Original Research

Comparative Evaluation Of prophylactic Use Of I/V Tramadol, I/V Dexmedetomidine For Prevention Of Shivering After Spinal Anaesthesia

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Abstract
Aim: To compare prophylactic use of I/V Tramadol, I/V Dexmedetomidine for prevention of shivering after Spinal Anaesthesia.
Material and Methods: The present placebo controlled prospective randomised comparative study was conducted in the Department of Anaesthesiology and Intensive Care over a period of twelve months after approval of the research review board. 90 patients of either gender belonging to ASA grade I and ASA II undergoing elective lower limb or lower abdominal surgery under spinal anaesthesia, after considering the inclusion and exclusion criteria were included. In the intra-operative and post-operative period Haemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure, arterial oxygen saturation, perioperative nausea, vomiting and itching was assessed. Grading of shivering and sedation was also assessed.
Results: MAP was statistically significantly low in Group C when compared to Group T and Group D after 5 mins of Spinal anaesthesia till 120 min ($p<0.01$).The incidence of shivering in Group T was 36.67%, Group D was 10% and Group C was 53.33%. Hence shivering was found to be maximum in group C while minimum in group D. Sedation score was found to be maximum in group D followed by group T and C.
Conclusion: We conclude that Dexmedetomidine is effective and comparably superior than tramadol in preventing shivering after spinal anaesthesia. Dexmedetomidine has quicker onset and also provides sedation without respiratory depression. Though with its use a fall in blood pressure and heart rate is foreseen.
Keywords: Spinal Anaesthesia, Shivering, Tramadol, Dexmedetomidine

Introduction:

Shivering may be defined as an involuntary, repetitive activity in the skeletal muscle. Shivering usually occurs as a thermoregulatory response to cold, although non-thermoregulatory shivering may also occur. The core temperature in humans varies with the circadian rhythm (and with the menstrual cycle in females), but is normally maintained within the narrow range of 36.5–37.0 °C. [Larry JC &Donal JB (2008)] Shivering is physiologic response to perioperative hypothermia. Shivering is a relative common problem encountered after neuraxial (spinal and epidural) anaesthesia. An incidence of shivering of up to 55% has been reported. [Larry JC &Donal JB (2008)]Apart from discomfort, postanaesthetic shivering may be associated with increased oxygen consumption, end tidal carbon dioxide elimination and minute ventilation, [Ciofolo MJ et al., (1989)] catecholamine release, increased cardiac output, tachycardia and hypertension, and increased intraocular pressure. [Mahajan RP et al., (1987)] Shivering may also decrease mixed venous oxygen saturation [Guffin A et al., (1987)] and may also interfere with hemodynamic monitoring. [Buggy DJ &Crossley AW (2000); de Courcy JG (1989)] Shivering is uncomfortable for the patients and has been reported worse than the surgical pain. [De Witte J &Sessler DI (2002)] Shivering may aggravate postoperative pain by stretching the surgical incision. The increase in metabolic requirement may predispose to difficulties in patients with existing intrapulmonary shunts, patients with fixed cardiac output states, or those with limited respiratory reserves. Both, the prevention and treatment

of shivering should be attempted in the perioperative period. Anaesthesiologists may therefore plan to prevent shivering by using pharmacological strategies in selected surgical patients. [Kranke P et al., (2004)] Therefore, shivering should ideally be prevented or treated by pharmacological or other means. Various methods are now available to control shivering during anaesthesia. These include nonpharmacological methods such as the use of radiant heat, covering the patient with blankets to prevent heat loss and warming the operating theatre to increase the ambient temperature and use of warm IV fluids. [Weinstein R et al., (2002)]Non-pharmacological method using equipment to maintain normothermia are effective but may be expensive and are not practical in all settings. Pharmacological methods include administration of drugs such as opioids (pethidine or tramadol), ketanserin, propofol, granisetron, doxapram, physostigmine, clonidine, and nefopam, but the debate on an "ideal antishivering drug" still continues. [Zhang Y & Wong KC (1999)]The problem gets further compounded because of restrictions on drug licensing for opioids like pethidine. [Batmanabane G (2014)] Pharmacological methods using drugs are cost-effective, simple, and easy to implement. [Shukla U et al., (2011)] Pharmacological agents such as ketamine and tramadol have been in use since long as agents for prevention and treatment of postanaesthetic shivering, however, dexmedetomidine's role in prevention of shivering has not been studied much. It has been used primarily as an analgesic and sedating agent. Ketamine causes sympathetic stimulation and vasoconstriction in patients at risk of hypothermia. Ketamine may control shivering by nonshivering thermogenesis either by its effects on the hypothalamus, or by the α-adrenergic effect of norepinephrine. Consequences of shivering are discomfort, increased post-operative pain, increased oxygen demand, increased cardiac output, tachycardia, hypertension, increased intraocular pressure, catecholamine release. We can overcome these problems by comparing drugs and find better one for prophylaxis of shivering. This type of research has not been conducted inour institute, so present study was taken up to find a better prophylactic drug after spinal anesthesia for prevention of shivering. The objectives of the study are as follows:

To compare the efficacy of IV tramadol and IVdexmedetomidine in prevention of shivering after spinal anaesthesia.

To compare adverse reactions of IV tramadol and IVdexmedetomidine when used for prophylaxis of shivering, if any. Material And Methods: This study was a placebo controlled prospective randomised comparative studyand was conducted in the Department of Anaesthesiology and Intensive Care for a period of 1 year. An informed written consent was taken from patients of either gender belonging to ASA grade I and ASA II undergoing elective lower limb or lower abdominal surgery under spinal anaesthesia. In theintra-operative and post-operative period Haemodynamic parameters like heartrate, systolic blood pressure, diastolic blood pressure, mean arterial pressure,arterial oxygen saturation, perioperative nausea and vomiting were assessed.Shivering was assessed and graded by a five-pointscaleas per Wrench et al ,where:

0. No shivering.

1. One or more of : Piloerection: Peripheral cyanosis without other cause, but without visible muscular activity .
2. Visible Muscular activity confined to one muscle group.
3. Visible Muscular activity in more than one muscle group.
4. Gross muscular activity involving the whole body.

Level of sedation was assessed by Modified Ramsay Sedation Scalewhere

1. The patient is anxious or agitated or both
2. The patient is cooperative, oriented, and tranquil
3. The patient responds to commands only
4. A brisk response to a light glabellar tap
5. A sluggish response to a light glabellar tap
6. No response

Perioperative nausea and vomiting was assessed using four-point ordinal scalewhere

0.No nausea/vomiting
1.Nausea
2.Retching
3.Vomiting.

Inclusive Criteria:

Patient with status ASA I and ASA II.

Age 21-60 years.

Patients who were going for elective lower limb and lower abdominal surgeries.

Exclusive Criteria:

- Refusal of patient to give informed consent
- Pre-existing coagulation disorder
- Morbid obesity
- Local infection
- Diabetes mellitus
- Pregnant female
- Patient with thyroid or neuromuscular disease
- Patient with history of febrile illness
- Patient who require blood transfusion during surgery

Patients fulfilling the inclusion criteria were randomly assigned into 3 groups of 30 patients each:

1. GROUP T-Patients receiving tramadol 1mg/kg diluted in 10ml of NS given as IV infusion over 10 min (5 min prior to subarachnoid block.
2. GROUP D-Patients receiving dexmedetomidine 0.5mcg/kg diluted in 10ml

of NS given as IV infusion over 10 min.
3. GROUP C- Patients receiving 10ml of normal saline (NS) given as IV infusion over 10min.

PRE ANAESTHETIC PREPARATION: Pre-anaesthetic check-up was done one day prior to surgery and it includeda detailed history, general physical as well as systemic examination and airway assessment of all patients. All the routine investigations and any other specific investigations deemed necessary for the patient was undertaken. Basic demographic profile like age, sex, weight, height, BMI was noted. All the patients were kept fasting eight hours prior to surgery and received a dose of Tab Alprazolam 0.25mg & Tab Pantoprazole 40mg orally night prior to surgery.

Anaes the tic Technique: On the morning of surgery in the preoperative room intravenous access with an 18 G or 20 G cannula was secured. The operating room temperature was kept at22°C ± 2°C. Preloading was done with RL (Ringer lactate) at appropriatetemperature @10ml/kg body weight. IV fluids were administered at roomtemperature. Anaesthetic equipment and emergency drugs were kept ready at hand.In the operating room, standard monitoring was done including level ofconsciousness, electrocardiogram, SPO_2, respiratory rate and non-invasive bloodpressure. Then the study drugs (Group T- Tramadol 1mg/kg diluted in 10ml of NSgiven as IV infusion over 10 min, Group C- Patients receiving 10ml of NS given asIV infusion over 10 min., Group D- dexmedetomidine 0.5mcg/kg diluted in10ml of NS given as IV infusion over 10 min) was injected 5 min prior togiving spinal anaesthesia. With all aseptic precautions, subarachnoid block wasperformed in L3-4 space in sitting position, with 27 G disposable Quincke's spinalneedle with 0.5% hyperbaric bupivacaine. The level of spinal block was determined by pinprick at the midaxillary line after 2 min interval following spinalanaesthesia till desired level was achieved. When a block of desired level wasachieved, patients were prepared for operation.IV metoclopramide 10 mg was given as rescue drug for nausea, vomiting. Theincidence of itching was noted in all the groups. Statistical analysis: Datacollected and was tabulated in an excel sheet, under the guidance of statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc, Chicago, USA). Difference between two groups was determined using t test as well as chi square test and the level of significance was set at $p < 0.05$. Results: Male: Female ratio of subjects in Group T was 20:10, in Group D was 19:11 and in Group C was 15:15. Mean age of subjects in Group T was 36.77±12.87, in Group D was 36.63±13.76 and in Group C was 34.27±12.85. Ratio of subjects of ASA I and ASA II in Group T was 13/17, in Group D 15/15 and in Group C 13/17. Mean weight of subjects in Group T was 60.97±12.23, in Group D was 59.47±9.39 and in Group C was 61.83±5.78. There was no significant difference among the groups when the demographic variables were compared between the groups. Mean duration of surgery in Group T was 55.67±9.46 min, Group D was 53.44±7.43 min and Group C was 57.17±8.05 min. There was a statistically significant difference between Group T and Group D ($p<0.01$) in all values of mean pulse rate except at baseline. There was a statistically significant difference between Group D and Group C ($p<0.01$) in all values of mean pulse rate. There was statistically significant difference between Group T and Group C from baseline to 10 mins and then sometimes in between. (Table 1)

Table 1: Comparison ofpulse rate at different intervals among the study groups

Pulse (BPM)	Group T		Group D		Group C		p value$^{\beta}$		
	Mean	SD	Mean	SD	Mean	SD	T vs D	T vs C	D vs C
Baseline	87.70	13.31	86.2	11.18	77.87	4.18	0.41	<0.01*	0.002*
After 5 Min	81.80	9.32	68.03	3.02	76.33	4.54	<0.01*	0.018*	<0.01*
After 10 Min	82.23	9.11	67.70	3.22	75.30	4.71	<0.01*	0.013*	0.007*
After 15 Min	79.67	8.46	58.80	2.75	76.73	5.09	<0.01*	0.07	<0.01*
After 20 Min	77.43	8.86	58	2.38	77.43	5.23	<0.01*	0.04*	<0.01*
After 25 Min	76.60	8.37	58.33	2.23	77.23	5.79	<0.01*	0.58	<0.01*
After 30 Min	76.97	9.49	58.90	2.23	76.50	5.57	<0.01*	0.67*	<0.01*
After 40 Min	74.90	8.98	57.67	2.36	76.07	4.20	<0.01*	0.09	<0.01*
After 50 Min	73.33	10.52	58.40	2.58	77.07	5.02	<0.01*	0.13	<0.01*
After 60 Min	74.04	7.71	58.73	2.07	76.57	5.27	<0.01*	0.46	<0.01*
After 70 Min	76.68	7.62	59.79	2.36	77.16	4.18	<0.01*	0.02*	<0.01*
After 80 Min	78.50	8.60	59.13	1.81	77.50	4.33	<0.01*	0.69	<0.01*
After 90 Min	74.35	8.64	59.35	2.49	79.67	4.19	<0.01*	0.026*	<0.01*
After 120 Min	79.80	9.95	58.31	1.93	79.27	4.03	<0.01*	0.64	<0.01*

*: statistically significant, β: t test

Mean arterial pressure (MAP) was recorded. MAP was statistically significantly low in Group D when compared to Group T after 10 mins of Spinal anaesthesia till 30 mins and was comparable thereafter but was also significantly low after 120 min (post-operative period) (p<0.01). MAP was statistically significantly low in Group C when compared to Group T and Group D after 5 mins of Spinal anaesthesia (p<0.01). (Table 2)

Table 2: Comparison ofMAP at different intervals among the study groups

MAP (mmhg)	Group T		Group D		Group C		p valueβ		
	Mean	SD	Mean	SD	Mean	SD	T vs D	T vs C	D vs C
Baseline	94.90	5.05	94.47	5.65	92.57	5.34	0.54	0.08	0.11
After 5 Min	95.33	5.25	94.17	6.29	90.40	4.22	0.17	0.007*	0.004*
After 10 Min	95.93	5.56	93.27	6.09	90.06	5.07	0.024*	0.016*	0.043*
After 15 Min	94	5.01	92.57	5.82	90.60	5.70	0.04*	0.008*	0.032*
After 20 Min	94.87	5.27	94.40	5.56	91.33	6.11	0.51	0.036*	0.027*
After 25 Min	94.70	5.64	92.50	6.77	88.70	4.32	0.044*	0.014*	<0.01*
After 30 Min	94.23	4.65	89.93	5.89	90.13	4.22	0.02*	0.70	0.005*
After 40 Min	94.73	4.41	93.77	5.44	87.70	5.49	0.34	0.009*	<0.01*
After 50 Min	94.07	5.77	94.57	7.17	88.48	4.54	0.19	0.005*	<0.01*
After 60 Min	94.15	4.56	93.77	4.22	88.46	3.86	0.38	<0.01*	<0.01*
After 70 Min	94.56	5.78	94.13	4.10	88.83	4.19	0.37	<0.01*	<0.01*
After 80 Min	95.38	3.89	93.18	6.43	88.50	5.76	0.09	0.012*	<0.01*
After 90 Min	95.80	5.02	93.55	3.91	89.75	2.86	0.08	0.021*	<0.01*
After 120 Min	94.60	5.23	91.08	5.25	89.64	2.94	0.023*	<0.01*	<0.01*

*: statistically significant, β: t test

There was statistically significant differenceamong the three groups, when overall shivering grades were compared. The incidence of shivering in Group T was 36.67%, Group D was 10% andGroup C was 53.33%. Hence shivering was found to be maximum in group C while minimum in group D (Table 3).

Table 3: Comparison ofshivering score among the study groups

Grade	Group T		Group D		Group C		p valueβ
	N	%	N	%	N	%	
0	19	63.33	27	90	14	46.67	0.007*
1	5	16.67	2	6.67	8	26.67	
2	3	10	1	3.3	5	16.67	
3	2	6.67	0	0	2	6.67	
4	1	3.3	0	0	1	3.33	

β: Chi square test,*: statistically significant

There was statistically significant differenceamong the three groups, when overall sedation scores were compared. Sedation score was found to be maximum in group D followed by group T and C (Table 4).

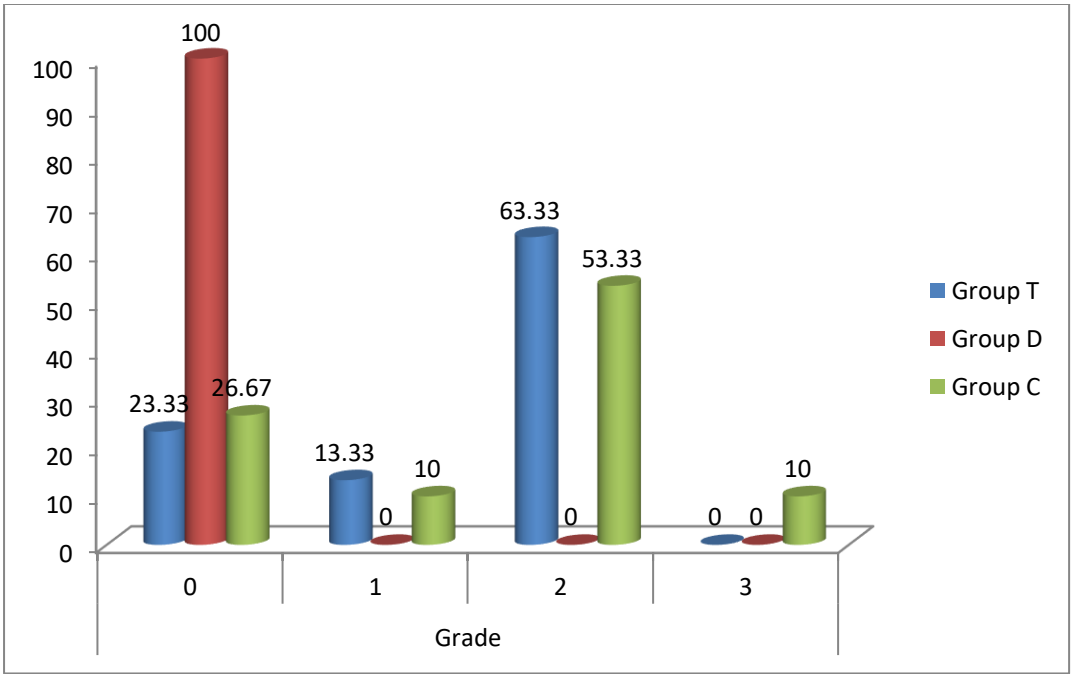
Table 4: Comparison ofsedation score among the study groups

Grade	Group T		Group D		Group C		p valueβ
	N	%	N	%	N	%	
0	0	0	0	0	0	0	0.004*
1	6	20	3	10	9	30	
2	22	73.33	14	46.67	20	66.67	
3	2	6.67	8	26.67	1	3.33	
4	0	0	5	16.67	0	0	

β: Chi square test, *: statistically significant

The incidence of nausea, vomiting was significantly higher in Group T, with 19 patients having Grade 2, requiring treatment. In Group D no such side effects were noted. In Group C incidence of nausea, vomiting was significantly higher with 16 patients having Grade 2. There was statistically significant difference in incidence of

nausea/vomiting when Group D was compared with Group T and Group C ($p<0.01$). There was no significant difference in Group T and Group C. (graph 1)



Graph 1: Comparison of side effects among the study groups

Discussion:

In present study, in Group T pulse rate decreased from baseline to 60 mins (74.04±7.71) and then from 70 mins to 120 mins (79.80±9.95) pulse rate increased. In Group D pulse rate (PR) decreased significantly from baseline, and was minimum after 20 mins (58±2.38) and then it started increasing and decreasing till 120 min. slightly (58.31±1.93). There was no severe bradycardia (PR < 50 bpm) or severe tachycardia (PR >100 bpm) in any of the patients. There was a statistically significant difference between Group T and Group D ($p<0.01$) in all values of mean pulse rate except at baseline. There was a statistically significant difference between Group D and Group C ($p<0.01$) in all values of mean pulse rate. There was statistically significant difference between Group T and Group C from baseline to 10 mins and then sometimes in between but it was almost comparable in both groups, it suggests that after giving tramadol to patients there was not much difference in heart rate as it was almost similar to control group. The PR was found to be significantly lower in Group D at 15 -120 min, but none of the patients had bradycardia (HR< 50 bpm). According to findings of Arora N (2014) heart rates (HR) were statistically significantly lower in Group D at 15 min, 30 min and 45 min following spinal anaesthesia. However, there was no evidence of severe bradycardia (HR 100 bpm) in any of their patients. Mean HR in Group T and Group D at baseline was 78±3.4 and 78.6±2.7 respectively. And mean HR in Group T and Group D at 120 min was 70.2±1.5 and 70.1±3.1 respectively. In present study, MAP was statistically significantly low in Group D when compared to Group T after 10 mins of Spinal anaesthesia till 30 mins and comparable thereafter but was also significantly low after 120 min (post-operative period) ($p<0.01$). MAP was statistically significantly low in Group C when compared to Group T and Group D after 5 mins of Spinal anaesthesia ($p<0.01$). This was because in Group C only normal saline was given (placebo group). There was no evidence of clinically significant hypotension (MAP <30% of pre-operative value) in any of the patients. In study done by Arora N (2014) the MAP was significantly lower in Group D than Group T till 60 min after spinal, but comparable thereafter. There was no evidence of clinically significant hypotension in any of the patients. MAP at baseline in Group T and Group D was 94.2±9 and 96.1±8.6 respectively. And MAP at 120 min (postoperatively) in Group T and Group D was 92.2±6.1 and 90.2±7.1 respectively. In this study, there was statistically significant difference among the three groups, when overall shivering grades were compared. The incidence of shivering in Group T was 36.67%, Group D was 10% and Group C was 53.33%. Hence shivering was found to be maximum in group C while minimum in group D.NiharAmeta et al (2018) in their study revealed similar findings too. According to Arora N (2014)overall incidence of shivering was 9/60 (15%),

mostly belonging to Grade 1. Only one patient in Group D had Grade 2 shivering 60 min following spinal anaesthesia but subsided with the use of blanket. The maximum incidence of shivering was 6.6% in Group T and 10% in Group D, with no significant difference between the two groups at any point in time. Tudimilla et al, (2021) noted that shivering was in 25 patients (83.3%) had effective control in Group T whereas 23 patients (76.67%) had effectivecontrol in Group N; three patients (10%) and two patients (6.67%) had a partial control in both Groups T and N. Dexmedetomidine in a dose of 1 μg/kg was used for prevention of post-operative shivering by Karaman S et al., (2013) as intraoperative infusion in patients undergoing general anaesthesia. The incidence of shivering was 10% in the dexmedetomidine group as compared to 46.6% in the placebo group. The incidence of bradycardia requiring atropine was more (6.6%) in the dexmedetomidine group. Bajwa SJ et al., (2012) found that dexmedetomidine in a dose of 1 μg/kg decreased the incidence of shivering (5%) as compared to placebo group (42.5%) in patients undergoing laparoscopic surgery under general anaesthesia. Dryness of the oral mucosa was the main side effect observed in 35% of patients. Bozgeyik S et al., (2014) compared the ability of preventing shivering of preemptive tramadol in a dose of 100 mg and dexmedetomidine in a dose of 0.5 μg/kg during spinal anaesthesia. The dose of tramadol was not titrated as per weight. The shivering scores at 20 min were significantly lower in both tramadol and dexmedetomidine when compared to placebo. No comparison was done between the tramadol and dexmedetomidine group. There was no significant difference between the placebo, tramadol and dexmedetomidine group at 30 min and post-operatively. In our study, the incidence of shivering was not found to be significantly different between the tramadol and dexmedetomidine groups. In the present study, there was statistically significant difference among the three groups, when overall sedation scores were compared. Sedation score was found to be maximum in group D followed by group T and C.NiharAmeta et al (2018) in their study revealed similar findings too. According to Arora N (2014) intraoperative sedation scores were significantly higher in Group D at 30 min. Whereas the sedation scores were significantly higher in Group T at 45 min. And thereafter till the post-operative period. Bozgeyik S et al., (2014) found their patients had higher sedation score at 5, 10, 15, 20, 30 min in the dexmedetomidine group.

Limitations: The limitations of our study include a relatively smaller size sample. Though dexmedetomidine was effective in the treatment of shivering, side effects were reported with it which was treatable. A larger study is needed to report an ideal drug for prevention and control of shivering. Secondly, the incidence of shivering would have been less if we have used external warming devices for all patients**.**

Conclusion: Tramadol and dexmedetomidine both worksimilarly to prevent postspinal shivering. No adverse hemodynamic events were observed in patients receiving dexmedetomidine, despite the hemodynamic profile remaining more stable in those receiving tramadol. Most individuals receiving dexmedetomidine had lower sedative scores and shorter sedation times than those receiving tramadol. Patients taking tramadol experienced more unpleasant symptoms, such as nausea/vomiting and itching. So, it was concluded from present study that due to its quicker onset and superior sedation, dexmedetomidine is superior to tramadol in the treatment of shivering. There were more side effects in tramadol and placebo group, suggesting dexmedetomidine is better than tramadol in term of side effects. So, for the prevention of postspinal shivering in short-term situations, dexmedetomidine may replace tramadol because it has a better sedative profile and fewer side effects.

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