Original Research Article

Prospective randomised study for comparison of intravenous tramadol and intravenous dexmedetomidine for the control of intraoperative shivering under spinal anaesthesia

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Abstract

Background: Shivering is an oscillatory, involuntary mechanical muscular activity and a natural protective mechanism to the reduction of body temperature. The reported median incidence of shivering related to neuraxial anesthesia in the control groups of 21 studies is up to 55% (40 – 64%).Shivering is one of the most common complications of a central neuraxial blockade. In present study, intravenous dexmedetomidine and intravenous tramadol were compared in terms of efficacy to treat the shivering in patients subjected to various surgeries under spinal anesthesia at our tertiary hospital. **Material and Methods:** Present study was a prospective, randomised, double-blind study, conducted in department of anaesthesiology, in patients18-60 years age of either gender, American Society of Anaesthesiologists (ASA) Grade I/II, scheduled for elective as well as emergency surgeries (lower abdominal, gynaecological, lower limb, orthopaedic and plastic) under spinal anaesthesia, had intraoperative shivering. **Results:** Total 60 patients were studied in present study, 30 patients each were divided in group D - intravenous dexmedetomidine 0.5 µg/kg and group T- intravenous tramadol 0.5 mg/kg. General characteristics such as mean age (years), gender (M:F), ASA grading (I/II), duration of surgery and duration of spinal anaesthesia were comparable in both groups and difference was not statistically significant. In present study, patients from general surgery, gynaecological and orthopaedic surgeries were included. Score 3 and 4 patients were treated, patients with score 3 were more than score 4 and difference between two groups was not statistically significant. Onset of shivering after spinal anaesthesia was at 25.4 ± 9.5 min in group D while at 24.7 ± 10.3 min in group T, difference was not statistically significant. **Conclusion:** Dexmedetomidine is faster, more effective with lesser side effects when compared to tramadol in control of intraoperative shivering after giving of spinal anesthesia.

Keywords: Dexmedetomidine; Tramadol; Shivering Grade, post-spinal anaesthesia shivering

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INTRODUCTION

Spinal anaesthesia has been established as simple and safe anaesthesia technique for short to intermediate duration of infra umbilical surgeries, it may not be very comfortable for all, especially those with intraoperative and postoperative shivering. Shivering is an oscillatory, involuntary mechanical muscular activity and a natural protective mechanism to the reduction of body temperature.[1] The body tries to raise the metabolic heat generation to restore homeostasis by shivering. The reported median incidence of shivering related to neuraxial

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anesthesia in the control groups of 21 studies is up to 55% (40 – 64%).[2] Shivering is one of the most common complications of a central neuraxial blockade. Spinal anaesthesia impairs thermoregulation, inhibits tonic vasoconstriction, and causes the redistribution of core heat from the trunk to the peripheral tissue.[3] Other possible mechanisms include central thermoregulation disturbance, internal body heat redistribution, and body heat loss to the environment. Shivering interferes with proper monitoring and is associated with several adverse effects, as it increases the circulating catecholamine, heart rate, cardiac output, minute ventilation, patient oxygen consumption, metabolic CO2 production, lactic acid level, intraocular and intracranial pressure, and postoperative pain from surgical incision stretching.[4] 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.[5] Tramadol is an opioid analgesic with opioid effect mainly mediated via mu receptor with minimal effect on kappa and delta receptors. The anti-shivering action of tramadol is probably mediated via its opioid or serotonergic and noradrenergic activity or both. Tramadol, is an inhibitor of the re-uptake of serotonin (5- HT) and norepinephrine in the spinal cord found to influence the thermoregulatory control mechanisms.[6] Dexmedetomidine is a highly selective α-2 adrenoceptor agonist with potent effects on the central nervous system. Intravenous dexmedetomidine reduces both the vasoconstriction and shivering thresholds.[7] Multiple studies have demonstrated the efficacy of dexmedetomidine in prevention of shivering. Few clinical trials investigated its efficacy in treatment of established shivering.[8] In present study, intravenous dexmedetomidine and intravenous tramadol were compared in terms of efficacy to treat the shivering in patients subjected to various surgeries under spinal anesthesia at our tertiary hospital.

MATERIAL AND METHODS

Present study was a prospective, randomised, double-blind study, conducted in Department of Anaesthesiology, Dr Ulhas Patil Medical College. Study duration was of 6 months (January 2020 to July 2020). Institutional ethics committee approval was taken for present study.

Inclusion criteria: 18-60 years patients of either gender,American Society of Anaesthesiologists (ASA) Grade I/II, scheduled for elective as well as emergency surgeries (lower abdominal, gynaecological, lower limb, orthopaedic and plastic) under spinal anaesthesia,had intraoperative shiveringand willing to participate in study.

The exclusion criteria included

- Patients undergoing lower segment caesarean section, and
- Patients suffering from epilepsy, liver disease, renal disease, suffering from any chronic pain syndrome, or having any psychiatric illness, hyperthyroidism, urinary tract infection, severe diabetes or autonomic neuropathies, known history of substance or alcohol abuse,
- Patients who had a history of known hypersensitivity to dexmedetomidine or tramadol
- Patients with spinal deformities, coagulation abnormalities, infection at spinal puncture site
- Patients who were not willing to participate,

Study procedure was explained to patients in local language prior to surgery and a written informed consent to participate in present study was taken. All patients who fulfilled the inclusion criteria and had of intraoperative shivering under spinal anaesthesia were randomised using computer generated chart with allocation ratio of 1:1 into either of the two groups (group D - intravenous dexmedetomidine 0.5 μg/kg and group T- intravenous tramadol 0.5 mg/kg). In the operation theatre, preloading was done with Ringer's Lactate solution 10 ml/kg before giving spinal anaesthesia and maintained at 6 ml/kg/h after spinal anaesthesia. Before starting the procedure, standard monitors were attached and all the baseline parameters were recorded. Spinal anaesthesia was administered with 0.5% heavy bupivacaine (10-20 mg, depending on type of surgery) at L3-4 or L4-5 interspace using 26G Quincke's spinal needle under aseptic conditions. Ambient temperature of around 24°C-25°C was maintained in operation theatre. Supplemental oxygen was administered to all the patients at the rate of 5 l/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, and SPO2 were recorded at intervals of every 5 min for first 30 min and every 15 min for the rest of the observation period. Continuous ECG monitoring was done. The attending anaesthesiologist recorded the time in minutes at which shivering started after spinal anaesthesia (onset of shivering), severity of the shivering, time to the disappearance of shivering and response rate (shivering ceasing within 15 min after treatment). Shivering was graded with a score validated by Crossley and Mahajan.[9]

Table 1:

Shivering score	Characteristic
0	No shivering
1	Piloerection or peripheral vasoconstriction, but no visible shivering
2	Muscular activity in only one muscle group
3	Muscular activity in more than one muscle group, but not generalised
4	Shivering involving the whole body.

If shivering was noted, patients were treated with intravenous dexmedetomidine (0.5 µg/kg IV) or tramadol (0.5 mg/kg IV). The anaesthesiologist conducting the case as well as recording the data were unaware of the drug being administered. Duration of surgery was recorded and duration of spinal anaesthesia was noted by assessing spontaneous recovery of sensory block using the pin-prick method and observing spontaneous movements of limbs in the post-operative period. If shivering was noted, patients were treated with additional doses of dexmedetomidine (0.5 µg/kg IV) or tramadol (0.5 mg/kg IV). The coding was opened after completion of the study to compile results. Data was collected and entered in Microsoft excel. Numerical data were presented as mean ± SD and categorical data as proportions (%).Comparative data was analysed using ANOVA Test and Chi- square test. Statistical significance was considered if $p < 0.05$.

RESULTS

Total 60 patients were studied in present study, 30 patients each were divided in group D - intravenous dexmedetomidine 0.5 µg/kg and group T- intravenous tramadol 0.5 mg/kg. General characteristics such as mean age (years), gender (M:F), ASA grading (I/II), duration of surgery and duration of spinal anaesthesia were comparable in both groups and difference was not statistically significant.

Table 1: General characteristics

Characteristic	Group D (n=30)	Group T (n=30)	p value
Mean Age (years, Mean ± SD)	35.7 ± 10.2	37.3 ± 9.5	0.96
Gender (M:F)	13:17	16:14	0.78
ASA grading (I/II)	18:12	15:15	0.89
Duration of surgery (min)	69.9 ± 22.8	71.2 ± 17.5	0.36
Duration of spinal anaesthesia (min)	121.4 ± 19.3	127.5 ± 17.6	0.29

In present study, patients from general surgery, gynaecological and orthopaedic surgeries were included. Distribution among two groups is shown in table 2 and difference between two groups was not statistically significant.

Table 2: Types of surgery

Types of surgery	Group D (n=30)	Group T (n=30)	p value
General surgery	14 (47%)	13 (43%)	0.89
Gynaecological	9 (30%)	11 (37%)	0.85
Orthopaedic	7 (23%)	6 (20%)	0.91

Score 3 and 4 patients were treated, patients with score 3 were more than score 4 and difference between two groups was not statistically significant. Onset of shivering after spinal anaesthesia was at 25.4 ± 9.5 min in group D while at 24.7 ± 10.3 min in group T, difference was not statistically significant. We noted delayed cessation of shivering after medication in group T (4.91 ± 0.93 min) than in group M (3.12 ± 0.71 min), difference was statistically significant (p-0.01). We noted 100% response in both groups. No recurrence or side effects were noted.

Table 3: Parameters for post-spinal anaesthesia shivering

Parameters	Group D (n=30)	Group T (n=30)	p value
Shivering Score			
3	19	21	0.82
4	11	9	0.81
Onset of shivering after spinal anaesthesia (min)	25.4 ± 9.5	24.7 ± 10.3	0.56
Time for cessation of shivering after medication (min)	3.12 ± 0.71	4.91 ± 0.93	0.01
Response rate (%)	100	100	1
Recurrence	0	0	--

DISCUSSION

Shivering is both morbid and uncomfortable for patients and may interfere with monitoring of electrocardiogram, blood pressure and pulse oxygen saturation. It escalates oxygen consumption, lactic acidosis and carbon dioxide production; thus, predisposing a patient with a low cardiopulmonary reserve to potential harm.[10] Risk factors that predispose the patient to hypothermia and shivering include young age, male gender, low body weight, or poor nutritional status, prolonged preoperative fasting, an American Society of Anesthesiologists (ASA) risk class higher than I, combined general-regional anesthesia and the extent of induced sympathetic blockade, administration of premedication, volatile anesthetics, and muscle relaxants.[11] Hypothermia is a major risk for shivering, but there is no definite linear relationship between body temperature and the occurrence of shivering. Other major risk factors include age, sensory block level, temperature of the operating room and temperatures of the IV solutions.[12] Non-pharmacological methods using equipment such as covering with drapes (by blanket), using radiant heat and warming up operating rooms to maintain the normal temperature of the body are effective.[13] Other non-pharmacological methods which use specialized equipments to prevent or to control shivering are expensive and are not practical in all clinical settings. The response rate of post-neuraxial anaesthesia shivering after treatment was found to be highest in the dexmedetomidine group, and it was significant when compared to the tramadol group ($p = 0.0012$).[14] With 0.5 mg/kg of tramadol, the response rate reported by Shukla *et al.*[15] was 92.5%, and 100% in study by Mittal G.[16] But use of tramadol is associated with many side effects like nausea, vomiting and dizziness which are unpleasant for the patient.[15] In study by Chirag Patel *et al.*,[17] they found that there was a significant statistical significance in response rate for treating shivering between dexmedetomidine and tramadol. 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. Similar results were noted in present study. In the meta-analysis by Wang *et al.*,[18] they compared the efficacy of intravenous dexmedetomidine and tramadol on the treatment of shivering after spinal anesthesia in adult patients. Dexmedetomidine is associated with higher effective rate of shivering control, shorter time to cease shivering, lesser recurrence of shivering, lower incidences of nausea and vomiting, higher incidences of hypotension, bradycardia and sedation than tramadol. Keerthi P found that the time interval from the commencement of treatment, to cessation of shivering is quite less with dexmedetomidine (3.12±0.90 minutes) than with butorphanol (4.09±1.57 minutes)and tramadol (5.03±1.12 minutes) which was highly significant.[19] Usta *et al.*,[8] studied the prophylactic effect of IV dexmedetomidine on shivering in patients who received spinal anaesthesia. They found that perioperative dexmedetomidine infusion significantly decreased the incidence and intensity of shivering, with no major adverse effects. In the study of Arora *et al.*,[20] the incidence of shivering in the tramadol group (1 mg/kg) was 6.6% and in the dexmedetomidine group (0.5 mg/kg) was 10% during spinal anesthesia, which was not significantly different. Bozgeyik *et al.* [21] 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 anesthesia. There was no significant difference between the placebo, tramadol and dexmedetomidine group at 30 min and post-operatively. The exact mechanism of dexmedetomidine in the control of shivering is unclear and complex. Suggested mechanism is, dexmedetomidine and other alpha-2 agonists reduce shivering by inhibiting central thermoregulatory control by restraining neuronal conductance and suppressing vasoconstriction and shivering thresholds. The sedation achieved is better in patients receiving dexmedetomidine than patients receiving tramadol. None of patients experiencing over sedation or respiratory depression is reported in the included studies. Therefore, dexmedetomidine may be a good choice for shivering control after spinal anesthesia because of its dual effects of anti-shivering and sedation.[16,22,23,24] Dexmedetomidine has been successfully used as an adjunct to local anaesthetics in spinal anaesthesia and peripheral nerve blockade, for the sedation of mechanically ventilated patients in the intensive care unit, as well as supplementation of post-operative analgesia.[25] Present study had relatively small sample size, short duration surgeries and core temperature was not monitored. To demonstrate dexmedetomidine as preferred anti-shivering agent, it needs to be seen in surgeries of longer duration where chances of developing hypothermia are more. For the same larger studies are required.

CONCLUSION

Intravenous dexmedetomidine controls shivering faster than intravenous tramadol and thereby reduces patient discomfort time. Slight sedation with dexmedetomidine proves beneficial. Tramadol had higher incidence of side effects and delayed onset of action. 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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