

## A Clinical Comparative Study Between Intra Venous Dexmedetomidine And Tramadol For Control Of Post Spinal Anesthesia Shivering

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**Abstract:** Shivering is a common problem in patients undergoing surgery under spinal anesthesia. Dexmedetomidine and Tramadol have been used to reduce the shivering threshold. The aim of the study was to compare the efficacy of dexmedetomidine and tramadol in the treatment of post-spinal anesthesia shivering as well as to compare their side effect profile.

**Materials and Methods:** A total of 60 American Society of Anaesthesiologist physical status class I and II adult patients (aged 18-65 years) undergoing lower limb surgery under spinal anesthesia and developed shivering received either dexmedetomidine 0.5µg/kg or tramadol 0.5mg/kg intravenously. The response rate, time to cessation of shivering, percentage of recurrence of shivering, sedation score and side effects (if any) was noted. Data was entered in M.S Excel software and analysed using R statistical software. For categorical data two tailed Fishers exact test was used to calculate the significance value (p value) with 95% confidence interval and p value less than 0.05 was considered statistically significant. For comparing means of two groups, students t test was used to calculate the significance value (p value) with 95% confidence interval and p value less than 0.05 was considered statistically significant.

**Results:** All the patients had grade III shivering. The time for onset of shivering in group D was 73.26±38.32 minutes and group T was 73.76±40.35 minutes (P value 0.96). The time interval between the drug administration after onset of shivering and cessation of shivering was significantly shorter in group D when compared to group T (172.189±16.32 seconds vs 279.16±24.32 seconds) P < 0.0001. Two patients (6.6%) in group D had recurrence of shivering where as in group T recurrence of shivering occurred in 5 patients (16.5%) and were treated with rescue doses of dexmedetomidine and tramadol respectively. The nausea (28%) and vomiting (8%) was observed only in tramadol group and there was no such incidence observed in group D (P value 0.001). Patients in group D were more sedated (28% in grade 2 score and 72% in grade 3 score) whereas group T 80% of patients had a sedation score 2 (P < 0.001).

**Conclusion:** Both dexmedetomidine (0.5µg/kg) and tramadol (0.5mg/kg) are effective in treating patients with post spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with dexmedetomidine as compared to tramadol. Furthermore, dexmedetomidine causes fewer adverse effects like nausea and vomiting. Sedation caused by dexmedetomidine provides additional comfort to the patients.

**Key words:** post spinal anesthesia, shivering, tramadol, dexmedetomidine.

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### I. Introduction

Shivering, a common post anaesthesia occurrence is defined as involuntary, repetitive activity of skeletal muscles. The incidence of shivering has been found to be quite high, approximately 40-50% in different studies (1, 3). Shivering is physiological response to core hypothermia in an attempt to raise the metabolic heat production. The main cause of intra/post-operative shivering are temperature loss, increase sympathetic tone, pain, and systemic release of pyrogens. Spinal anaesthesia significantly impairs the thermoregulation system by inhibiting tonic vasoconstriction, which plays a significant role in temperature regulation. It also causes a redistribution of core heat from trunk (below the block level) to the peripheral tissues. These factors predispose patients to hypothermia and shivering (2).

Anaesthetic induced inhibition of thermoregulation resulting in hypothermia is an important cause of postanaesthesia shivering. Pain, uncontrolled spinal reflexes, cutaneous vasodilation are the other suggested mechanisms involved in pathogenesis of shivering (4).

Opioid receptors,  $\alpha_2$  receptors, and serotonergic receptors are involved in the pathogenesis of shivering (5). Different pharmacological agents studied for their potential in prevention of peri-or post-operative shivering include clonidine, tramadol, dexmedetomidine, ondansetron, granisetron, ketamine, and pethidine (10).

Tramadol is  $\mu$  receptor agonist and also inhibits the reuptake of norepinephrine and 5-hydroxytryptamine (5-HT) and also improves the release of 5-HT. This pharmacological mechanism of tramadol is postulated to be useful for control of thermoregulation (6). However, it has adverse effects like nausea, vomiting, dizziness etc. which causes further discomfort to the patients (7).

Dexmedetomidine, a congener of clonidine, is a highly selective  $\alpha_2$ -adrenoceptor agonist. It has been used as a sedative agent and is known to reduce the shivering threshold (8). Few studies which have explored its anti-shivering potential have inferred that dexmedetomidine is an effective drug without any major adverse effect and provides good haemodynamic stability (9).

## II. Materials And Methods

The study was conducted at Guntur Medical College which is attached to Government General Hospital, Guntur. After taking approval from the Institutional ethical committee. All subjects gave written informed consent to participate in the study during the period of October 2018 to March 2019.

In this prospective, double blind, randomized controlled trial, American Society of Anaesthesiologist physical status Class I and II consecutive patients of either sex, aged between 18 years to 65 years scheduled for elective lower limb surgeries under spinal anaesthesia and developed intra operative shivering post spinal anaesthesia lasting for minimum period of 2 min were included in this study.

### Exclusion criteria:

Patients with known hypersensitivity to dexmedetomidine and tramadol, known history of alcohol or substance abuse, hyperthyroidism, cardiovascular disease, psychological disorders, severe diabetes or autonomic neuropathies, ASA grade III or IV, patients refusal, infection at the site of injection were excluded from the study.

Detailed preanaesthetic checkup of all patients was done 24 hours prior to surgery. All patients were kept nil by mouth for >8 hours before surgery.

All patients who fulfilled the inclusion criteria and developed postspinal anaesthesia shivering were enrolled and randomized into either of the two groups

**GROUP D (n=30)** were administered dexmedetomidine 0.5  $\mu$ g/kg IV

**GROUP T (n=30)** were administered 0.5 mg/kg IV at the onset of shivering.

After arrival in the operation theater, standard monitors were attached and base line vital parameter of heart rate, electrocardiogram, pulse oximetry, and non invasive arterial blood pressure, and body temperature (axillary) were recorded. An intravenous line was secured and patients were preloaded with Ringer's lactate @20ml/kg, 15 mins before initiation of spinal anaesthesia. Under all aseptic and antiseptic conditions, subarachnoid block anaesthesia was administered with 0.5% heavy bupivacaine (12.5mg) with 25 Gauge Quinke's needle, using mid line approach at L<sub>2-3</sub> or L<sub>3-4</sub> intervertebral space. All operations theaters were maintained at an ambient temperature of around 24°C. supplemental oxygen was administered to all the patients at the rate of 5L/Min with face mask and patients were covered with drapes but not actively warmed. IV fluids and anaesthetics were administered at room temperature. Vital parameters such as HR, NIBP, SPO<sub>2</sub> were recorded at intervals of every 5 minutes for the first 30 minutes and every 15 minutes for the rest of the observation period, continuous ECG monitoring was done. Shivering was graded using a four point scale as per **Wrench** (11).

### WRENCH SHIVERING GRADE:

**Grade 0:** No shivering

**Grade 1:** One or more of the following: Piloerection, peripheral vasoconstriction, peripheral cyanosis but without visible muscle activity.

**Grade 2:** Visible muscle activity confined to one muscle group

**Grade 3:** Visible muscle activity in more than 1 muscle group

**Grade 4:** Gross muscle activity involving the whole body.

Patient who developed either Grade III and IV shivering were included in the study. Either of the two drugs was given as slow IV bolus injection. The drugs were diluted to a volume of 10ml in 10ml syringe. The attending anaesthesiologist recorded the time in minutes at which shivering started after spinal anaesthesia (onset of shivering), severity of shivering, time to disappearance of shivering and response rate (shivering ceasing within 15 min after treatment). Duration of surgery was recorded and duration of spinal anaesthesia was noted by

assessing the spontaneous return of sensory block using pin prick method and observing spontaneous movements of limbs in the postoperative period. Recurrence of shivering was also noted. In case there is recurrence of shivering, patients was treated with an additional dose of dexmedetomidine (0.5µg/kg) and tramadol (0.5mg/kg) in the respective groups. Adverse effects such as nausea, vomiting, bradycardia (<50/minutes), hypotension (>20% of baseline), dizziness and sedation score was noted. The degree of sedation was graded on four point scale as per Filos et al (12).

**FILOS SEADATION SCORE:**

**Grade I:** awake and alert

**Grade II:** Drowsy, responsive to verbal stimuli

**Grade III:** Drowsy, arousable to physical stimuli

**Grade IV:** unarousable.

Bradycardia, hypotension and vomiting were treated with atropine 0.6mg, mephentermine 3mg and ondansetron 4mg respectively, in titrated doses when required.

Data was entered in M.S Excel software and analysed using R statistical software. For categorical data two tailed Fishers exact test was used to calculate the significance value (p value) with 95% confidence interval and p value less than 0.05 was considered statistically significant. For comparing means of two groups, students t test was used to calculate the significance value (p value) with 95% confidence interval and p value less than 0.05 was considered statistically significant.

**III. Results And Observation**

A total of 60 patients ( male n=28 and female n = 32) enrolled in the present study were randomized into two groups of 30 each. Both groups were comparable with respect to age, gender, ASA grade, duration of surgery and duration of spinal anaesthesia. There was no significant difference in any of these parameters between two groups for all.

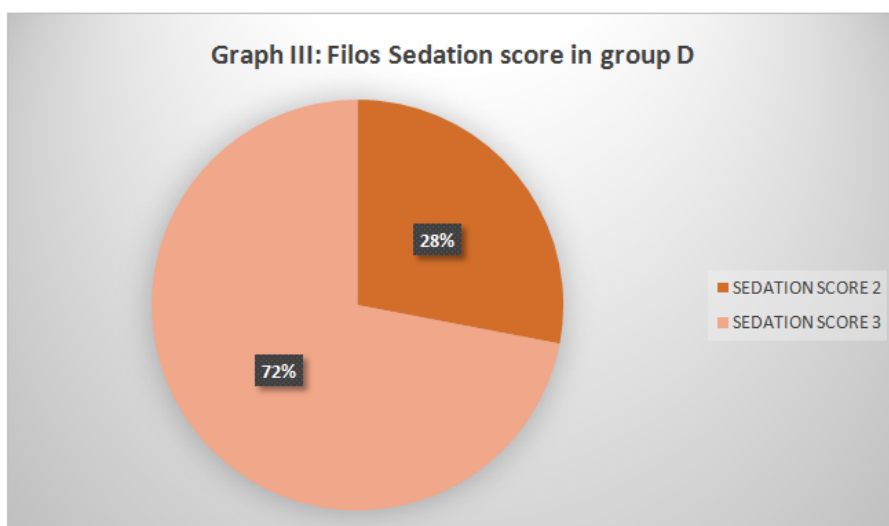
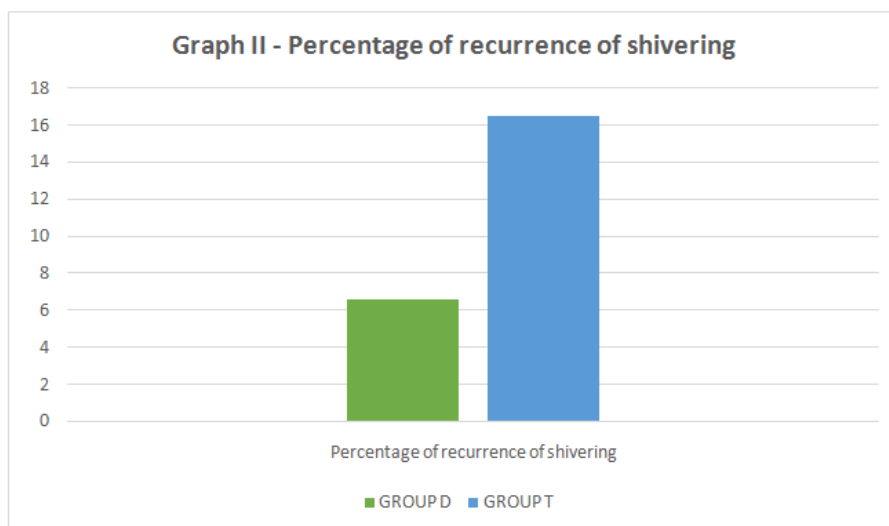
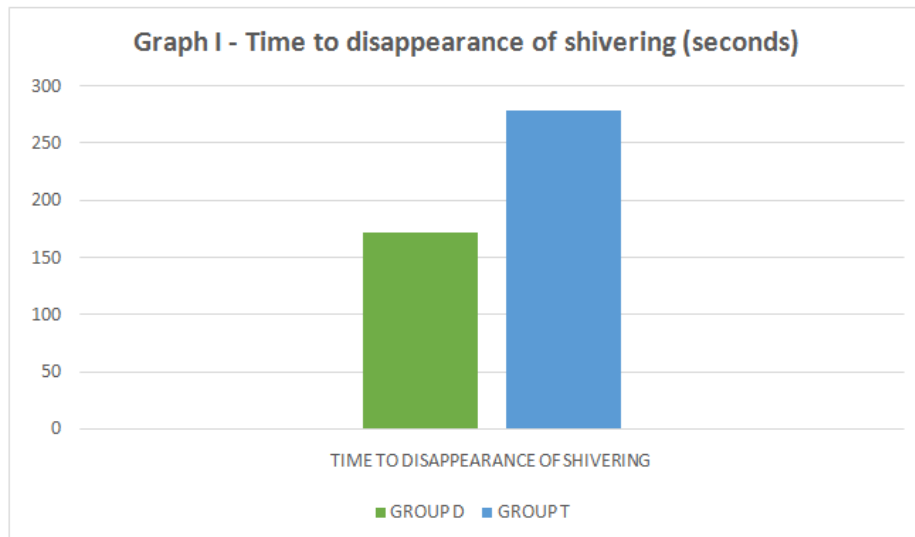
**Table 1: Demographic profile**

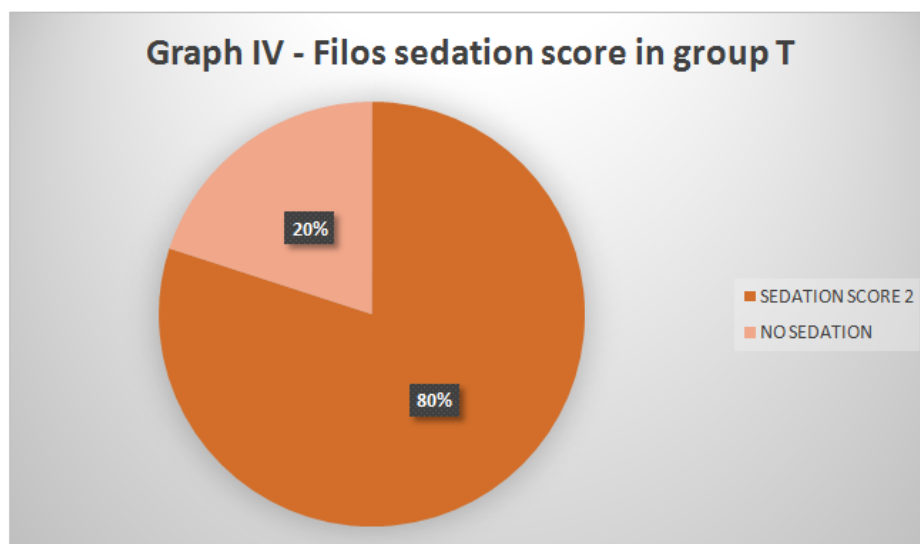
| Parameters                               |          | Group D (n=30) | Group T (n=30) | P value |
|--|----------|----------------|----------------|---------|
| Age (years)                              |          | 48.75±13.25    | 47.42±12.18    | 0.68    |
| Sex                                      | Male     | 13             | 15             | 0.79    |
|  | Female   | 17             | 15             |         |
| Weight (kg)                              |          | 75.74±10.2     | 74.92±9.42     | 0.74    |
| ASA grade                                | Grade I  | 20             | 20             | 1.0     |
|  | Grade II | 10             | 10             |         |
| Duration of surgery(minutes)             |          | 80.12±30       | 82.16±30       | 0.79    |
| Duration of spinal anaesthesia (minutes) |          | 125.9±25.6     | 130.30±24.0    | 0.49    |

**Table 2: Comparison of the time of onset of shivering, severity of shivering, time to disappearance of shivering, and time of recurrence in the two study groups**

| Parameters                                   | Group D (n=30)             | Group T (n=30)                | P value |
|--|----------------------------|-------------------------------|---------|
| Time of onset of shivering (min)             | 73.26±38.32                | 73.76±40.35                   | 0.96    |
| Severity of shivering                        | 3.94±0.18                  | 3.95±0.18                     | 0.83    |
| Time to disappearance of shivering (seconds) | 172.189±16.32              | 279.16±24.32                  | <0.0001 |
| Time of recurrence (minutes)                 | 69.12±18.42                | 74.65±18.16                   | 0.24    |
| Percentage of recurrence of shivering        | 6.6% (2patients)           | 16.5% (5 patients)            | <0.001  |
| Percentage of Nausea and vomiting            | 0 (nausea)<br>0 (vomiting) | 28% (nausea)<br>8% (vomiting) | <0.001  |
| Sedation score                               | 28% - 2<br>72% - 3         | 80% - 2                       | <0.001  |

All the patients had grade III shivering. The time for onset of shivering in group D was 73.26±38.32 minutes and group T was 73.76±40.35 minutes (P value 0.96) which was statistically not significant. The time interval between the drug administration after onset of shivering and cessation of shivering was significantly shorter in group D when compared to group T (172.189±16.32 seconds vs 279.16±24.32 seconds) P < 0.0001 which was statistically highly significant (Table 2, Graph I). Two patients (6.6%) in group D had recurrence of shivering where as in group T recurrence of shivering occurred in 5 patients (16.5%) and were treated with rescue doses of dexmedetomidine and tramadol respectively. The nausea (28%) and vomiting (8%) was observed only in tramadol group and there was no such incidence observed in group D (P value 0.001). Patients in group D were more sedated (28% in grade 2 score and 72% in grade 3 score) whereas group T 80% of patients had a sedation score 2 (P < 0.001) which was statistically significant.





#### IV. Discussion

Shivering is a frequent concern of in patients undergoing surgery. Post spinal anaesthesia shivering is unpleasant and discomforting problem in many patients (14). The mechanism which leads to shivering after regional anaesthesia is not very clear, but the probable mechanism could be decrease in core body temperature secondary to sympathetic block; peripheral vasodilatation; increase in cutaneous blood flow, which leads to increase heat loss through skin; cold temperature of the operation theatre; rapid infusion of cold IV fluids; and effects of cold anaesthetic drugs upon the thermosensitive receptors in the spinal cord (13)

We studied the efficacy of dexmedetomidine in the treatment of post spinal anaesthesia shivering in adults and compared its efficacy with tramadol for the treatment of shivering after spinal anaesthesia in patients undergoing lower limb surgeries.

Tramadol is an opioid analgesic with opioid effect mainly mediated via mu receptor with minimal effect on kappa and delta receptors. It also activates the monoaminergic receptors of the descending spinal inhibitory pain pathway. The antishivering action of tramadol is probably mediated via its opioid or serotonergic and noradrenergic activity or both.

Dexmedetomidine is an  $\alpha_2$  adrenoceptor agonist, with antihypertensive, sedation, analgesic, and anti shivering properties. The anti shivering effects of alpha adrenoceptor agonists are mediated by binding to  $\alpha_2$  receptors that mediate vasoconstriction and the anti-shivering effects. It also has hypothalamic thermoregulatory effects. Dexmedetomidine comparably reduces the vasoconstriction and shivering threshold, thus suggesting that it acts on the central thermoregulatory system rather than preventing shivering peripherally (15).

In a study by Easley et al (16) all children who had post anaesthesia shivering were treated with a single IV bolus dose of dexmedetomidine 0.5  $\mu\text{g}/\text{kg}$  over 3-5 minutes. All children had cessation of shivering behavior within 5 minutes following the completion of dexmedetomidine administration. There was no recurrence of shivering and no adverse effects occurred. In our study the cessation of shivering occurred in group D was  $172.189 \pm 16.32$  seconds ( $2.9 \pm 0.3$  minutes) ( table II, graph I ) which was similar to Easley et al studies. The time taken for cessation of shivering in group T was  $279.16 \pm 24.32$  seconds ( $4.66 \pm 0.4$  minutes) (graph I, table II) P value  $< 0.001$  which was statistically highly significant. The incidence of nausea and vomiting with tramadol in our study was 28% (nausea) 8% (vomiting), whereas in group D neither nausea nor vomiting was observed P  $< 0.001$  which was highly significant ( table II ). These results are in accordance with that of other studies by Reddy and Chiruvella, Tsai and Chu; Bansal and Jain. 6.6% patients in group D had recurrence of shivering. About 16.5% patients in group T had recurrence of shivering ( P  $< 0.001$  ) ( table II, graph II ). This incidence was similar to available literature (17). The sedation score observed in group D was 28% - score 2 , 72% - score 3 ( graph III ). In group T the sedation score was 2 in 80% of patients ( graph IV). However the level of sedation in these patients never went above grade 4 and were able to maintain their airway and spo<sub>2</sub> on room air. This sedation was found to be beneficial in the post spinal anaesthesia patients who were more comfortable in recovery room with some amount of sedation from which they could be easily awoken. The results of this study indicate that dexmedetomidine takes lesser time to control shivering. The incidence of adverse effects like nausea and vomiting was found to be higher in case of tramadol compared to dexmedetomidine.

## V. Conclusion

Both dexmedetomidine (0.5µg/kg) and tramadol (0.5mg/kg) are effective in treating patients with post spinal anaesthesia shivering, but time taken for complete cessation of shivering was shorter with dexmedetomidine as compared to tramadol. Furthermore, dexmedetomidine causes fewer adverse effects like nausea and vomiting. Sedation caused by dexmedetomidine provides additional comfort to the patients.

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