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Randomised Double Blind Study of Dexmedetomidine Versus Tramadol for Post Spinal Anaesthesia Shivering

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Abstract

Shivering is one of the most common complications of a central neuraxial blockade. Shivering is defined as involuntary, spontaneous, oscillatory mechanical activity of skeletal muscle associated with increased oxygen consumption. Shivering can be thermo regulatory or non thermo regulatory. Its mere presence per operatively is very unpleasant and even physiologically stressful. It is managed per operative either by non pharmacological means such as warm blankets, drapes, warm intravenous fluids or by pharmacological means using various drugs like intravenous opioids, HT3 antagonists, Dexmedetomidine (α-2 agonist). Our study was planned to study the efficacy of Dexmedetomidine with that of Tramadol for control of shivering after spinal anesthesia given in patients for various surgical indications. 60 Patients of age group 15-70 years of ASA grade I & II were divided in two groups Group D (to receive Inj. Dexmedetomidine 0.5 µg/kg intravenously slowly) and Group T (to receive Inj. Tramadol 1 mg/kg intravenously slowly) intra operatively who developed shivering of the Grade 3 and 4. We found that Dexmedetomidine in the dose of 0.5 µg/kg intravenously controls shivering faster than Tramadol 1 mg/kg, reduces patient discomfort experience time, and also induces sedation without any nausea and vomiting. Hence Dexmedetomidine seems to be a better alternative to Tramadol for per operative and post operative shivering during central neuraxial blockade.

Keywords: Dexmedetomidine; Tramadol; Shivering Grade.

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Introduction

A Safe and widely used subdural anesthesia (spinal anesthesia) has a incidence of per operative and post operative shivering in almost 40-70% of patients. Shivering is one of the most common complications of a central neuraxial blockade. Shivering is defined as involuntary, spontaneous, oscillatory mechanical activity of skeletal muscle associated with increased oxygen consumption. Shivering can be thermo regulatory or non thermo regulatory. Its mere presence per operatively is

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very unpleasant and even physiologically stressful. Complications or side effects of shivering may be increased oxygen requirement along with increased CO_2 production leading to adverse cardiac event, increased chances of infection and increased surgical bleeding. In Central neuraxial blockade (spinal anesthesia), thermoregulatory control may be hampered secondary to autonomic blockade [2]. Intra operative shivering is managed both by non pharmacological and pharmacological means. Non pharmacological aids like increasing ambient temperature of OR, covering the patient with warm blanket or surgical drapes, warm intravenous fluids.

Many drugs have been tried to reduce this not properly explained per operative shivering after central neuraxial blockade. These include opioids like alfentanyl, pethidine, tramadol, 5HT3 antagonists [3]. Dexmedetomidine a α-2 agonist also has been tried exploring its sedative properties. In our study efficacy of Dexmedetomidine and Tramadol were compared in terms of efficacy to reduce or curb the shivering in patients subjected to various surgeries under spinal anesthesia. The drugs were compared in aspect of onset, degree of control and any recurrence along with any systemic side effects.

Methodology

After approval from the hospital ethical committee, this present was planned to include 60 patients of age 18-70 years and ASA gr I and II, posted for various surgeries under spinal anesthesia randomly distributed to receive either:

Group D: Inj. Dexmedetomidine 0.5 µg/kg intravenously diluted to 10 ml in normal saline

Group T: Inj. Tramadol 1 mg/kg intravenously diluted to 10 ml in normal saline.

Patients with psychological disorders, allergy to study medications, already given any adjuvant in spinal anesthesia were excluded from this study.

Securing an appropriate size of intravenous cannula, preloading patient with 500 ml of Inj. Ringer Lactate, and premedicating patients with Inj. Ondansetron 0.08 mg/kg intravenously. Preoperative vital parameters of patients were noted. Spinal anesthesia was given using 23G Quincke needle, inj. Bupivacaine 0.5% in sitting position under proper anti septic precautions. Sensory and motor level of anesthesia was noted. Ambient temperature of OR was maintained to around 21^0- 23^0C and all the intravenous fluids and drugs were administered at room temperature. Patients were included in study only if shivering occurred. Once shivering occurred, the patients were randomly selected to receive either drug (Group D and Group T). If at all the shivering occurred the grade of shivering was decided as per "Tsai and Chu Grading":

0 – No shivering

1 – Pilo erection or peripheral vasoconstriction with no visible shivering.

2 – Visible muscular activity in only one muscle group.

3 – Visible muscular activity in more than one muscle group, but not generalized

4 – Shivering involving the whole body.

Patients with grade 3 & 4 of shivering were subjected to treatment with either of the drug. Patients were observed and time noted from the time of giving of study drug to the disappearance of shivering. Other parameters noted were reappearance of shivering, adverse events if any, hemodynamic monitoring (the time of administration of study drug was considered to be zero and hemodynamic monitoring was done every five minutes there after). If shivering did not subside in 10 minutes, the study drug was considered not effective for this study and further rescue dose of either drug was given. Continuous variables, hemodynamic parameters, respiratory rate, adverse events were noted and compared in between two groups using chi-square test. $p < 0.05$ was considered to be statistically significant.

Results

The present study of 60 patients who developed per operative shivering after spinal anesthesia were treated with either of the drug in our study.

Group D: Inj. Dexmedetomidine 0.5 µg/kg intravenously diluted to 10 ml in normal saline

Group T: Inj. Tramadol 1 mg/kg intravenously diluted to 10 ml in normal saline.

Demographically there was no any statistical difference between the groups in regards to age, sex, and ASA grading (Table 1).

The dose of bupivacaine given intrathecally was as per body weight and the sensory block achieved was up to T6 in majority of the patient except for one patient in which escalated to T4 level. But overall the statistical difference was not significant between both the groups (Table 2).

If shivering occurred post spinal in any of the patient the variable and degree of shivering was noted in both the groups and only patients with shivering grade 3 & 4 were included as case study. Table 3 and Graph 1 shows the number of patients who had shivering of 3 or 4 grade, with values near about similar (p>0.05). When subjected to treatment with either dexmedetomidine or tramadol, it was observed that shivering subsided in 29/30 patients receiving Inj. Dexmedetomidine while it subsided in 26/30 patients receiving Inj. Tramadol. (p=0.001) these results are shown in table 4 and graph 2.

Table 5 shows the time duration for the shivering to subside after giving the study drug. It was 139 ± 76.02 seconds in Group D as compared to 329 ± 162.87 seconds in Group T. This difference was highly significant statistically. More over there was reappearance of shivering in both the group but the incidence was low in Group D (1 patient) as compared to Group T (3 patients).

Hemodynamic changes of pulse rate and Blood pressure in both the groups were compared from the time of giving drug onwards every five minutes. There was a slight fall in the pulse rate and blood pressure with Inj. Dexmedetomidine which was not seen with Inj. Tramadol. Though the fall was significant it didn't deviate >20% from the base line.

Graph 5 and Graph 6 display the adverse events in Group T and Group D respectively. Incidence of nausea after Tramadol injection was bit high as compared to dexmedetomidine. Bradycardia and hypotension occurred in around 3-8 patients receiving dexmedetomidine but it was not that alarming.

Table 1: Demographic Variables

Parameters	Group D (n=30)	Group T (n=30)	p value
Mean Age (years)	39.47 ± 16.027	39.73 ± 14.300	0.946
Sex Ratio (M:F)	20:10	22:8	0.317
ASA grading (I/II)	14:16	14:16	1

Values are Mean ± SD or numbers

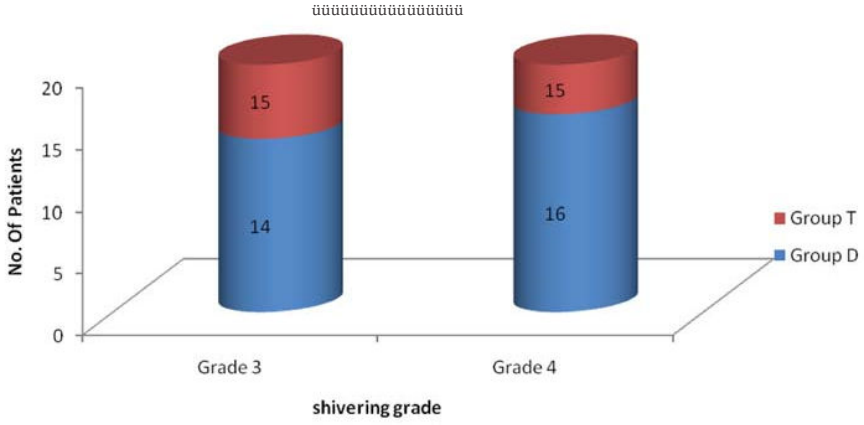
Table 2: Sensory Block Level

Parameter		Group D (n=30)	Group T (n=30)	p value
Volume of Inj. Bupivacaine 0.5% intrathecally		3.47 ± 0.305	3.473 ± 0.330	0.968
Sensory Block	T4	1	0	0.313
	T6	1	9	0.781
	T8	6	8	0.541
	T10	9	9	1
	T12	4	4	1

Values are Mean ± SD or numbers

Table 3: Comparison of the Grade of Shivering

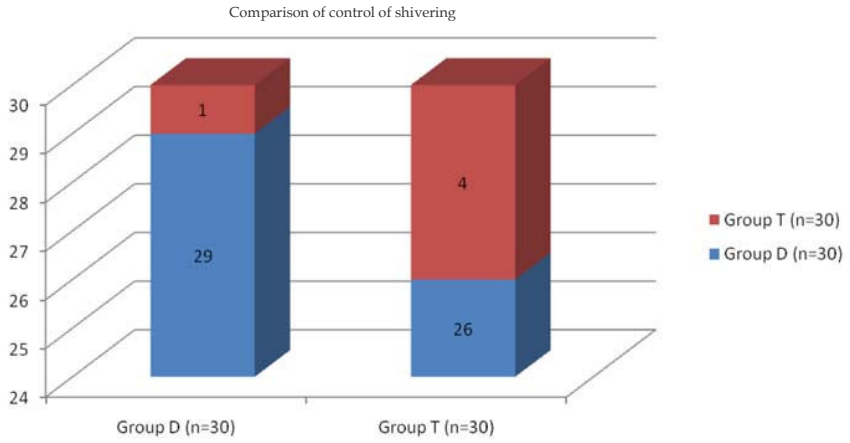
Shivering Grade	Group D (n=30)	Group T (n=30)	p value
3	14	15	0.796
4	16	15	0.796



Graph 1:

Table 4: Showing Comparison of Control of Shivering

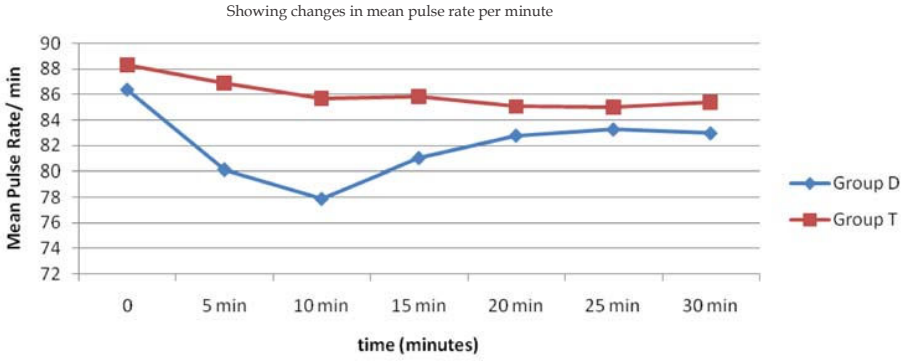
Control of Shivering	Group D (n=30)	Group T (n=30)
Yes	29 (96.67%)	26 (86.67%
No	1 (3.33%)	4 (13.33%)



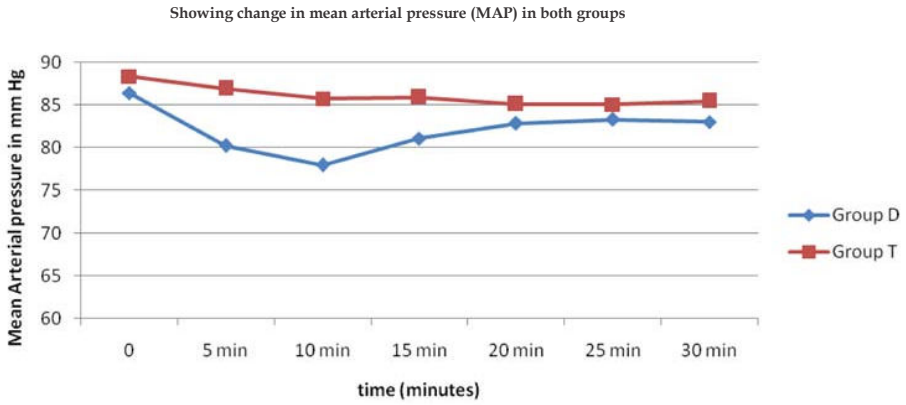
Graph 2:

Table 5: Time Required for Complete Loss of Shivering

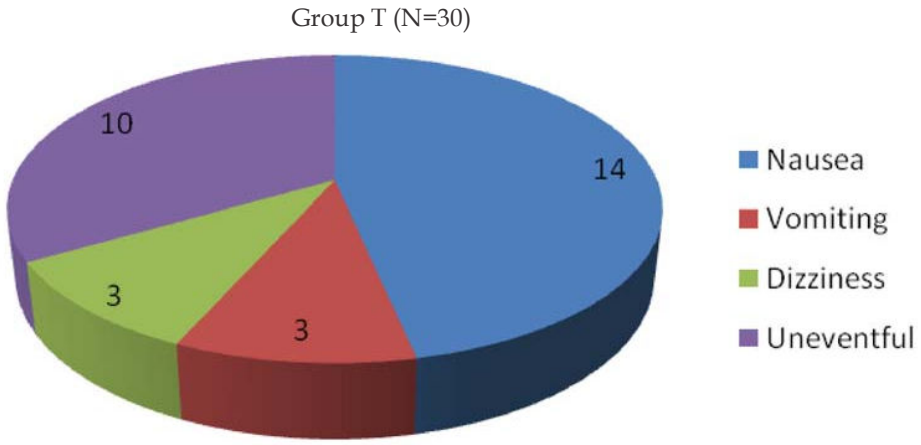
Time of Complete loss of shivering	Group D	Group T	p value
In seconds	139.17 ± 76.02	329.73 ± 162.87	0.0001



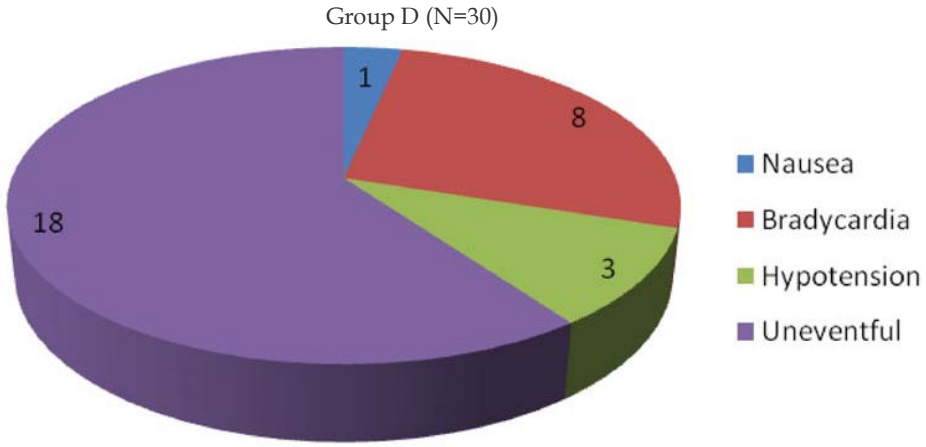
Graph 3:



Graph 4:



Graph 5: Adverse Events in Group T



Graph 6: Adverse events in Group D

Discussion

A large number of studies have been done to assess the role of prophylactic pharmacological intervention for post spinal anesthesia shivering. In spite of high incidence (40-60%) of shivering we chose to do pharmacological interventions only after shivering develops post spinal anesthesia. We included only those patients in our study that developed grade – 3 or 4 shivering. There was a widespread muscular contraction which may increase metabolic requirement and affect core body temperature significantly. Keeping all the non pharmacological variables like ambient or temperature, use of warm blankets, warm iv fluids to a standard level we aimed at only treatment of the shivering if it occurred. S. Mathew et al compared prophylactic 1 mg/kg of Inj. Tramadol with placebo for per operative shivering and concluded that Tramadol considerably reduces the incidence of shivering. Horn EP et al. (1998) studied Dexmedetomidine 0.5 µg/kg for post operative shivering and concluded that dexmedetomidine if given before emergence of anesthesia considerably reduces the incidence of post operative shivering.

In our study we found that there was a significant statistical significance in response rate for treating shivering between dexmedetomidine and tramadol (Table 4). Moreover the incidence of reappearance of shivering was also quite less with dexmedetomidine (3.45%) as compared to tramadol (11.54%). The effectiveness of dexmedetomidine in treating shivering was also faster as compared to tramadol (Table 5).

In similar studies with Tramadol 0.5 mg/kg the response rate of disappearing of shivering was 92.5% (Shukla et al.) [5], 87% (Tsai and Chu) [6] and with a dose of 1 mg/kg we had 100% response

in treating the shivering. Similarly we had 100% response with dexmedetomidine in a dose of 0.5 µg/kg [1] (similar results were also observed by Easley in pediatric patient) along with sedation which was an additional benefit.

Hemodynamically the changes in pulse rate and Mean arterial blood pressure (Graph 3 & 4) were studied only after administration of the study drug (trying not to consider the hemodynamic changes secondary to spinal anesthesia). Shivering leads to tachycardia and we found a drop in heart rate after administration of drug in both the group. No significant change in the Blood pressure (SBP, DBP and MAP) was seen after administration of study drug and results were comparable.

The incidence of side effects of both the drugs as shown in Graph 5 and Graph 6 were also not much which are similar to other studies done by Shukla U [5] et al., Kulshrestha S et al. [4] (2013)

Only limitation to our study was that we could not measure core body temperature as putting a esophageal probe in awake patients was bit cumbersome and we didn't try the rectal probe.

We observed the study cases only for 120 minutes after the administration of the study drugs. It was also found that shivering re appeared after 3-4 hours more commonly in surgeries that lasted long and this can probably be because of the excess heat loss in such cases.

Conclusion

Dexmedetomidine in a dose of 0.5 µg/kg intravenously controls shivering faster that Tramadol 1 mg/kg thereby reducing patient discomfort time. The success rate with dexmedetomidine is also more with less chance of recurrence as compared to Tramadol. Slight sedation with dexmedetomidine proves beneficial. Hence can be concluded that dexmedetomidine is faster, more effective with lesser side effects when compared to Tramadol in control of per operative shivering after giving of spinal anesthesia.

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