



Anesthesiology

A COMPARATIVE STUDY OF EFFECT OF CLONIDINE TRAMADOL AND NALBUPHINE ON POSTSPINAL ANAESTHESIA SHIVERING.

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*Corresponding Author**ABSTRACT**

Background and Aim: Post spinal shivering is an unpleasant and physiologically stressful condition for the patient. The study was done to compare the effect of drugs on shivering, its efficacy, potency and side effect.

METHODS: This is a prospective randomized double blind study was carried out at a tertiary health care hospital on patient undergoing caesarean section under spinal anaesthesia, 75 ASA 1 or 2 patients were randomly allocated into 3 groups. group T-25, group C-25, group N-25. The hemodynamic parameter, efficacy and side effect were analyzed using chi-square test and one way anova test.

RESULT: Post spinal shivering is better controlled with clonidine than tramadol and nalbuphine

CONCLUSION: It can be concluded that clonidine iv is better for control of shivering in parturient undergoing caesarean section than tramadol and nalbuphine.

KEYWORDS : Caesarean section, post spinal shivering, parturient, tramadol nalbuphine, clonidine.

INTRODUCTION

Perioperative hypothermia is the primary cause for shivering which occurs due to neuraxial blockade induced inhibition of thermoregulatory centre and peripheral vasodilation. Shivering is a bodily function in response to early hypothermia.

When the core temperature drops the shivering reflex is triggered to maintain haemostasis. Shivering is a serious complication leading to increased metabolic rate, increased oxygen consumption, increased CO₂ production. It may cause arterial hypoxemia, lactic acidosis, increased ocular pressure, increased intracranial pressure, increased surgical bleeding, wound infection and interferes with pulse rate, blood pressure and ECG monitoring. It is detrimental to patients with low cardiorespiratory reserve.

Various pharmacological and non pharmacological methods used to control shivering we undertook a prospective, randomized clinical study to compare the efficacy of low dose tramadol (0.5mg/kg), clonidine (0.5µg/kg) and nalbuphine (0.1 mg/kg) in the treatment of shivering after spinal anaesthesia in caesarean patient.

AIM OF THE STUDY:

This study was done to compare the efficacy, potency, complications of intravenous clonidine, tramadol and nalbuphine in treating post spinal shivering in caesarean section.

Materials and methods:

75 ASA 1 and ASA 2 patients undergoing caesarean section under spinal anaesthesia in a tertiary hospital who satisfy the inclusion criteria were studied.

Inclusion criteria:

Patients of ASA physical status 1 and 2, aged between 20-30 yrs, undergoing elective and emergency caesarean section who subsequently developed shivering were included.

Exclusion criteria

Patients with systemic diseases like cardiovascular, renal, hepatic, respiratory and neurological disorder. Patients with thyroid disease, eclampsia, GHT, GDM and obesity. Patients with known hypersensitivity to tramadol, clonidine and nalbuphine. Patients on long term phenothiazines and MAO 1 inhibitor. Patients who did not give valid consent were excluded.

Written informed consent was obtained from all patients. After connecting routine monitoring including pulse oximetry, NIBP, ECG, ambient temperature was noted.

The volume of local anaesthetic, Injection Bupivacaine 0.5% 2ml was given to all patients as determined. Patients who developed shivering

after neuraxial blockade were included in the study. Shivering was graded as per Wrench,

Grade 0- No shivering

Grade 1- piloerection, peripheral vasoconstriction, without visible muscle activity.

Grade 2- Visible muscle activity confined to one muscle group.

Grade 3- visible muscle activity in more than one group.

Grade 4- Gross muscle activity involving the whole body.

All the patients who developed shivering grade 3 or 4 were included in the study randomly divided in one of the three groups.

Group-T receiving 0.5mg/kg tramadol IV Group-C receiving 0.5µg/kg clonidine IV and Group-N receiving 0.1mg/kg Nalbuphine.

All the patients were assessed for grade of shivering, its disappearance, hemodynamic status and side effects if any. Recurrence of shivering and requirement of additional doses were also noted.

Data thus obtained is analysed using Microsoft excel software. Statistical analysis was done using chi-square test and one way ANOVA wherever applicable.

Statistics and Results:**Table-1 Age Distribution**

Study Group	Mean	SD	P Value	Significant
Group T	25.80	2.739	0.375	Not Significant
Group C	26.24	2.773	>.05	Significant
Group N	26.84	2.322		

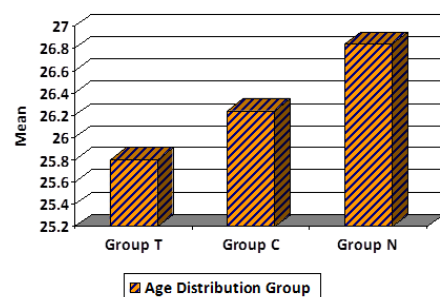
Graph 1 : Age Distribution Group

Table:2 ASA GRADING

	GROUP T	GROUP C	GROUP N	TOTAL	STATISTICAL INFERENCE
I	20 (80%)	17 (68%)	19 (78%)	56 (74.7%)	X ² = 0.98 P= 0.611>0.05 Not Significant
II	5 (20%)	8 (32%)	6 (24%)	19 (15.2%)	

In the study , Group T has 80% ASA I patients and 20 % ASA II patients, Group C has 68% ASA I patients and 32 % ASA –II patients and in group N, it is 78% and 24% for ASA I & II. The statistical analysis is not significant for ASA grading (p=0.611) between groups.

Graph 2 : ASA Grading

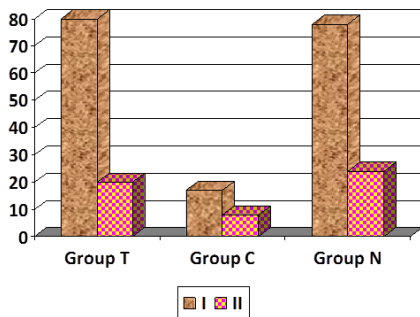


Table 3 Time For Onset Of Shivering (mts)

Study group	Onset time	Mean difference	P value	Significant
Group T	20.5 mts	21.53%	0.068>0.05	NOT SIGNIFICANT
Group C	21.5 mts			
Group N	22.6 mts			

The mean time for onset of shivering in group T was 20.5mts, and in the Group C was 21.5 mts and in group N was 22.6 mts . The statistical analysis showed the time of onset of shivering is not significant(p=0.68) between groups.

Graph 3 : Onset of Shivering

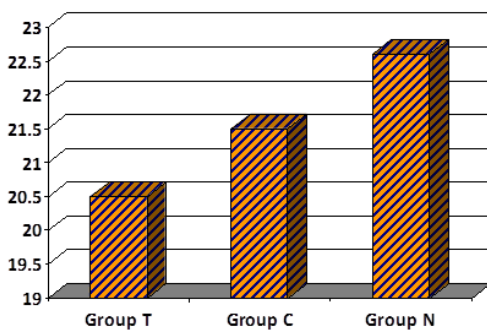
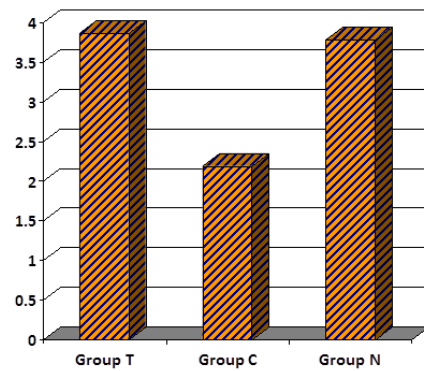


Table 4 : TIME INTERVAL FOR DISAPPEARANCE OF SHIVERING

Group	Mean (mts)	SD	P Value	Significant
Group T	3.864	0.25	0.00<	Highly Significant
Group C	2.184	0.188	0.05	
Group N	3.780	0.410		

In this study the time interval for disappearance of shivering was noted, among groups. In Group T the mean time interval for disappearance was 3.864 +0.25mts, in Group C it is 2.184 + 0.188mts and in Group 'N' the mean time intervals is 3.78+0.410 mts. The 'P' value here is <0.00 <0.05 which is highly significant .Requesting that clonidine group achieved lesser time for complete of shivering when compared to tramadol & nalbuphine group.

Graph 4: TIME INTERVAL FOR DISAPPEARANCE OF SHIVERING



Graph 5 : Trend of mean Spo2

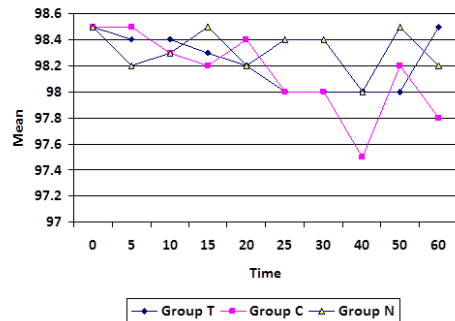


TABLE-5 Comparison of Mean Respiratory Rate

Groups	Mean Respiratory rate	SD	Statistical inference
Group T (n=25)	23.84	0.473	P value =0.06 >0.05 Not significant
Group C (n=25)	20.96	0.200	
Group N (n=25)	21.92	0.277	

In this study, mean respiratory rate was compared, there is no statistical significance between groups

Graph 6 : Comparison of mean Respiratory rate

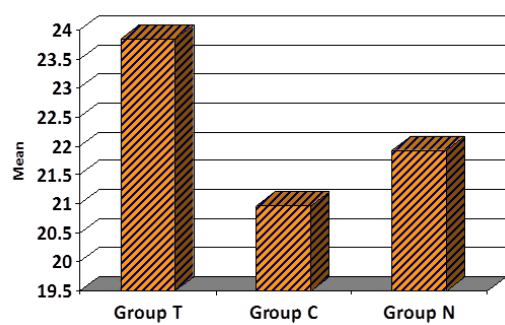
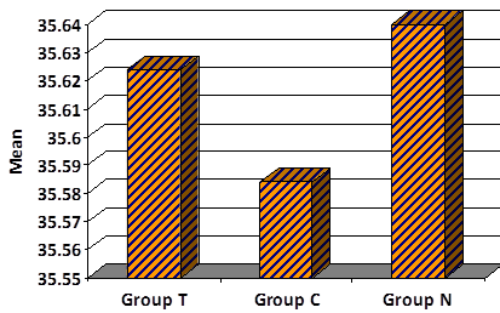


Table 6 : Comparison of mean body Temperature

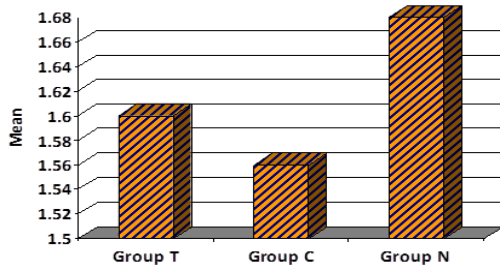
Group	Mean	SD	F	P	Significant
Group T (n=25)	35.6240	0.14514	1.012	0.368 > 0.05	N.S
Group C (n=25)	35.5840	0.14629			
Group N (n=25)	35.6400	0.13844			

The comparison of mean body temperature between group showed a mean value of 35.58 and the p value is not significant between groups.

Graph 7 : Comparison of mean body Temperature



Graph 8 : Comparison of Sedation Score



Graph 9: Comparison of Shivering Score

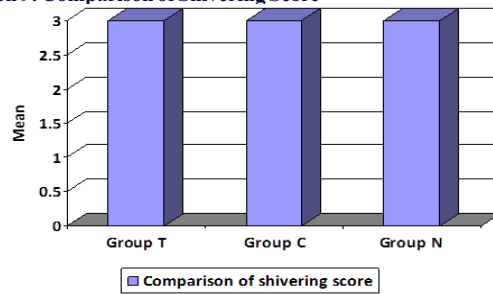


Table 7 : Recurrence of Shivering

Shivering Recurrence	Groups			Total n= 75	Stated istical Inference	Significance
	T (n=25)	C (n=25)	N (n=25)			
Nil	23 (92%)	25(100%)	23 (92%)	71(94.7 %)	$X^2 = 2.113$	Not significant
Yes	2(8%)	0	2(8%)	4 (5.3%)	$P = 0.348 > 0.05$	

In our study there is no recurrence of shivering in group C, in Group T there were two patient with recurrence of shivering and in Group N there were 4 patients with recurrence of shivering. The statistical analysis revealed there is no significance between groups.

Graph 10 : Recurrence of Shivering

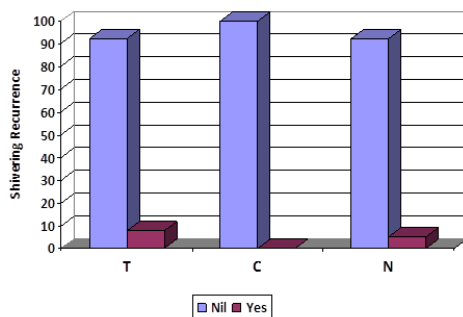
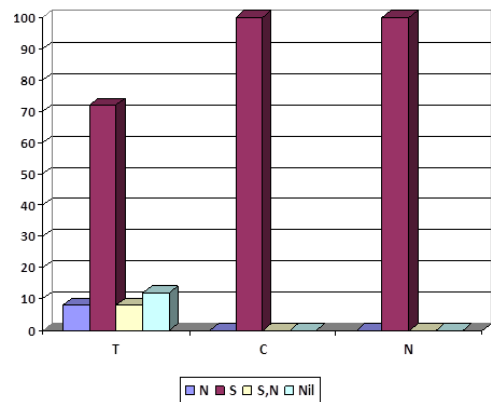


Table 8 : Comparison of Side effects

Comparison	Group			Total (n=75)	Statistical inference	Significance
	T= n=25	C (n=25)	N (n=25)			
N	2 (8%)	0	0	2 (2.7%)	$X^2 = 15.441$ Df =6	
S	18(72%)	25 (100%)	25 (100%)	68(90.7 %)		
S,N	2 (8%)	0	0	2(2.7%)		
Nil	3 (12%)	0	0	3(4%)	$P= 0.17 < 0.05$	N.S

Comparison of side effects between study group showed two patients with nausea and sedations, two patients with nausea alone in Group T. In Group C and N all patients were sedated, statistical analysis showed no significance between groups.

Graph 11 : Comparison of side effects



DISCUSSION :

Hypothalamus is the seat of thermoregulation. The importance of temperature monitoring was unknown till mid 1960, Spinal anaesthesia is emerging as safe and popular technique both in elective and emergency surgeries. Incidence of postspinal shivering is high. Shivering is an unpleasant experience. The exact mechanism of development of postanesthesia shivering is not known. Many pharmacological methods are used to reduce shivering. The anti-shivering effect of tramadol, clonidine and nalbuphine is studied in this study. Tramadol is likely to have better clinical utility causing less sedation, less respiratory depression. It has potential use in the control of shivering. The dose of 0.5mg/kg is selected similar to the study conducted by Usha Shukla et al. Nalbuphine is a semisynthetic opioid analgesic has less ability to depress respiratory function. The dose of 0.1mg/kg is selected for the study similar to study of okyokong et al. Clonidine is a centrally acting selective alpha2 agonist. It exerts anti-shivering at three levels, hypothalamus, spinal cord and locus coeruleus. It is highly lipid soluble and crosses the blood brain barrier and has quick onset. The dose of clonidine is selected as 0.5µg/kg which was similar to the study conducted by Kulshrestha et al.

In our study, statistical analysis of collected data showed no statistical significance among demographic data, age distribution and ASA grading between three groups. The onset of shivering between groups were with a mean difference of 21.53 ±2minutes. It showed no statistical significance between groups.

The time interval for disappearance of shivering were noted and found that group-c with a mean of 2.184±2mts and p value of 0.000 analysed by one way anova test, group T with a mean time of 3.864±0.2mts and group N with a mean time of 3.780±0.25mts. These results were similar to the study of Usha Shukla et al in 2011, where they concluded clonidine was superior in controlling shivering than tramadol with significant side effects of nausea, vomiting and dizziness.

The recurrence of shivering after 15mts of response time was noted. In our study group-C showed no recurrence of shivering whereas group-T and group-N showed recurrence in two patients with p value of 0.348>0.05; which was similar to the study conducted by Oranuch

Kyokong et al in 2007.

The comparison of heart rate, systolic, diastolic blood pressure, respiratory rate and mean Spo₂ between groups showed no statistical significance which was similar to study of Kranche p et al. in 2000. The sedation score as stated by Filos were used for evaluation. There is no statistical significance between the groups. It was similar to the study of Vander stapen et al in 2007.

The comparison of side effects in our study; two patients in group -T with nausea and sedation; two patients with nausea alone and others with sedation noticed. In group-C and group -N all the patients had sedation. No other side effects noticed.

Statistical analysis revealed significant response with 0.5 µg/kg iv clonidine when compared with 0.5 mg/kg of tramadol and 0.1 mg/kg of Nalbuphine. Also Clonidine was found to have better control over hemodynamics especially at 2 mts of post anaesthetic shivering and also better sedation.

CONCLUSION

Three drugs were used in the treatment of post anaesthesia shivering. Among them clonidine took lesser time to achieve complete cessation of shivering and maintained better hemodynamics throughout the study. Tramadol and Nalbuphine were also equally effective in controlling shivering and can be used as a safe alternative drug.

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