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TRAMADOL VERSUS CLONIDINE ON MANAGEMENT OF POST NEURAXIAL SPINAL ANAESTHESIA INDUCED SHIVERING – A RANDOMISED STUDY

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ABSTRACT

The aim of the study is to ascertain the efficacy, potency of clonidine as compared to Tramadol Hydrochloride in managing post spinal anaesthesia induced shivering. In this randomised clinical trial, 80 American Society of Anaesthesiologists Grade – I (ASA – I) patient within the age group of 20 to 50 years where scheduled for various surgical procedures under spinal anaesthesia who subsequently developed shivering were included. The patients were divided into 2 Groups, Group C (n=40), Group C comprised of patients who were given Clonidine 0.50 µg/kg and another group receiving Tramadol 0.60 mg/kg intravenously. We observed Grades of shivering, hemodynamics and side effects at specified intervals. Absence of shivering was significant in Group C (2.54 ± 0.76) than in Group T (5.01 ± 1.02) (p = 0.0000001). On analysis it was found response to treatment in Group C was more (95 %) compared to Group T (90 %). Side effects like nausea vomiting were high in Group T and patients in Group C were more sedated. We infer that the drug Clonidine Hydrochloride has better thermodynamics than Tramadol with less side effects.

INTRODUCTION

Neuraxial Spinal Anaesthesia is now the safest anaesthetic method of choice vis-à-vis general anaesthesia in lower abdomen, pelvic, lower limb, gynaecologic elective surgeries and emergency operations like caesarean sections, etc.

But unfortunately shivering is one of the frequent complic ations of post spinal anaesthesia which is very distressing to the patient and to the anaesthetist. This distress is relieved by giving either Tramadol or Clonidine (which is an alpha 2 agonist)

Shivering is very unpleasant and physiologically stressful for the patient undergoing surgery, not only that some patients find the accompanying cold sensation to be worse than the surgical pain. Though the mechanism of shivering is not still fully clear but various hypothesises are there to explain its occurrence. Perioperative hypothermia is the primary cause which is due to neuraxial anaesthesia induced inhibition of thermos regulatory mechanism.

Shivering occurs as a thermos regulatory response to hypothermia or muscle activity with tonic or clonic patterns and various frequencies had been noticed. [5] However in the post-operative period, muscle activity maybe increased even with normothermia suggesting that other mechanism than heat loss with subsequent decrease in core temperature, is the origin of shivering. There may be uninhibited spinal reflexes, sympathetic over activity, adrenal suppression, pyrogen release. [5]

There are various ways to control shivering post anaesthesia both pharmacological and non-pharmacological. Non pharmacological methods using equipment to maintain normothermia , an effective but expensive and impractical ,whereas pharmocological drugs are more simple and cost effective and easy to administer like pethidine , clonidine , doxapram, etc.

The aim of this study is to clinically compare the efficacy, potency, hemodynamic effects and complications of clonidine with those of Tramadol for abolishing of shivering.

METHODS

After obtaining approval of ethical committee and informed consent 80 ASA Grade – I patients of either sex aged 20 to 50 years posted for elective, gynaecological, orthopaedic and abdominal surgeries, under spinal anaesthesia, with prior pre medication were included in this prospective randomised clinically controlled study. Patients with known hypersensitivity to Clonidine and Tramadol, history of alcohol and drug abuse, hyperthyroidism, cardiac diseases and diabetic and autonomic neuropathies were excluded. All patients developing post spinal shivering were randomly allocated to two Groups. Group C received Clonidine 0.5 µg/kg (n = 40) and Group T (n = 40) received Tramadol 0.60 mg/kg I.V.

Spinal sub arachnoid anaesthesia was administered with injection bupivacaine 0.5% 12 -15 mg at L_{2-4} interspace with 26-gauge needle Quincke's needle. All operation theatres having constant humidity at 70% and ambient temperature around 20 to 23 degree centigrade. No means of active re-warming was used. I.V. fluids and drugs are administered at room temperature. At the commencement of spinal anaesthesia standard monitoring procedures were established, including axillary body temperatures were recorded at the commencement of surgery and thereafter every 5 minutes from the baseline for 1 hour and every 15 minutes for the rest of the observation period.

Grading of shivering was done as per Wrench [6] which is as follows:
Grade 0: No shivering

Grade 1: One or more of the following: Piloerection, peripheral vasoconstriction, peripheral cyanosis with 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.

Patients who developed either Grade 3 or Grade 4 shivering are included. The onset of post spinal shivering is recorded, severity of the shivering, time to disappearance of shivering (In minutes) and response rate (shivering ceased after treatment in 15 minutes). Duration of surgery was noted and duration of spinal anaesthesia was noted. If the shivering did not abolish within 15 minutes, the treatment was considered to be ineffective. Recurrence of shivering was also noted. Patients who did not respond or in whom recurrence of shivering occurred were treated with additional dose of clonidine 0.50 µg / kg and tramadol 0.60 mg/ kg. Side effects like nausea, vomiting and brachycardia (below 50 per minute) hypotension (less than 20% of baseline).

Sedation score was assessed with a 4-point scale as per Filos [7]:
1) Awake and alert

2) Drowsy, responsive to verbal stimuli
3) Drowsy arousal to physical stimuli
4) Unarousable

RESULTS

A total of 80 patients were enrolled with 40 patients in each group. Both the groups were comparable in respect to age, sex, weight, duration of surgery, type of surgery and duration of spinal block. The mean age of the patients in Group C was 30.03 ± 3.80 years and patients in Group T 28.80 ± 3.47 years (Table 1)

Table 1 : Demographic data of patients in the two groups

Parameter	Group	
	C (*n=40*)	T (*n=40*)
Age (years)	30.03 ± 3.80	28.81 ± 3.47
Sex :		
M	29	28
F	11	12
Weight (kg)	72.1 ±10.3	68.90 ± 9.21
Duration of surgery (min)	58.6 ± 7.20	58.91 ± 11.15
IV Fluid	22332.85 ± 256.12	2141.25 ± 211.12
Type of Surgery		
Herniorraphy	25	24
Abdominal hysterectomy	05	04
Vaginal hysterectomy	06	08
K-nailing	02	02
Dynamic hip screw	02	02
Duration of spinal block (min)	128.60 ± 10.30	126.60 ± 9.21

Shivering disappeared in 38 (95 %) patients who received clonidine and 36 (90%) who received tramadol, so both the drugs were found to be effective in reducing shivering.

The mean interval between the injection of drug and the completion of cessation of shivering was 2.54 ± 0.76 and 5.01 ± 1.02 minutes respectively (clonidine and tramadol). Time of onset of shivering and severity were not statistically significant between the two groups, however the drug clonidine weighs over tramadol in overall abolishment of shivering. Bradycardia occurred in two patients in Group C and one patient in Group T. In Group C 3 patients suffered from hypotension and one patient complained of dry mouth both of which absent in Group T (Table 2)

Table 2 : Post- Spinal anaesthesia shivering and responses

Parameter	Group		P value	Significance
	C (*n=40*)	T (*n=40*)		
Onset of shivering (min)	6.8 ± 4.1	6.1 ± 3.8	t=0.79 ,df=78, p= 0.43	NS
Severity of shivering (grade)	3.1 ± 0.7	2.9 ± 1.2	t=1.02 ,df=78, p= 0.309	NS
Time interval from Rx to cessation of shivering (min)	2.54 ± 0.76	5.01 ± 1.02	t=12.28 ,df=78, p= 0.0000001	HS
Response Rate (%)	38 (95)	36 (90)	-	-
Recurrence of shivering (%)	Nil	2(5)	-	-

DISCUSSION

Regional anaesthesia, be it central neuraxial or peripheral nerve block, is very popular technique for surgical anaesthesia. However, 40 to 75 % of patients undergoing central neuraxial anaesthesia develop shivering which though very less but nevertheless not uncommon after general anaesthesia.

The mechanism of shivering is not very clear but probable mechanism could be decrease in core body temperature secondary to sympathetic block, peripheral vasodilation, increased cutaneous blood flow, cold temperature of the operation theatre, rapid infusion of cold intravenous fluids.

There are many non-pharmacological and pharmacological methods used to prevent heat loss and decreased shivering. Non pharmacological methods include radiant heat warmers, warming the operation theatre, blankets, warm I.V. fluids and using anaesthetic drugs at body temperature.[10-11]

In the present study the factors that influence the occurrence of shivering like temperature of I.V. fluids and drugs were not tightly controlled but this should not invalidate our study because the present study is focused on response to treatment rather than the incidence of shivering.

Pharmacological methods to treat shivering include, pethidine, tramadol, doxapram, nefopam, alfentanyl, etc.

A limitation of study is that we could not measure the core temperature of the body.

In the present study we compared the efficacy of clonidine versus tramadol after spinal anaesthesia. Clonidine is a centrally active selective α2 agonist exerting its anti-shivering effects at three levels: Hypothalamus, locus ceruleus and spinal cord. At the hypothalamus, it decreases thermos regulatory threshold for vasoconstriction and shivering [12,13]. It also reduces firing at locus ceruleus, a pro shivering centre in pons [14]. At the spinal cord it activates the α2 adrinoceptors and release dysnorphin, norepinephrine & acetylcholine [14]. The depressor effects of these neuro transmitters at the dorsal horn modulate cutaneous thermal inputs [15]. Clonidine is highly lipid soluble and easy crosses blood brain barrier [16] Due to this merits, interaction at the 2 adrenoceptors at spinal and supraspinal sites occurs within the central nervous system. [17]

Tramadol is opiod analgesic with opiod action mediated via μ (mu) receptor with minimal effect on kappa and delta binding sites. Tramadol also activates the nonadrenergic receptors of the descending neuraxial inhibiting pain pathwave. The antishivering action of Tramadol is probably mediated via its opoid or serotonergic and non-adrenergic activity or both. [18-20]

In the present study we found that clonidine is as effective as Tramadol but the time interval from the commencement of treatment to cessation of shivering is quite less with clonidine than with Tramadol.

The complications were found to be higher in case of tramadol compared to clonidine, like nausea vomiting and dizziness. In case of Group C , 10 patients (25%) had sedation Grade 2 while in Group T it was 5 patients (12.5 %) No patient in either group had sedation of Grade 3 or 4, 1 patient of Group C had dry mouth which was not present in Group T. 2 Patients of Group T had recurrence of shivering in post-operative period while no patient in Group C that is clonidine Group suffered recurrence of shivering , these findings were similar to the findings of other researchers who compared shivering with other drugs having anti shivering properties [21-23]. Bradycardia occurred in 2 patients of Group C while it was 1 in Group T. Hypotension occurred in 3 patients of Group C, on overall analysis higher complications were noted in Group T patients compared to Group C patients.

It was found in the present study that clonidine was quicker than Tramadol in providing relief to shivering. Zavaherf oroush et al [21] compare clonidine with pethidine and phe ntanyl for treating post spinal anaesthesia shivering in elective caesarean section and found it to be better

thermodynamically than pethidine. The present study also found that patients of clonidine group were more sedated. This is similar to the findings of other researchers [22].

CONCLUSION

Both Tramadol and clonidine effectively treated patients with post anaesthesia shivering but tramadol took longer time to achieve compared to clonidine. Difference being statistically significant, so we conclude that clonidine offers better thermodynamics than tramadol with lesser side effects.

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