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A prospective randomised study of nlbuphine versus tramadol in control of intra operative shivering

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Abstract
Background: The incidence of shivering ranges from 40 to 70% in patients undergoing surgery under regional anaesthesia. Shivering is distressing for the patient and may exacerbate post-operative pain, increased intracranial pressure and induce cardiopulmonary complication.
Objective: To compare the efficacy, potency and side effects of tramadol versus nalbuphine in control of shivering after spinal anaesthesia
Methods: 60 patients of American society of anaesthesiologist grade 1 and 2.patient of either sex aged 18 to 60years who are scheduled for lower abdominal and lower limb surgery, under intrathecal block, were included this prospective double blind randomized study. These patients were allocated by closed envelop technique to two groups: Group T (n=30) received tramadol 0.5mg/kg (intravenously) IV, and Group N (n=30) received nalbuphine 0.1mg/kg IV. Heart rate, respiratory rate, non-invasive arterial blood pressure, peripheral oxygen saturation (SpO 2) and body temperature (axillary) were recorded at 5 minutes intervals during the pre-and the post anesthesia period. After intrathecal injection the degree of sensory and motor block was assessed every 5 minutes in the first 20 minutes after intrathecal injection. The time in minutes at which shivering started, severity of shivering, time of disappearance of shivering and response rate were recorded. Recurrence of shivering was also noticed until the patient left the operation theatre. The degree of sedation was also assessed.
Results: No drug showed any statistically significant advantage over other. No major haemodynamic changes were seen in the study groups. Recurrence rate of shivering was same in both groups.
Conclusion: Both tramadol (0.5mg/kg) and nalbuphine 0.1mg/kg had the same effect in the treatment of post spinal anaesthesia shivering. With no statically significant difference between them.

Keywords: incidence, shivering, difference, intra

Introduction

Shivering is known to be a frequent complication, reported in 40to70%of patients undergoing surgery under regional anesthesia. Post-anesthetic shivering is spontaneous involuntary, rhythmic, oscillating, tremor-like muscle hyperactivity that increases metabolic heat production up to 600% after general or regional anesthesia. Post anesthetic shivering may cause discomfort to patients, and aggravate wound pain by stretching incisions and increase intracranial, and intraocular pressure. Various methods are available for control of shivering; these may be non-pharmacological or pharmacological methods using drugs which have anti-shivering properties. Tramadol (0.5 mg/kg) was found to be an effective treatment for shivering after intrathecal block. The intravenous (IV) administration of nalbuphine (0.1mg/kg) provides a rapid and potent anti-shivering effect on post anesthesia shivering.

Nalbuphine: semisynthetic opioid related to both naloxone and oxymorphine and has the characteristic of u receptor antagonist and kappa agonist activity. Nalbuphine has high affinity for k-opioid receptors in the central nervous system. Nalbuphine provide a rapid and potent anti-shivering effect.it is due to rapid onset of action, effective control, less recurrence rate.

Tramadol: is a centrally acting analgesic that has weak opioid agonist properties. tramadol also inhibits serotonin and norepinephrine uptake in the spinal cord and effective in treatment of intraoperative shivering after spinal anaesthesia. This study is conducted to know the efficacy of nalbuphine versus tramadol in control of intraoperative shivering after spinal anaesthesia.

Methods

- **Place of study**: After obtaining ethical committee clearance study was conducted at KVG Medical College & Hospital.
- **Study subjects**: Patients undergoing elective lower limb and lower abdominal surgeries were assessed for the inclusion and exclusion criteria and were included in the study after obtaining written informed consent.
- **Study design:** Prospective randomised control study.
- **Sample size:** 60 (30 each)

Statistical methods

- Descriptive statistical analysis, was carried out in the present study. Results on continuous measurements are presented on mean ± 5D(min- Max) and results on categorical measurements are presented at 5% level of significance. One way ANOVA test has been used to find the significance of study parameter between the two groups of patients. Chi square test has been used to find the significance of study parameters on categories scale

between two groups.
- Significant figures
- Suggestive significance (p value 0.05< p<0.10)
- Moderately significance (p value 0.01< p0.05)
- Strongly significance (p value <0.01)
- Power of study was kept at 80%, levels significance 5% at two tailed test.

Inclusion Criteria
- Patients posted for elective surgeries
- Patients in the age group of 20 to 40 years of age
- American Society of Anesthesiologists physical status I and II
- Patients who develop intraoperative shivering under spinal anaesthesia

Exclusion Criteria
- Patients belonging to the following classes:
- Patients having any absolute contraindications for spinal anesthesia like raised intracranial pressure, severe hypovolemia, injection site infection.
- Patients with spinal deformities.
- Refusal by the patient.
- History of allergy to any of the drugs used in the study.
- History of convulsion / epilepsy
- Patients with history of bleeding disorders or abnormal coagulation profile.
- Patients with neuro-muscular disorder
- Outcome Measure
- Primary Measure
- To evaluate the efficacy of tramadol, and nalbuphine in
- controlling Post anaesthesia shivering after lower limb and lower abdominal surgeries
- Secondary measure
- Time of onset of shivering after spinal Anaesthesia
- Time interval of disappearance of shivering after the drug given iv.
- Side effects

Procedure
- After getting informed written consent from all participating patients, this randomized double blind clinical study was conducted in our institution. Ambient temperature was noted, baseline vital parameters were recorded. iv fluid started with iv access of 18 G cannula. The volume of the local anaesthetic, use of vasopressors, volume of fluid is determined by the attending anaesthesiologist and was not affected by inclusion in the study.
- Baseline preoperative axillary temperature was noted in all the patients. A standard double layered blanket was used to cover the chest and upper limb of the patient. All the preloading fluid and drugs were given at room temperature. Oxygen at rate of 5L / min was administered through facemask.
- Monitoring of NIBP, pulse oximetry, ECG was done throughout the procedure. Central neuraxial blockade was given with Inj. bupivacaine (0.5%) given as per protocol.
- Patients who developed Shivering after neuraxial blockade were included in the study. A total of 60 cases filling the above criteria were selected for study were randomly divided in two groups.

Data Collection
- The drug was administered by another personnel who is blinded to whether the drug contains tramadol or nalbuphine.
- The same person assessed the effect of the drug administration based on the format provided. All the patients were assessed for grade of shivering, onset of shivering, disappearance, and recurrence of shivering, requirement of any additional dosage.
- hemodynamic status and side effects if any Patients were observed at intervals of 1mt till 5 mts and there after 10,20,30,45,60 mts. Baseline pulse rate, BP, SPO2, Respiratory rate and temperature were noted, during shivering and after the drug administration at regular intervals. Recurrence of shivering and requirement of additional dose were also noted.
- Group T - 30 Patients receiving 0.5 mg /kg Tramadol IV
- Group N - 30 Patients receiving 0.1 mg /kg nalbuphine IV
- Shivering was graded as follows as per Wrench which is as follows Grade 0 - No shivering
- Grade 1 - One or more of the following, piloerection peripheral vasoconstriction, peripheral cyanosis or without visible muscle activity.
- Grade 2 - Visible muscle activity confined to one muscle group.
- Grade 3 - Visible muscle activity in more than one muscle group.
- Grade 4 - Gross muscle activity involving the whole body.
- All the patients who developed shivering of grade 3 or 4 of shivering
- were included in the study randomly divided in one of the two groups.

Result

Table 1: Demographic Data

	Groupt	Groupn	P value	Significant
Age(average)	33.3±12.2	32±12.3	0.7	NS
Weight(kg)	73±11.2	72.6±9.6	0.8	NS
Height(cm)	168±7.1	169±7.8	0.7	NS
Male	18(60%)	23(76.7%)		
Female	12(40%)	7(23.3%)		

Table 2: Asa Grading

	tramadol	nalbuphine	Total	Statical Interference
Asa1	24(80%)	23(76.8)	47(78.4%)	P=O.611>O.005, NS
Asa2	6(20%)	7(23.2%)	13(21.6%)	

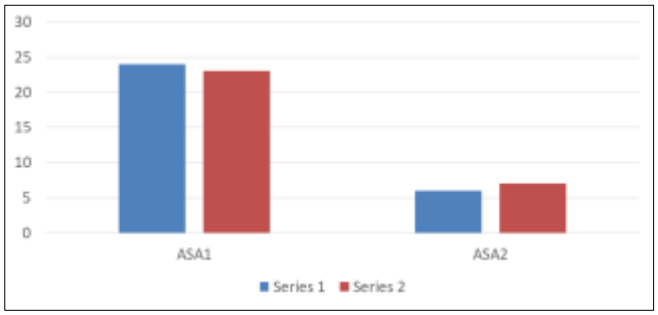

Fig 1

Table 3: Time for onset of Shivering

Study group	Onset time	Mean difference	P value	Significant
Group T (n=30)	20.5 mts	21.53%	0.068>0.05	Not significant
Group N (n=30)	22.6 mts			

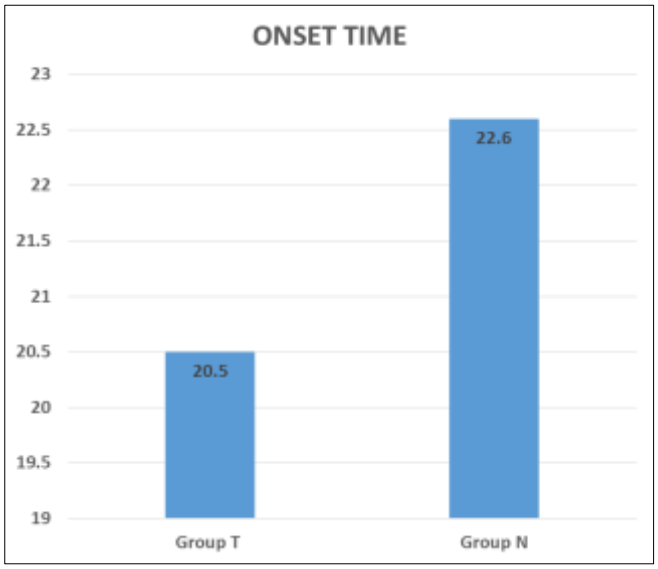

Fig 2

Table 4: Time Interval for Disappearance of Shivering

Study group	Onset time	SD	P value	Significant
Group T	3.864	0.25	0.00< 0.05	Highly significant
Group N	3.780	0.410		

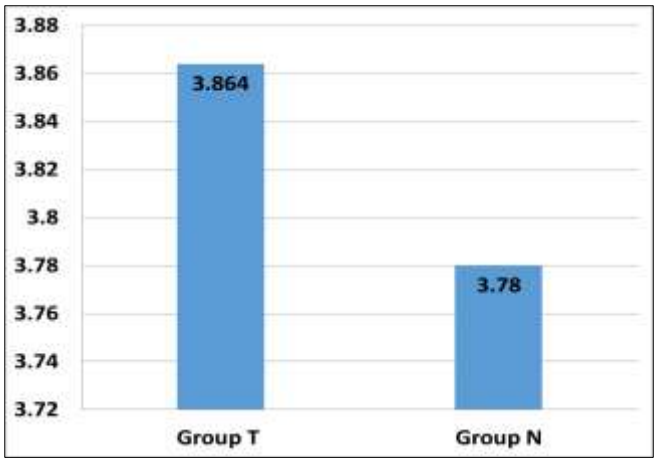

Fig 3

Table 5: Recurrence of shivering

Shivering Recurrence			Groups		
	T (n=30)	N (n=30)	Total n= 60	Statistical Inference	Significance
Nil	26 (92%)	27(90%)	53(91.0%)	X2 = 2.113	Not significant
Yes	4(8%)	3(10%)	7(9.0%)	P = 0.348 >0.05	

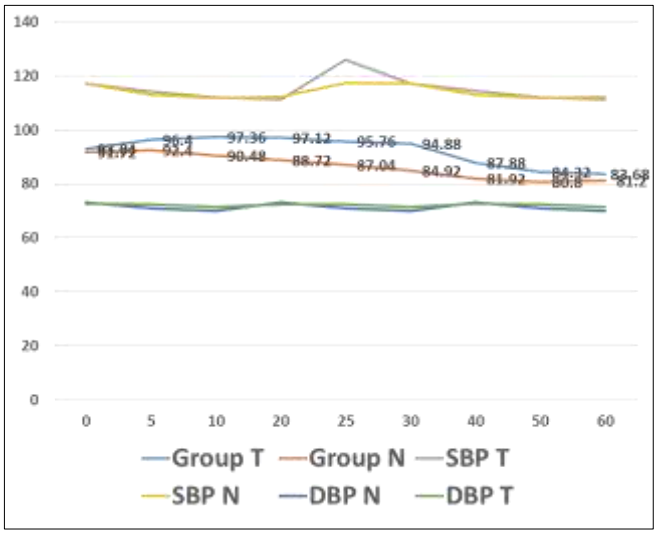

Fig 4: Comparison of Heart Rate and Blood Pressure

Table 6: Comparison of Mean Spo2

mts	Group T (HR)	Group N (HR)	P Value
0	98.5	98.5	0.799>0.05
5	98.4	98.2	0.769>0.05
10	98.4	98.3	0.748>0.05
20	98.3	98.5	0.434>0.05
25	98.2	98.2	0.584>0.05
30	98	98.4	0.302>0.05
40	98	98.4	0.650>0.05
50	98	98	0.321>0.05
60	98.2	98.5	0.570>0.05

Table 7: Side Effects

	Group T	Group N	Total	significsnce
nausea	2(6.6%)	0	2(3.3%)	NS
sedation	21(70%)	30(100%)	51(85%)	
Both	2(6.6%)	0	2(3.3%)	
Nill	5(16%)		5(9.4%)	

Discussion

- There are various methods available to control shivering during anesthesia, which include non-pharmacological methods and pharmacological methods using drugs which have anti shivering properties. In the present study, we compared the efficacy, potency and side effects of tramadol and nalbuphine in control of shivering after intrathecal block**.**
- Statistical analysis of collected data showed no statistical significance among demographic datas, age distribution and ASA grading between two groups. The onset of shivering between groups were with a mean difference of 21.53 ± 2 minutes. It showed no statistical significance between groups.
- The time interval for disappearance of shivering Group

T with a mean time of 3.864 ±0.2 mates and Group N with a mean time of 3.780 ± 0.25 mts. These results analysed by one way ANOVA test,

- were similar by the study of Usher Shukla *et al.* in 2011 [1], where they concluded tramadol good in controlling shivering, with significant side effects of nausea, vomiting and dizziness.
- The recurrence of shivering after 15 mts of response time was noticed. group – T showed recurrence in 4 patients (10%) and group –N showed recurrence in 3 patients (8%) with p value of 0.348>0.05; which was similar to the study conducted by oranuch Kyokong *et al.* in 2007 [2].
- The comparison of heart rate, systolic, diastolic, blood pressure respiratory rate, and mean Spo2 between groups showed no statistical significance which was similar to studies of Kranke P *et al.* in 2004 [5].
- The body temperature was measured from axilla, before giving anaethesia and then when patients developed shivering. The mean body temperature was calculated and statistical analysis between two groups was 35.60, with a p value of 0.368 ($P < 0.05$) not significant. Sessler DI, *et al.* studied the temperature monitoring and thermoregulation under anaesthesia" in 2002. They concluded that core temperature is the best indicator of thermal status of humans.

Conclusion

In conclusion tramadol (0.5mg/kg) and nalbuphine (0.1mg/kg) had the same effect in the treatment of post spinal anesthesia shivering, with no statistically significant difference between them.

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