

Spinal anesthesia is a safe and popular anesthesia technique used world over for various surgeries. Spinal anesthesia is a type of central neuraxial blockade, the other commonly used techniques being epidural anesthesia. The incidence of shivering in patients receiving regional anesthesia is 19–33%.^[1,2] The physiologic role of shivering is to provide heat, but its occurrence in relation to anesthesia is inconsistent and incompletely understood. The probable mechanism under regional anesthesia could either be a result of decrease in core body temperature, misinformation from receptors, or impairment of the physiologic set points.^[2]

Variety of factors contributes to decrease the core body temperature in patients receiving spinal anesthesia. These include

Table 1: Demographic characteristics among study participants

Sex	Group B (n=38)	Group T (n=38)	P	Result
Male	19	19	0.819	NS
Female	19	19		
Total	38	38		
Age (years) Mean±SD	36.76±9.82	32.45±8.56	0.545	NS
Weight (Kg) Mean±SD	61.63±12.78	59.74±11.71	0.502	NS

SD: Standard deviation, NS: Non-significant

Table 2: Types of surgeries among study groups

Types of surgeries	Group B	Group T	Frequency (%)
Abdominal	13	12	25 (32.89)
Lower limb	16	20	36 (47.37)
Urological	9	6	15 (19.74)
Total	38	38	76 (100)

Table 3: Grade of shivering in study groups

Grade of shivering	Study group		Total
	B	T	
	Count (%)	Count (%)	Count (%)
2	31 (81.58)	29 (76.32)	60 (78.95)
3	7 (18.42)	9 (23.68)	16 (21.05)
Total	38	38 (100)	76 (100)

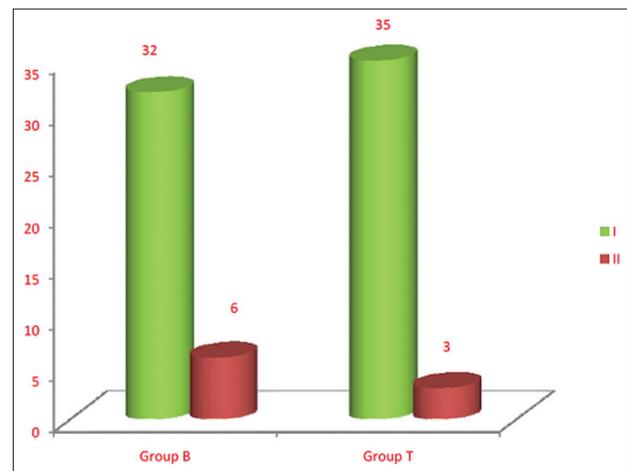


Figure 1: ASA grade of patients

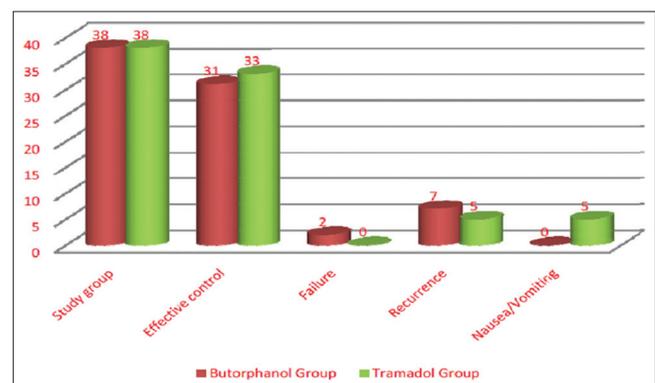


Figure 2: Summary presentation of results of different study related parameters in both the study groups

Table 4: Group statistics among study subjects - Student's t-test

Characteristics	Study group	n	Mean±SD	t	P	Result
Temperature before spinal anesthesia (°C)	T	38	37.11±0.23	0.294	0.769	NS
	B	38	37.13±0.24			
Temperature before spinal anesthesia (°C)	T	38	36.22±0.23	0.213	0.832	NS
	B	38	36.23±0.31			
Time for onset of shivering (min) (D)	T	38	27.29±8.57	1.128	0.263	NS
	B	38	30.34±14.31			
Time for control of shivering (s) (Ct)	T	38	205.47±33.09	1.419	0.16	NS
	B	38	190.53±55.87			

SD: Standard deviation, NS: Non-significant

Table 5: Vital data in group statistics - Student's t-test

Characteristics	Study group	n	Mean±SD	t	P	Result
Heart rate during shivering	T	38	81.37±9.85	0.086	0.932	NS
	B	38	81.16±11.41			
SBP during shivering	T	38	119.21±6.84	0.964	0.338	NS
	B	38	120.74±6.97			
Heart rate during shivering	T	38	27.29±8.57	1.128	0.263	NS
	B	38	30.34±14.31			
DBP during shivering	T	38	77.32±6.75	0.384	0.702	NS
	B	38	77.89±6.37			
SpO ₂ during shivering	T	38	99.74±1.11	1.217	0.227	NS
	B	38	98.42±1.15			
Temp. during shivering	T	38	36.22±0.23	0.213	0.832	NS

SD: Standard deviation, NS: Non-significant, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

Table 6: Hemodynamic changes in both the study groups

Comparison during shivering to after control	Study group	n	Mean±SD	t	P	Result
Heart rate/min	T	38	78.71±8.24	0.512	0.61	NS
	B	38	77.71±8.78			
SBP (mmHg)	T	38	116.58±6.50	0.965	0.338	NS
	B	38	118.37±9.40			
DBP (mmHg)	T	38	75.74±5.87	1.314	0.193	NS
	B	38	77.45±5.11			
SpO ₂ %	T	38	99.47±0.56	16.153	<0.001	NS
	B	38	99.67±0.55			

SD: Standard deviation, NS: Non-significant

Table 7: Summary of results in both the study groups

Characteristics	Butorphanol group (%)	Tramadol group (%)
Study group	38 (100)	38 (100)
Effective control	31 (81.75)	33 (86.84)
Failure	2 (5.26)	0
Recurrence	7 (18.42)	5 (13.16)
Nausea/vomiting	0	5 (13.16)

sympathetic block causing peripheral vasodilation, increased cutaneous blood flow resulting in increased heat loss through skin, cold operating room, rapid i.v. infusion of cold i.v. fluids, and direct effect of cold anesthetic solution on the thermosensitive structures of the spinal cord.^[2,11]

Ours was a prospective study conducted between June 1, 2011 and August 3, 2012. In this study, we compared an opioid butorphanol

with tramadol, the efficacy of the latter to control shivering has been proved in numerous studies. Earlier studies conducted by Vogelsang and Hayes^[12] showed that butorphanol was better alternative to pethidine. Studies by Dhimar *et al.*,^[9] De Witte *et al.*,^[13] and Tsai and Chu^[10] showed that tramadol was effective in controlling shivering in patients during epidural anesthesia, and tramadol was superior to pethidine which has been considered as the "gold standard" to control shivering. Study by Bharat *et al.*^[14] compared 20 µg/kg butorphanol against 1 mg/kg tramadol in controlling shivering in patients under spinal anesthesia. They deduced that tramadol was faster in controlling shivering and more efficacious, then butorphanol which also had more nausea and vomiting and sedation.

In this study, we recorded temperature using mercury thermometer placed in the vicinity of the axillary artery. This was as per deductions by Sessler^[6] in his study, wherein he concluded that axillary temperatures were fairly good indicator of core body temperature when the thermometer was placed in the vicinity

of the axillary artery, and the patients did not have extremes of thermal perturbations.

Following spinal anesthesia, the mean temperature at which shivering occurred in patients in this study was $36.22 \pm 0.27^\circ\text{C}$. This result was in accordance to the study by Dhimar *et al.*,^[9] wherein the mean temperature at which shivering occurred was $36.2 \pm 0.4^\circ\text{C}$. In this study, shivering disappeared within 190.53 ± 55.87 s of drug administration in patients in the butorphanol group while it was 205.47 ± 33.09 s in patients in the tramadol group, although there was no statistically significant difference between the two. This result was unlike that noted by Bhaarat *et al.*^[14] in their study wherein tramadol controlled most of shivering within 2 min while butorphanol took 3–5 min to control shivering. They had concluded that results were faster and better with tramadol. However, in this study, butorphanol failed to control shivering in two patients even after 30 min of its administration as against no such failure in the tramadol group.

Earlier studies also showed that butorphanol did not relieve shivering in all the patients.^[14] Regarding recurrence, shivering reappeared in 18% of patients at the end of 40 min in patients receiving butorphanol while in 13% of patients at the end of 25 min in patients receiving tramadol. This result was in condolence with earlier study by Dhimar *et al.*^[9] which had 10% recurrence at 50 min in patients receiving tramadol.

In this study, there were no significant differences in core body temperature preoperatively or intraoperatively, and both drugs gave good hemodynamic stability throughout the course of study in all patients. We observed significant improvement in SpO_2 values in both groups after control of shivering and heart rate also decreased when compared to it at time of shivering. This was at par with earlier studies by Dhimar *et al.*^[9] and Bhaarat *et al.*^[14] which reported similar observations with respect to hemodynamics.

Earlier studies found high incidence of nausea and vomiting with both drugs and more so with butorphanol.^[9,14] They suggested slow i.v would reduce the incidence of nausea and vomiting.^[9] In our study, we injected drugs slow i.v in both groups for all cases. We observed 13.16% incidence of nausea and vomiting in patients receiving tramadol while no such untoward incident with butorphanol in contrast to the study by Bhaarat *et al.*^[14] This was, however, statistically highly significant difference between the two groups.

The study by Bhaarat *et al.*^[14] found tramadol to be more effective than butorphanol. Even in this study, tramadol was found to be more effective than butorphanol in controlling shivering. However, butorphanol had no incidence of nausea and vomiting. Hence, we conclude that tramadol (1 mg/kg) administered i.v is more effective than butorphanol (20 $\mu\text{g}/\text{kg}$) in controlling shivering in patients following spinal anesthesia. However, the incidence of nausea and vomiting was more in the tramadol group.

CONCLUSION

Our study was a prospective, randomized comparison of two i.v. administered drugs butorphanol 20 $\mu\text{g}/\text{kg}$ and tramadol 1 mg/kg to control intraoperative shivering in patients who

received spinal anesthesia for surgery. 76 patients were studied between June 1, 2011 and August 3, 2012. When shivering was observed, the patient was randomly allotted to one of the two groups and study conducted as per protocol. 38 patients were studied in butorphanol group while 38 patients were studied in the tramadol group. Both drugs were found to be effective in controlling shivering, and there was no statistical difference between the two [Figure 2]. There was statistically significant improvement in the SpO_2 values in both groups following control of shivering while no significant change was noticed w.r.t. other vital parameters in the patients.

The incidence of side effects such as nausea and vomiting was absent with butorphanol but was seen with tramadol, which was statistically significant. The present study concludes that tramadol 1 mg/kg is more effective in controlling shivering than butorphanol 20 $\mu\text{g}/\text{kg}$ following spinal anesthesia [Figure 2].

Tramadol is more effective than butorphanol in controlling shivering following spinal anesthesia. There is significant improvement in the SpO_2 values following control of shivering. Control of shivering causes a decrease in the patient's heart rate which is statistically significant compared to the values at the time of shivering. There is no significant effect on other vital parameters in the patients with either of the drug. The occurrence of side effects such as nausea and vomiting was absent with butorphanol but was present with tramadol which was statistically highly significant.

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How to cite this Article: Chandan RK, Manohar CV, Vidushi, Sharma K, Lonikar MP, Sen S. A comparative study of intravenous tramadol versus butorphanol for control of shivering in patients undergoing spinal anesthesia. *Asian Pac. J. Health Sci.*, 2018; 5(2):142-147.

Source of Support: Nil, **Conflict of Interest:** None declared.