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COMPARATIVE STUDY OF TRAMADOL WITH THAT OF BUTORPHANOL FOR THE CONTROL OF SHIVERING IN PATIENTS UNDERGOING NEURAXIAL BLOCKADE

Anaesthesiology

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ABSTRACT

Aim: To compare the efficacy of Tramadol with that of Butorphanol for the control of shivering in patients undergoing neuraxial blockade.
Materials And Methods: A randomized, double blind study of 60 patients undergoing lower abdominal and lower limb surgery under spinal anesthesia who got shivering during intra operative period up to 60minutes. Out of which 60 patients, who will develop shivering after neuraxial blockade will be randomly allocated to one of the following groups. Each group contains 30 patients.
Group I: (Tramadol Group) Patients received tramadol intravenously (50mg)
Group II: (Butorphanol Group) Patients received butorphanol intravenously (1mg)
Inclusion criteria: ASA Grade I Or II, age 18 to 60 years, weight 30 to 70 kg, lower abdominal and lower limb surgery under spinal anesthesia.
Exclusion Criteria: Patients not willing to take part in study, ASA grade >2, significant systemic illness, patients with fever, pregnancy, patients with history of seizure, patient on oral anticoagulant therapy, emergency surgeries, conditions where neuraxial blockade will be contraindicated.
Result: Time taken to control Shivering was significantly lower in Group I (Tramadol) as compared to group II (Butorphanol), more patients with higher sedation score with Butorphanol group compared to Tramadol Group, Nausea and vomiting higher in Tramadol Group compared to Butorphanol Group.
Conclusion: Tramadol is most rapid acting & effective in control of shivering with neauraxial block without any significant side effects and least reappearance of shivering as compared to Butorphanol.

KEYWORDS

Neuraxial blockade, Tramadol, Butorphanol, Shivering.

INTRODUCTION

Shivering is defined as readily detectable fasciculation or tremor of face, jaw, head, trunk, or extremities lasting longer than 15 secs. It is an involuntary, oscillatory muscular activity that augments metabolic heat production and it occurs when the balance between heat production and heat loss is disturbed. The reported incidence of shivering following general anaesthesia varies between 5% and 65%. While about 33- 60% of the patients under regional anaesthesia developed shivering. Neuraxial blockade i.e. epidural and spinal anaesthesia decrease the vasoconstriction and shivering threshold to a significant degree. Shivering is not only, uncomfortable to the patients, but it also causes increased oxygen consumption up to 600% above basal level. Shivering leads to increased carbon dioxide production,increased cardiac output, tachycardia and hypertension raised intraocular pressure, raised intra cranial pressure and lactic acidosis.

MATERIALS AND METODS

We have undertaken the randomized, double blind study of 60 patients undergoing lower abdominal and lower limb surgery under spinal anesthesia in one year period from June 2019 to May 2020, who developed shivering during intraoperative period up to 60 mins. The study was conducted in ABVIMS and Dr. R.M.L. Hospital, New Delhi. The study was randomized by closed envelope method. In this 90 envelops were prepared and sealed, each contains information about either group l, Il or Ill.

Material and Selection of Patient

Consecutively 141 of either sex with ASA grade I and Il status posted for elective surgery under regional anesthesia were included in the study. Out of which 60 patients, who developed shivering after neuraxial blockade were randomly allocated to one of the following groups. Each group contains 30 patients.

- **Group I: (Tramadol Group)** Patients were received tramadol i.v. (50 mg)
- **Group II: (Butorphanol Group)** Patients were received butorphanoli.v (1 mg)

INCLUSION CRITERIA

- ASA grade 1 or 2
- Age 18 to 60 years
- Weight up to 30-70 kg
- Lower abdominal and lower limb surgery under spinal anesthesia

EXCLUSION CRITERIA

- ASA grade >2
- Significant systemic illness
- Allergic reaction to drug
- Patients on MAO inhibitors, tricyclic antidepressant
- Patients with fever, pregnancy
- Patients with history of seizure
- Conditions where neuraxial blockade was contraindicated
- Patients who have received opioid analgesics before surgery
- Patient on oral anticoagulant therapy
- Emergency surgeries.

Patients were evaluated preoperatively and inj. Glycopyrolate 0.2 mg IV was given as a premedication. Preloading of fluid was done with one liter of warm Ringer lactate. Monitors were attached and base line vitals were recorded when patient was taken into operation theatre. Spinal anesthesia was instituted at L3-L4 or L2-L3 interspace in sitting position with spinal needle no.25G. Bupivacaine heavy 0.5% was used for spinal anaesthesia. Surgery was started after achievement of the adequate level of sensory and motor block.

The temperature of the operating room was maintained at 21^{o}C—23^{o}C, with a room humidity of approximately 60%. Thermistor was used to record the temperature of the patient. Axillary artery was palpated and temperature probe was fixed over the course of artery in the axillary area and then arm was adducted for continuous measurement of axillary temperature. The volume of I.V. fluid and the use of ephedrine for hypotension were determined by attending anesthesiologists. The administration of pre or intra operative opioids was not permitted. Patients were supplemented with oxygen 6 L/min by face mask during and in the recovery room. Post operatively patients were kept in the recovery room with all monitors attached and covered with sterile

blankets. Same temperature and humidity was maintained as in the operation theatre. When patient developed shivering, vitals were noted and its grade was decided as per grading given below.

Table 1 : Shivering Grade

Grade 0	**No Shivering**
Grade 1	Mild fasciulations of face or neck, ECG disturbances in absence of voluntary activity of arms
Grade 2	Visible tremors involving more than one group of muscle
Grade 3	Gross muscular activity involving the entire body, bed shaking

Table 2 : Demographic Data

	Tramadol (n=30)	Butorphanol (n=30)	p-value	
Age (yrs.)	36.86±13.79	37±13	>0.05	NS*
Sex (M:F)	19:11	21:9	>0.05	NS*
Weight (Kgs)	48.33±8.33	46.6±6.34	>0.05	NS*
ASA (I:II)	14:16	13:17	>0.05	NS*
Axillary Temp. (^{0}C)	36.1+0.3	36.2+0.4	>0.05	NS*
Shivering grade	2.27+0.449	2.3+0.466	>0.05	NS*
Duration of Surgery (hrs.)	2.22+0.81	2.08+0.82	>0.05	NS*

***NS= Statistically not significant.**

Table 3 : Control of Shivering

Time (Minutes)	Tramadol (n=30)	Butorphanol (n=30)	p-value	
0	16(53.33%)	1(3.33%)	<0.05	S*
2	27(90.0%)	7(23.33%)	<0.05	S*
5	30(100%)	16(53.33%)		
10	30(100%)	25(83.33%)		
20	30(100%)	30(100%)		
30	30(100%)	30(100%)		
40	30(100%)	30(100%)		
50	16(53.33%)	21(70.0%)		
60	27(90.0%)	23(6.66%)		

***S= Statistically significant.**

Table 4 : Hemodynamic

	Tramadol (n=30)	Butorphanol (n=30)	p-value		
Pre shivering Mean BP	118.6+10.94	119.0+13.0	0.660	>0.05	NS*
Mean PR	83.93+7.05	85.0+7.0	0.020	>0.05	NS*
During shivering Mean BP	117.8+10.42	117.0+10.0	0.159	>0.05	NS*
Mean PR	88.23+7.67	90.0+6.4	1.696	>0.05	NS*
Post shivering Mean BP	118.93+11.37	119.0+9.7	0.610	>0.05	NS*
Mean PR	85.0+7.04	85.0+7.01	0.209	>0.05	NS*

***NS= Statistically not significant.**

Table 5 : Recurrence and complications

	Tramadol (n=30)	Butorphanol (n=30)	p-value	
Recurrence	3(10.0%)	15(50.0%)	<0.05	S*
Nausea and Vomiting	2(6.66%)	6(20.0%)	>0.05	NS*

***S= Statistically significant.,*NS= Statistically not significant.**

RESULTS

In our study, both the groups were comparable with regards to age, weight, gender, and ASA physical status.

There was no significant difference found in the duration of surgery, axillary temperature as well as shivering grades at the start of study between the two groups.

The onset of disappearance of shivering was found at around 1minute and 3 minutes in Group I and Group II respectively. Regarding the disappearance of shivering in both the groups, we found a statistically significant difference as shown in the table-3. Stoppage of shivering occurred earlier in Group I in comparison to Group II (P<0.001) as shown in Table 3.

Haemodynamically there was no significant difference found between the two groups as shown in table 4.

The recurrence of shivering was observed approximately after 50 minutes and the incidence of recurrence was 50% in Butorphanol group while only in 10% in Tramadol group as shown in Table 5.

After repeating the drug shivering had disappeared completely. Complications like nausea and vomiting occurred in 20% in Butorphanol group while only 6.66% in Tramadol group. However the difference is statistically insignificant (P> 0.05).

DISCUSSION

Neuraxial block is a popular technique for lower abdominal. and lower limb surgeries. Approximately 33-60 % of patients undergoing neuraxial block suffer from shivering as reported.

The factors causing decrease in core body temperature include, sympathetic block causing peripheral vasodilation, increased cutaneous blood flow resulting in increased heat loss through skin, cold operating room, rapid infusion of cold i.v fluids, direct effect of cold anaesthetic solution upon the thermosensitive structures of spinal cord.

Shivering is an unwarranted discomfort under neuraxial block where patients remain quite alert; it increases oxygen consumption up to 600%. Shivering may lead to increased carbon dioxide production, increased cardiac output, tachycardia, hypertension & increased intra ocular intra cranial pressure, lactic acidosis. Many Opioids like Alfentanyl, Tramadoland Butorphanol have been used by intravenous or epidural route to prevent or control shivering with varying degree of success reported by many Workers.

Various nonpharmacological and pharmacological methods have been used to prevent body heat loss. Nonpharmacological methods like electrical heaters, forced air warmers, blankets, radiant heat, and warming the operating room suite. The use of warm local anaesthetic solutions or warming of i.v fluids are also effective to reduce shivering. Pharmacological methods using KetanserineNefopam, Pethidine, Alfentanyl, Doxapram,Tramadol, Clonidine etc have been tried and compared by many studies. These drugs are used effectively when clinically indicated and they are easily available to all centers and prove to be practical in the many settings.

In our study we have compared recently introduced synthetic opioid Tramadol with Butorphanol, which was gold standard for control of shivering. Tramadol a synthetic opioid agonist prevents shivering by inhibiting the reuptake of norepinephrine and serotonin, hence activating the descending inhibitory spinal pathways. It also modulates the activity of nucleus median raphe acting centrally on the m opioid receptors predominantly with minimal effects on k and d receptors whereas Butorphanol acts through kappa receptors for its anti-shivering effects.

In our study we observed that shivering disappeared by 1 minute in case of Tramadol and 5 minutes in case of Butorphanol and in comparison to earlier study. Furthermore, the complete disappearance of shivering took 10 minutes in Tramadol group and 20 minutes in Butorphanol group. However in our study the complete disappearance of shivering occurred by the end of 5 minutes in case of Tramadol and 20 minutes in Butorphanol group.

Regarding recurrence, shivering reappeared after 50 minutes in 10% patients of Tramadol group and 50 % in Butorphanol Group. The difference was statistically significant (P<0.05). Thus various studies including ours there was higher rate of recurrence with Butorphanol in comparison to Tramadol. The probable reason for recurrence of shivering could be result of low plasma concentration of the active drug, when hypothermia is still persisting and individual variations in the core temperatures. Till date it is not clear whether higher shivering grades requires higher doses of the drug.

In our study both the drugs gave good and better haemodynamic stability throughout the course of the study in all the patients. No respiratory depression was observed in any of the cases. Only in 20 % of cases from Butorphanol group had nausea and vomiting which was easily treated with H2 receptor blocker and antiemetic drug.

Bhatnagar S. et al (2001) has also reported that Tramadol has more sustained effect than Clonidine.

CONCLUSION

From our study we conclude that Tramadol is effective in treating shivering under regional anaesthesia due to its rapid onset, effective control, less recurrence rate and minimum side effects, when compared to Butorphanol. Similarly Tramadol was effective and safe in comparison to Butorphanol for control of shivering.

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