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# COMPARISON OF EFFICACY OF DEXMEDETOMIDINE AND TRAMADOL FOR PROPHYLACTIC USE IN POST SPINAL ANAESTHESIA SHIVERING. A PROSPECTIVE RANDOMIZED CONTROLLED STUDY

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**Keywords:**

Dexmedetomidine, Tramadol, Post-spinal anaesthesia, shivering

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**ABSTRACT: Background:** Shivering is one of the most troublesome and distressing experiences for the patient encountered intraoperatively following spinal anaesthesia. Tramadol is very commonly used in clinical practice for post-spinal shivering but has side effects. The study aimed to compare the efficacy of dexmedetomidine with that of tramadol for prophylactic use in post-spinal anaesthesia shivering. **Methods:** A prospective, randomised controlled study was conducted on 210patients (American Society of Anaesthesiologists class I and II) of either gender, aged between 18 and 65, scheduled for elective lower abdominal and lower limb surgeriesunder spinal anaesthesia. The patients were randomized into three groups of 70 patients each. Group D received dexmedetomidine (0.5 µg/kg in 100 ml NS), Group T received tramadol (0.5 mg/kg in 100 ml NS) and Group C received 100 ml NS. All the drugs were given as an infusion over 10 min.The incidence and severity of shivering were recorded at 0min, 5min, 10min, 15 min and then every 15min till the end of surgery. The data was analyzed using IBMSPSS20 for windows. **Results:** The present study showed that dexmedetomidine and tramadol effectively prevent post-anaesthesia shivering, though the incidence was significantly less with dexmedetomidine (p value = 0.001). **Conclusion:** Dexmedetomidine is effective and comparably better than tramadol for prophylaxis of post-spinal anaesthesia. It also provides sedation without respiratory depression.

**INTRODUCTION:** Shivering is the involuntary, mechanical, and repetitive activity of skeletal muscles which occurs due to thermaldys regulation as a compensatory mechanism in patients receiving anaesthesia [1]. Shivering is one of the most troublesome and distressing experiences for the patient encountered intraoperatively following spinal anaesthesia [2]. Multiple mechanisms are suggested to explain the occurrence of shivering such as inhibition of central thermoregulation or inhibition of the autonomic vasoconstrictive tone in the lower half of the body after spinal anaesthesia

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leading to redistribution of core temperature to the peripheral tissues and then to the environment leading to hypothermia [3].

It causes several undesirable physiologic consequences, including increased oxygen consumption, increased CO2 production and increased minute ventilation leading to arterial hypoxemia, lactic acidosis and increased intraocular and intracranial pressure [4]. In pharmacological methods, many drugs such as opioids, $\alpha_2$agonists, anticholinergics, central nervous system stimulants, and corticosteroidshave been shown to be effective for the prevention and treatment of perioperative shivering [1]. Tramadol, which is commonly used in the treatment of post anaesthesia shivering, causes nausea and vomiting [5]. Dexmedetomidine $\alpha_2$ adrenergic agonist decreases vasoconstriction and the incidences of post anaesthesia shivering [6].

**MATERIAL AND METHODS:** This study was conducted in the department of Anaesthesiology at NSCB Medical College and Hospital, Jabalpur. It was a prospective, randomized control study.

American Society of Anaesthesiologists (ASA) class I and II patients of either sex, aged between 18-65 years scheduled for elective lower abdominal and lower limb surgeries under spinal anaesthesia were recruited. Prior ethical permission was taken from the institutional ethics committee along with the review board. Written informed consent was taken from all recruited patients.

For this study, 210 patients were recruited and randomly allocated into three groups. Each group was allotted 70 patients using random allocation software. Group D patients received Dexmedetomidine (0.5mcg/kg in 100ml NS as an infusion over 10 min before subarachnoid block), Group T patients received Tramadol (0.5 mg /kg in 100 ml NS as an infusion over 10 min before subarachnoid block) and Group C patients received 100ml NS as an infusion before the subarachnoid block.

Patients with a history of hypersensitivity with Dexmedetomidine and Tramadol, drug and alcohol abuse, cardiovascular disorders, psychological disorders, and neurological disorders, thyroid disorders, bleeding diathesis, and patients with core body temperature more than 38°C or <36°C were excluded from the study.

After a thorough pre-anaesthetic check-up and fitness approval, the patients were randomly divided into three groups on the day of surgery. The study drugs were given to the patients 10 min before the subarachnoid block.

A volume of 3ml (15mg) of hyperbaric Bupivacaine 0.5% was injected using a 25 G Quincke spinal needle while the patient was in sitting position. After the subarachnoid block, patients were repositioned supine, and oxygen at a flow rate of 5 l/min was started *via* Hudson mask.

All parameters were measured immediately after subarachnoid block and then at 5 min, 10 min, 15 min and then every 15 min till the end of surgery. Motor block was assessed using a Modified Bromagescale [7]. Assessment of the level of sensory block was evaluated by loss of sensation to pin-prick method.

Shivering was assessed and graded on ascalesimilarto that validated by Tsai and Chu.

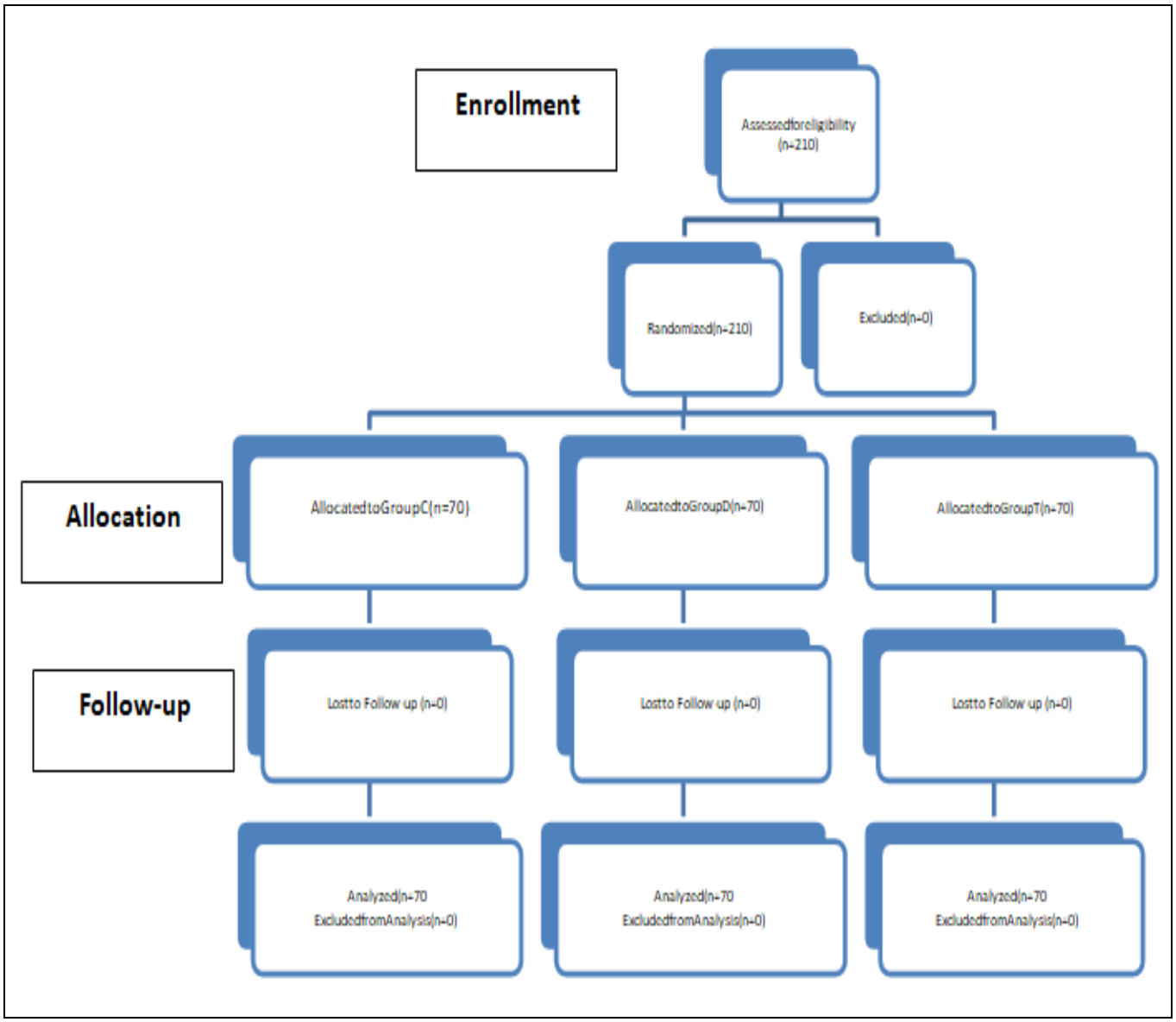
1. No shivering.
2. Piloerection or Peripheral vasoconstriction but no visible shivering, visible muscular activity inonlyone musclegroup.
3. Muscular activity in morethanone muscle group but not generalized.
4. Gross muscular activity involving the whole body.

The incidence and severity of shivering were recorded at 0 min, 5 min, 10 min, 15 min, and then every 15 min till the end of surgery.

Any side effects like hypotension, bradycardia, nausea and vomiting, and sedation if happened, were recorded and managed accordingly.

**Statistical Analysis:** The data of the present study was entered in the Microsoft Excel 2011 worksheet and after its proper validation and check for errors, resolving inconsistencies and illogical entries, coding & decoding were compiled and analyzed with the help of IBMSPSS20 for windows.

**Flow Chart in the Study:**




**RESULTS:** In our study, the mean age of patients in Group C, Group D and Group T were 33.07, 41.31 and 38.46, respectively **Fig. 1.**

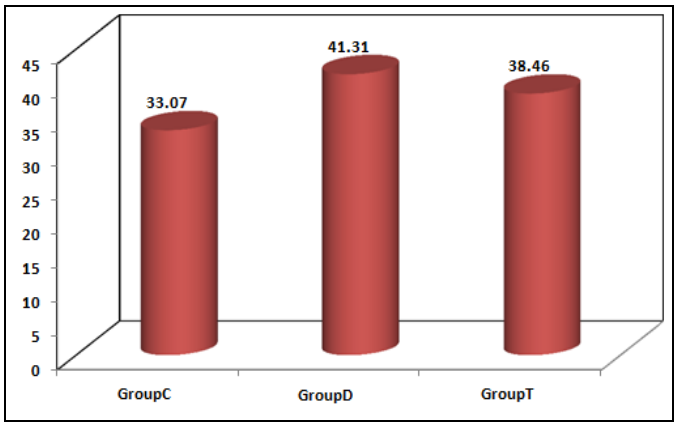



**FIG. 1: DEMOGRAPHIC DATA (AGE IN YEARS)**

There was no statistically significant difference between the groups in respect to all pre-op vitals (p-value > 0.05) except respiratory rate (p-value = 0.006) **Table 1.**

There was no statistically significant difference between the groups in respect to all post-op vitals (p-value > 0.05) except Systolic BP (p-value = 0.003) **Table 2.** In the present study, there was a significant mean difference in HR and SBP in all the groups between pre-op and post-op vitals **Table 3.**

The incidence of shivering who had undergone surgery under spinal anesthesia was 22 (31.4%) patients in group C, 5 (7.1%) patients in group D

and 10(14.3%) patients in group T (p value= 0.001). The result was statistically significant with the lowest incidence of shivering observed in group D **Fig. 2, Table 4.**

**TABLE 1: DEMOGRAPHIC DATA (PRE-OP VITALS)**

| Pre-Opvitals | Group | Mean±SD | Pvalue |
|---|---|---|---|
| HR | C | 72.41±11.855 | 0.223 |
| | D | 73.4± 9.287 | |
| | T | 75.67±12.669 | |
| SBP | C | 129.43±10.591 | 0.113 |
| | D | 131.29± 14.478 | |
| | T | 127±10.892 | |
| DBP | C | 66.43±10.949 | 0.885 |
| | D | 66.09±8.997 | |
| | T | 66.94±6.941 | |
| $SPO_2$ | C | 96.64±1.642 | 0.102 |
| | D | 96.4± 1.959 | |
| | T | 95.94±2.232 | |
| RR | C | 15.53±1.932 | 0.006 |
| | D | 14.56±2.211 | |
| | T | 15.49±1.894 | |

HR – Heart Rate, SBP – Systolic Blood Pressure, DSP – Diastolic Blood Pressure, RR – Respiratory rate.

**TABLE 2: DEMOGRAPHIC DATA (POST-OP VITALS)**

| Post-Opvitals | Study Group | Mean±SD | P-value |
|---|---|---|---|
| HR | C | 69.01±7.711 | 0.097 |
| | D | 67.91±10.662 | |
| | T | 71.59±11.923 | |
| SBP | C | 119.43±13.021 | 0.003 |
| | D | 113.19±11.456 | |
| | T | 115.31±7.756 | |
| DBP | C | 67.50±12.298 | 0.293 |
| | D | 64.61±10.871 | |
| | T | 65.30±10.829 | |
| $SPO_2$ | C | 96.53±1.631 | 0.736 |
| | D | 96.31±1.593 | |
| | T | 96.46±1.717 | |
| RR | C | 14.71±1.505 | 0.423 |
| | D | 15.03±2.014 | |
| | T | 14.71±1.298 | |

HR – Heart Rate, SBP – Systolic Blood Pressure, DSP – Diastolic Blood Pressure, RR – Respiratory rate.

**TABLE 3: MEAN DIFFERENCE BETWEEN PRE-OP VITALS AND POST-OP VITALS**

| GROUP | | Paired Differences (Mean±SD) | T | p |
|---|---|---|---|---|
| C | HR | 3.400±11.886 | 2.393 | .0190* |
| | SBP | 9.725±14.640 | 5.518 | .0000* |
| | DBP | -1.071± 14.760 | -.607 | .5460 |
| | $SPO_2$ | .114 ±2.657 | .360 | .7200 |
| D | RR | .814 ±2.561 | 2.660 | .0100* |
| | HR | 5.486±11.229 | 4.062 | 0.0000* |
| | SBP | 18.100±14.619 | 10.359 | 0.0000* |
| | DBP | 1.471±12.779 | .963 | 0.3390 |
| | $SPO_2$ | 0.086±2.125 | 0.338 | 0.7370 |
| | RR | -0.471± 3.771 | -1.046 | 0.2990 |
| T | HR | 4.086±10.155 | 3.366 | 0.0010* |
| | SBP | 11.686±12.705 | 7.696 | 0.0000* |
| | DBP | 1.643±13.209 | 1.041 | 0.3020 |
| | $SPO_2$ | -0.514± 2.848 | -1.511 | 0.1350 |
| C | RR | 0.771±1.811 | 3.564 | 0.0010* |

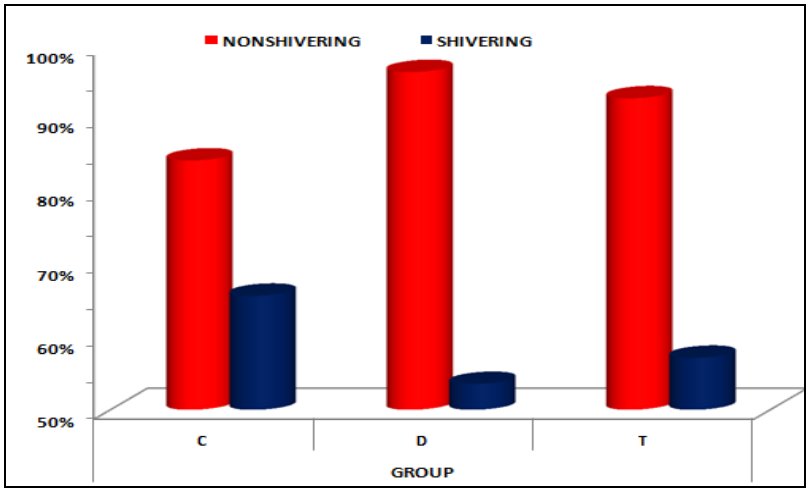



**FIG. 2: OVERALL INCIDENCE OF SHIVERING**

**TABLE 4: OVERALL INCIDENCE OF SHIVERING**

| Shivering | GROUP | | | Total (%) | Chi squared $\chi^2$ |
|---|---|---|---|---|---|
| | C(%) | D(%) | T(%) | | |
| Non Shivering | 48(68.6) | 65(92.9) | 60(85.7) | 173(82.4) | $\chi^2$= 15.02 |
| Shivering | 22(31.4) | 5(7.1) | 10(14.3) | 37(17.6) | P= 0.001 |
| Total | 70 (100.0) | 70 (100.0) | 70 (100.0) | 210 (100.0) | |

The use of Dexmedetomidine was associated with hypotension in 22 (31.4%) patients, bradycardia in 25 (55.7%) patients, and sedation in 19 (7.1%) patients who were less compared to those seen in Tramadol group **Fig. 3.** There was no significant difference between the groups for shivering Grade **Table 5.**

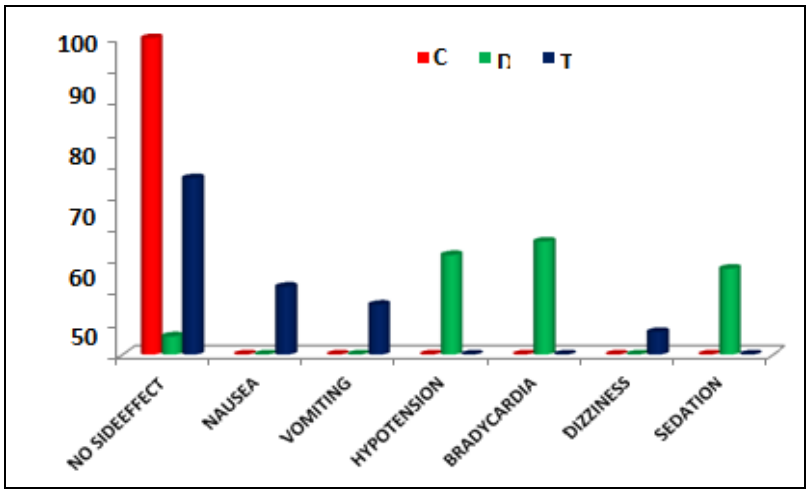



**FIG. 3: SIDE EFFECTS**

**TABLE 5: SHIVERING GRADE AT DIFFERENT INTERVALS (NUMBER OF PATIENTS EXPRESSED AS PER GRADE 0/1/2/3)**

| Intervals | Group C | Group D | Group T |
|---|---|---|---|
| 0 | 37/33/0/0 | 68/2/0/0 | 57/13/0/0 |
| 5 | 8/56/6/0 | 68/2/0/0 | 52/18/0/0 |
| 10 | 6/50/14/0 | 67/3/0/0 | 49/21/0/0 |
| 15 | 3/25/42/0 | 60/1/0/0 | 42/27/1/0 |

| | | | |
|---|---|---|---|
| 25 | 2/17/46/5 | 67/3/0/0 | 42/27/1/0 |
| 40 | 2/20/37/11 | 66/4/0/0 | 44/26/0/0 |
| 60 | 2/31/22/15 | 70/0/0/0 | 62/8/0/0 |
| 90 | 5/34/31/0 | 70/0/0/0 | 54/16/0/0 |
| 120 | 14/39/17/0 | 69/1/0/0 | 55/14/1/0 |
| 150 | 20/38/12/0 | 70/0/0/0 | 70/0/0/0 |

Compared to group T, the sedation score was higher in group D without respiratory depression, and early cessation of shivering was also observed in group D. This shows Dexmedetomidine to be better than tramadol for prevention of shivering in post spinalanaesthesia.

**DISCUSSION:** The current study showed that both Dexmedetomidine 0.5 µg/kg and Tramadol 0.5mg/kg decreased the incidence and intensity of shivering in patients exposed to elective operations under spinal anaesthesia when compared to the control group, but these drugs could not prevent the significant decrease in the core temperature after the subarachnoid block. This anti-shivering effect was not associated with increased side effects [8].

In addition, Dexmedetomidine was superior in increasing the level of sedation which is sufficient to prevent anxiety with fewer side effects. Since the elimination half-life of Dexmedetomidine was short (2 hours) and had a single dose application, long-term postoperative follow-up was not found to be necessary.

In a study conducted by Gertler *et al.* [9] in Intravenous regional anaesthesia cases where Dexmedetomidine 1µg/kg was used in premedication to prevent post-anesthetic shivering at a loading dose of 1µg/kg, respiratory depression was not reported. The results of the study are comparable to the results of the study done by Bozgeyik *et al* [10] where the authors have concluded that pre-emptive Tramadoland Dexmedetomidine are effective in preventing shivering after spinal anaesthesia. Dexmedetomidine also provided sedation, sufficient to prevent anxiety without any adverse effect [11, 12]. Usta *et al.* reported effective prevention of shivering and adequate sedation with the use of Dexmedetomidine infusion in patients during spinal anaesthesia [13]. Usta *et al.* [13] found that Dexmedetomidine decreases the incidence of shivering from 57% in the control group to 10%; the side effects were found to be higher in the case of Tramadol as compared to Dexmedetomidine.

In this study, the incidence of nausea was highly significant in the Tramadol group compared to the Dexmedetomidine group ($P < 0.001$). Similarly, the incidence of vomiting was significantly higher in the Tramadol group compared to the Dexmedetomidine group ($P = 0.041$). These results are similar to those found in a study by Li S *et al.*[14] Postoperative nausea and vomiting (PONV) is a very unpleasant experience for the patient [15]. Postoperative vomiting/retching can lead to severe but rare medical complicatins, such as aspiration of gastric contents, suture dehiscence, oesophageal rupture, subcutaneous emphysema, or pneumothorax [16]. PONV may delay discharge from PACU and can be the leading cause of unexpected hospital admission after ambulatory anaesthesia [17].

The limitation of our study was that the core body temperature could not be measured. For measurement of core body temperature, the probe needs to be put in the mid-esophagus, near the tympanic membrane, or in the urinary bladder. While a probe in the mid-esophagus or near the tympanic membrane is uncomfortable and unacceptable for patients who have been given SA, a probe in the urinary bladder would be an undue source of infection for the patient. Axillary temperature was recorded at regular intervals perioperatively until the end of the study.

**CONCLUSION:** Dexmedetomidine can be a good anti-shivering agent as it is effective and comparably better than Tramadol in preventing post-spinal anaesthesia shivering. It also provides sedation without respiratory depression and favours surgical conditions. However, it also has some side effects, like hypotension and bradycardia. Further research is required to search for an ideal drug for the prevention of post anaesthesia shivering.

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**CONFLICT OF INTEREST:** NIL

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