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Comparison between Butorphanol and Tramadol as an Anti-Shivering Agent in Patients Undergoing Spinal Anesthesia for Lower Limb Orthopedic Surgeries

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Abstract

Introduction: Shivering can be defined as a physiological response to core hypothermia. Occurrence of shivering is common in patients of regional anesthesia as well as general anesthesia. Shivering cause some serious health consequences so efforts should be taken to prevent or treat at earliest. *Aim:* To compare efficacy and safety of butorphanol over tramadol as anti-shivering agent under spinal anesthesia and to watch for any side effects. *Material and Methods:* A prospective randomized comparative study was conducted in 80 patients who developed shivering under spinal anesthesia posted for lower limb orthopedic surgeries. At onset of shivering, patients were randomly allocated in two study groups and study drug was given as slow intravenous injection. *Group B* - Injection butorphanol (1 mg) 1 ml slow iv. *Group T* - Injection tramadol (50 mg) 1 ml slow iv. Time taken to complete control of shivering, failure rate, recurrence rate, hemodynamic changes and side effects (nausea, vomiting, itching and sedation) were recorded during study period. Data were collected and analysed using statistical methods. *Result:* Response rate is similar in both groups. At 1 min post treatment, butorphanol group had more patients with complete control of shivering. There was significantly less chance of reccurence in butorphanol group. Hemodynamic parameters were comparable in both study groups through entire study. Butorphanol treated patients had mild to moderate degree of sedation than tramadol group. *Conclusion:* Both butorphanol and tramadol are effective in control of shivering under spinal anesthesia. Butorphanol has advantage of faster onset and lesser recurrence rate, only disadvantage being mild to moderate sedation which may warrant observation of respiration.

Keywords: Shivering; Butorphanol; Tramadol.

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Introduction

Shivering is defined as involuntary repeated skeletal muscular activity in response to core hypothermia to augment metabolic heat production [1]. Spinal anesthesia is commonly used in various lower limb orthopedic surgical procedures. Shivering following spinal anesthesia is very common and incidence may varies from 40-60% [1,2]. Shivering can also occur in patients recovering from general anesthesia as well.

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Shivering following spinal anesthesia is due to impairment of thermoregulatory autonomic control under anesthesia. Spinal induced vasodilatation and decrease in shivering threshold by 0.5^0C- 1^0C cause redistribution heat from core to periphery [3]. Perioperative hypothermia is a major cause of shivering under spinal anethesia [4,5]. Other causes may include cold operating room atmosphere, cold intravenous fluids, drug reactions, transfusion reaction, high grade fever and septicemia.

Shivering under anesthesia may have serious consequences to patient. It can cause increase oxygen consumption, increase carbon dioxide production and hence lactic acidosis [5,6]. It can cause tachycardia and hypertension. Thus patient with cardiac disease or patients with low cardio pulmonary reserve, shivering may be detrimental [5,7]. Other problems are increase in intraocular pressure, increase in intracranial pressure and increase in minute ventilation [5,8,9]. Shivering is also undesirable to surgeon and anesthetist, besides stressful to patient.

Shivering under anesthesia has serious health consequences and various methods should be applied to prevent or control it. Various non pharmacological methods include ambient operating room temperature, iv fluid warmers, radiant heaters and space blankets [9,10]. Pharmacological drugs include two groups mainly, opioids (like morphine, pethidine, tramadol, butorphanol) and non opioids (like ketamine, magnesium sulphate, doxapram, granisetron, propofol).

Our study was carried out to compare butorphanol over conventional antishivering agent tramadol in control of shivering under spinal anesthesia in lower limb orthopedic surgical procedures. Our aim is to find more effective, safer and faster acting antishivering agent with minimal side effects.

Materials and Methods

A prospective randomized double blind comparative study was conducted in our institute during June 2018 to Dec 2018. Total 80 patients with either gender between 20 to 40 years of age with ASA grade 1 or 2, posted for lower limb orthopedic surgery, who developed shivering under spinal anesthesia were included in our study.

Exclusion criteria

ASA grade 3 or 4

Patients with major systemic disease

History of allergy to study drugs

Head injury

Coagulation disorders

Patients with history of fever or sepsis

Informed written consent was taken from patients. Randomisation is done by sealed envelope technique. The cases were randomly allocated to two study groups, Group B (butorphanol) and Group T (tramadol).

All patients included in our study were evaluated pre operatively. After applying monitors, baseline vitals were recorded in operating room. The temperature of operation theatre was maintained between 22^0C-24^0C in all cases. Baseline axillary temperature was recorded by mercury thermometer. All patients in our study received spinal anesthesia in sitting position. Spinal anesthesia was instituted in L2-L3 space with 23 G spinal needle.0.5% bupivacaine heavy was given 3 ml with aiming to achieve T10 dermatome sensory block. Surgery was permitted to start after achieving adequate level of spinal block.

When patient developed shivering grade 2 or 3 after giving spinal anesthesia, study drug was given as per study groups. All patients were given supplemental oxygen 6 liter / min via oxymask.

Group B - Inj. Butorphanol 1 mg (1 ml) iv diluted in 10 cc normal saline

Group T -Inj. Tramadol 50 mg (1 ml) iv diluted in 10 cc normal saline

Shivering is graded as follow

Grade 0	No shivering
Grade 1	Mild fasciculations of head and neck
Grade 2	Moderate / visible tremors involving more than one group of muscles
Grade 3	Severe / gross muscular activity involving entire body

Sedation score is graded as follow

Grade 0	Alert
Grade 1	Arousable to verbal command
Grade 2	Arousable to gentle tactile stimulation
Grade 3	Arousable to vigourous tactile stimulation
Grade 4	No awareness

The study drug was given over 1 minute. Time taken for complete abolition of shivering (Grade 0) was noted from end of injection. Patients were monitored after giving study drug at 1 min, 3 min, 5 min, 10 min, 20 min, 45 min. Vitals (temperature, pulse, systolic BP, diastolic BP, SpO_2) were recorded during shivering and post treatment. If shivering

is not completely controlled (Grade 0) after 20 min of administering drug, it was considered as failure and patients were warmed by space blankets or heat warmers. Patients were closely monitored for recurrence of shivering, sedation and side effects (nausea vomiting, itching).

Recurrence of shivering within 20 min post treatment in any patient was actively treated by space blankets and heat warmers. Sedation score was assessed in both study groups. Any patient who developed nausea/vomiting was treated with iv injection ondansetron. Any patient who developed itching was treated with inj chlorpheniramine.

Statistical Analysis

All data were collected and analysed with SPSS 17 software. Statistical methods such as student's t test and chi square test were performed to find level of significance of our data values of both groups.

Results

In our study, patients of both groups were comparable in regards to demographic characteristics, duration of surgery and ASA grade. (p value > 0.05, insignificant) (Table 1).

There was no significant difference among both groups in regards to axillary temperature (baseline and during shivering) and shivering grade at onset of shivering. There was slight fall in axillary temperature in both groups during shivering but difference is not statistically significant. Most of patients had grade 2 shivering at onset in both study groups.

Time taken to complete control of shivering at 1 min was significantly higher in group T compared to group B (p value<0.05). Complete cessation of shivering was 95% in group B compared to 85% in group T (p value >0.05). (Table 2 and 3).

Hemodynamic parameters were comparable in both groups during shivering and post treatment at 15 min. There is no statistically significance difference in both study groups (p value >0.05). There is rise in pulse rate during shivering in both study groups (Table 3,4).

Failure to control shivering (grade 0) within 20 min of injecting study drug was higher in tramadol group (15%) as compare to butorphanol group (5%), difference was statistically insignificant. Recurrence of shivering was observed significantly higher in tramadol group (35%) compared to butorphanol group (10%). Incidences of nausea / vomiting were found in both groups with no significant difference. Incidence of grade 1 and grade 2 sedation was

Table 1: Demographic characteristics (Mean ± SD and p value)

	Group B	Group T	p value
Age (years)	28.45 ± 8.56	30.36 ± 7.43	0.28
Weight (kgs)	50.32 ± 12.65	52.78 ± 10.54	0.34
Gender (M:F)	32/8	35/5	0.12
ASA grade(1/2)	36/4	38/2	0.39
Duration of surgery(min)	76.45 ± 12.88	74.34 ± 15.65	0.51

Table 2: Axillary temperature and shivering grade (Mean ± SD and p value)

		Group B	Group T	P value
Axillary temperature	Baseline	36.48 ± 0.56	36.68 ± 0.42	0.07
	During shivering	35.25 ± 0.67	35.46 ± 0.42	0.09
Shivering grade	Grade 2	35(92%)	38(95%)	0.58
	Grade 3	5(8%)	2(5%)	0.58

Table 3: Response rate as anti-shivering agent

Time to control shivering	Group B (n=40)	Group T (n=40)	p value
1 min	16 (40%)	6 (15%)	0.012
3 min	10 (25%)	8 (20%)	0.59
5 min	7 (17.5%)	10 (25%)	0.41
10 min	4 (10%)	7 (17.5%)	0.33
20 min	2 (5%)	3 (7.5%)	0.64
45 min	2 (5%)	6 (15%)	0.13

Table 4: Hemodynamic parameters (Mean ± SD)

Vitals		Group B	Group T
Systolic blood pressure	Baseline	116.65 ± 12.43	117.54 ± 11.67
	During shivering	114.43 ± 10.65	116 ± 13.76
	Post treatment (20 min)	117.12 ± 10.23	116.65 ± 10.87
Diastolic blood pressure	Baseline	70.54 ± 13.56	72 ± 11.34
	During shivering	70 ± 10.67	72.12 ± 12.63
	Post treatment (20 min)	72.12 ± 11.45	71.45 ± 10.37
Heart rate	Baseline	76.12 ± 14.56	78 ± 15.67
	During shivering	86.54 ± 12.67	86.57 ± 13.76
	Post treatment (20 min)	78.43 ± 12.45	82.34 ± 12.67

Table 5: Incidence of complications

	Group B (n= 40)	Group T (n= 40)	p value
Failure	2(5%)	10(25%)	0.0128
Recurrence	4(10%)	14(35%)	0.007
Nausea / vomiting	4(10%)	6(15%)	0.50
Itching	2(5%)	1(2.5%)	0.55
Sedation (grade 1 or 2)	10(25%)	1(4%)	0.008

significantly higher in butorphanol group (25%) as compared to tramadol group (4%), difference being highly significant. Itching was observed only in two patients in group B and one patient in group T, difference was statistically insignificant.

Discussion

Spinal anesthesia is commonly used in lower limb orthopedic surgeries. Shivering can occur in patients receiving spinal anesthesia as well as patients recovering from general anesthesia. Incidence of shivering under spinal anesthesia can range from 40-60% [1,2]. Shivering is body's compensatory mechanism to minimize heat loss and to increase metabolic heat production. Risk factors associated with shivering may include age, type and duration of surgery and level of spinal block [11].

Perioperative hypothermia is most common factor involve in incidence of shivering. Shivering under spinal anesthesia is due to sympathetic blockage induce vasodilatation and resultant heat loss below the level of block. Other contributing factors are rapid intravenous fluid infusions, cold operating room atmosphere and cold irrigating solutions [12].

Shivering is common perioperative problem encountered under spinal anesthesia, which has adverse health impacts on patients. Shivering causes tachycardia, hypertension, acidosis, increase oxygen consumption and increase carbon diaoxide production. Shivering can cause serious health consequences in patients with preexisting cardiac disease. Shivering can cause discomfort to patients besides interfering with baseline monitoring intraoperatively (blood pressure, oxygen saturation) [5]. So atmost care should be taken to prevent or control shivering as early as possible. Both nonpharmacological and pharmacological measures should be applied to effectively control shivering under spinal anesthesia.

Pharmacological methods by drugs like ketamine, propofol, granisetron, morphine, pethidine, tramadol, butorphanol and clonidine, shivering can be effectively controlled. Among them, opioids hold important place in a list of antishivering agents. Opioids acts as anti shivering agents by modulation of central thermoregulation (anterior hypothalamus, raphe nucleus and raphe magnus) [9]. In our study we compared efficacy of synthetic opioids (butorphanol and tramadol) in control of shivering. Tramadol exerts its anti shivering effect by its agonistic action on μ receptors thus preventing neuronal uptake of serotonin and noradrenaline. Butorphanol acts anti shivering agent by agonistic action on μ and ƙ receptors [13].

We compared tramadol and butorphanol as anti shivering agent in regards to their efficacy, onset of action and side effects (nausea, vomiting, itching and sedation).

In our study we had used axillary temperature by putting thermometer in axilla. Axillary temperature could be fairly good indicator of core temperature. Sessler et al. [2] had also revealed same findings in his study.

There were not any significant differences in baseline mean temperature preoperatively. Mean temperatures at onset of shivering were 35.25 ± 0.67^{0}C and 35.46 ± 0.42^{0}C. Difference in both study groups was not significant. Dhimar et al. [14] also found in their studies that mean temperature at onset of shivering was 36.2 ± 0.4^{0}C. Shivering was graded in our study on basis of Tsai and Chu scale (0-3 scale) [15].

In our study we found that butorphanol and tramadol both were effective in controlling shivering under spinal anesthesia. Butophanol and tramadol both had nearly similar results in regards to effective control of shivering. Our finding was accordance with findings of Bansal et al. [5] and Bhatanagar et al. [16]. In contrast to our findings, Mustak ali et al. [9] observed in their study that tramadol is more effective than butorphanol in control of shivering.

In our study we observed that response rate within 1 minute was more with butorphanol group compared to tramadol group, indicating butorphanol had more faster onset in control of shivering. Our findings were in correlation to findings of bansal et al. [5] and krithika et al. [11]. According to Bharat et al. [13], tramadol was faster in onset in control of shivering which was contradiction to our findings.

Our studies showed that there was lesser incidence of recurrence of shivering in butorphanol treated group compared to tramadol group. Butorphanol was highly effective to prevent recurrence. Our finding were similar to study done by Dhimar et al. [14] and Krithika et al. [11] who also demonstrate butorpanol had lesser chance of recurrence. In contrast to our study, Bharat et al. [13] who observed lower rate of recurrence in tramadol treated patients compared to butorphanol group.

There were no significant alterations in hemodynamic parameters during course of study in all patients both study groups. There was slight rise in pulse rate during shivering which was insignificant. Our findings were in correlation to studies of Dhimar et al. [14] and Mathews at al. [17] who also observed same.

We found no significant differences in regards to nausea, vomiting and itching in post treatment period in both study groups. Bansal et al. [5] also stated in their studies that incidences of nausea/ vomiting were comparable in butorphanol group and tramadol group. Sedation is assessed by using 4 point sedation scale. In our study, there was higher incidence of sedation in butorphanol group compared to tramadol group. Degree of sedation (grade 1/2) was significantly higher in butorphanol treated patients. Our findings were similar to study done by Joshi et al. [12] indicating that butorphanol treated patients had more sedation than tramadol treated group.

Limitations

There are a few the limitations of our study. Relatively small sample size is limitation of our study in regards to common perioperative problem. We have used axillary temperature as indicator of core temperature due to unacceptability of esophageal or rectal temperature probe.

Conclusion

On basis of our study we can conclude that butorphanol and tramadol both are effective in control of shivering after spinal anesthesia. Butorphanol has added advantage of faster onset, lesser recurrence rate and mild to moderate sedation over conventional antishivering agent tramodol.

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