



COMPARISON OF INTRAVENOUS DEXAMETHASONE AND TRAMADOL FOR PREVENTION OF SHIVERING IN ADULT PATIENTS UNDERGOING SPINAL ANAESTHESIA: A RANDOMIZED DOUBLE-BLIND TRIAL

Anaesthesiology

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ABSTRACT

Post spinal shivering is a common complication that affects patient comfort, oxygen consumption, and haemodynamic monitoring despite optimal warming. This randomized double-blind study compared the efficacy of intravenous dexamethasone 4 mg (Group D, n = 50) with tramadol 50 mg (Group T, n = 50) for preventing shivering in adults undergoing infraumbilical and lower limb surgery under spinal anaesthesia. The demographic data, type and duration of surgery, active warming, and core temperature were similar in both groups. The time interval for drug administration and the time for onset of shivering were also similar. Shivering was significantly reduced with dexamethasone compared with tramadol (16% vs 40%, $p = 0.0135$), with a reduced mean shivering grade and absence of grade 4 shivering in patients receiving dexamethasone. Only 2% patients in the dexamethasone group required rescue medication for shivering, compared with 34% patients receiving tramadol ($p < 0.001$). Early PONV and ondansetron use were more common with tramadol, as were hypotension and bradycardia. Dexamethasone 4 mg was found to be more effective and better tolerated compared to tramadol 50 mg for the prevention of postspinal shivering.

KEYWORDS

Spinal Anaesthesia, Shivering, Dexamethasone, Tramadol, Randomized Controlled Trial

1. INTRODUCTION

The common and clinically significant phenomenon of shivering following spinal anaesthesia results in increased total body oxygen consumption and production of carbon dioxide, increased myocardial work, and interference with the electrocardiogram, pulse oximeter, and noninvasive blood pressure tracing, which can confound the true haemodynamic trend (López, 2018). Shivering is one of the most uncomfortable perioperative experiences for the patient, and the presence of persistent tremor can cause problems in busy operating suites (Amsalu et al., 2022).

Spinal anaesthesia reduces the hypothalamic thresholds for vasoconstriction and shivering and accelerates the redistribution of central body heat loss by sympathectomy. Hence, under routine conditions in the operating room, hypothermia and shivering can occur (López, 2018). Despite the use of prewarming, forced air warming devices, and warmed intravenous fluids, the incidence of shivering remains high in the neuraxial group, which has sustained interest in the prevention of shivering (Shen et al., 2020; Esmat et al., 2021).

Non-pharmacological methods are the mainstay for the prevention, and many groups use a single preventative drug that is known, inexpensive, and easy to incorporate into the pre-incision routine (Amsalu et al., 2022). Tramadol, with its mild μ opioid receptor agonism and monoaminergic reuptake inhibition, has been shown to be effective for the prevention of post-spinal shivering, though it causes nausea and vomiting (Lema et al., 2017; Lakhe et al., 2017; Fenta et al., 2022). Dexamethasone has been commonly used for the prevention of PONV, and it has been shown that it reduces postoperative shivering too (Entezariasl & Isazadehfar, 2013; Esmat et al., 2021; Tu et al., 2023).

This trial compared the effects of low-dose intravenous tramadol and dexamethasone as single pre-emptive agents for the prevention of post-spinal shivering for infra-umbilical and lower limb surgeries.

2. MATERIALS AND METHODS

2.1 Study Design and Participants

This prospective randomized double blind controlled trial was carried out in the Department of Anaesthesiology of a tertiary referral hospital from June 2024 to December 2025. Adults aged 18-60 years, American Society of Anesthesiologists (ASA) physical status I-II, undergoing elective infra-umbilical or lower limb surgery under spinal anaesthesia (expected duration of procedure and surgery 60-180 minutes) were included. Exclusion criteria included refusal, contraindications for spinal anaesthesia, allergy to the drugs, presence of any systemic disease (ASA \geq III), baseline core temperature outside the range of 36.0 °C and 37.5 °C, thermoregulatory disorders, pregnancy or lactation, and the use of drugs affecting thermoregulation.

The sample size was calculated to detect a 25% absolute difference in shivering incidence (40% vs 15%) with alpha 0.05 and 80% power,

giving 49 patients per group; 50 were recruited in each group. Patients were randomized 1:1 to dexamethasone (Group D) or tramadol (Group T) using a computer-generated sequence and allocation was concealed with sequentially numbered, opaque, sealed envelopes.

2.2 Interventions and Anaesthetic Technique

The same 10 ml syringe containing dexamethasone 4 mg IV (Group D) or tramadol 50 mg IV (Group T) was used. Normal saline was used for diluents. The drugs were administered slowly over 2-3 minutes at an interval of 17-19 minutes from spinal block.

The spinal anaesthesia was performed by injecting 0.5% hyperbaric bupivacaine 2.5-3 ml between L3-4 or L4-5 interspaces in the sitting position with a 25 G spinal needle under aseptic precautions.

The patients were positioned appropriately for surgery, and routine monitoring and core temperature measurements were instituted.

The non-pharmacological warming measures included an ambient temperature of 22-24 degrees C, IV fluids warmed whenever possible, forced air warming for the majority of patients, and minimising exposed body surfaces.

Hypotension was treated with fluid and mephentermine.

Bradycardia was treated with atropine.

2.3 Outcomes and Analysis

Shivering was assessed intra-operatively and for 60 minutes post-operatively in PACU by the Wrench 0-4 scale, and clinically significant shivering was defined as grade ≥ 2 , which prompted rescue with 0.5 mg/kg IV pethidine. The primary outcome was the incidence of shivering (grade > 0) from the end of spinal block until 60 minutes post-operatively from arrival in PACU. The secondary outcomes included shivering grade, onset and end times, duration, requirement for rescue, PONV within 0-2 hours post-operatively, ondansetron use, hypotension, bradycardia, and treatment.

Data are presented as mean \pm SD or n (%); continuous data are analyzed by Student's t-test, and categorical data by Chi-square test or Fisher's exact test, with a p-value < 0.05 being significant.

3. RESULTS

3.1 Baseline Characteristics

All 100 patients (50 patients per group) completed the trial. Patients' data regarding age (45.96 ± 11.35 vs 45.80 ± 11.57 years; $p = 0.944$), sex distribution, height, weight, and BMI (all p values > 0.15) did not show significant differences between Groups D and T. ASA I/II classification (74% vs 26% vs 70% vs 30%; $p = 0.824$), type of surgery performed (anorectal, gynaecologic, lower abdominal, lower limb orthopedic, urologic; $p = 0.858$), and duration of surgery (82.48 ± 20.09 vs 80.96 ± 22.72 minutes; $p = 0.724$) were comparable.

Intraoperative sedation was used in 15/50 (30%) versus 18/50 (36%) patients ($p = 0.671$); active warming was used in 31/50 (62%) versus 30/50 (60%; $p = 1.000$); and the patients' basal core temperature was 36.57 ± 0.19 °C versus 36.61 ± 0.17 °C ($p = 0.303$) in Groups D and T, respectively.

Mean time of study drug administration was 19.12 ± 7.13 vs 17.36 ± 7.55 minutes ($p = 0.234$).

3.2 Shivering Outcomes

Shivering of any grade occurred in 8/50 (16%) in the dexamethasone group and 20/50 (40%) in the tramadol group ($p = 0.0135$). The mean shivering grade was found to be less in the dexamethasone group compared to the tramadol group, i.e., 0.30 ± 0.76 in Group D and 0.92 ± 1.28 in Group T ($p = 0.0042$). Similarly, 42 in the dexamethasone group and 30 in the tramadol group had grade 0, i.e., no shivering, and grade 4 shivering was found only in the tramadol group, i.e., 2 patients.

The mean onset time of shivering in Group D was 4.06 ± 9.81 minutes, in Group T it was 9.26 ± 12.41 minutes ($p = 0.0223$). Similarly, the stop time of shivering was found to be 5.30 ± 12.61 in Group D and 13.46 ± 17.29 in Group T ($p = 0.0084$), and the duration of shivering was 1.24 ± 3.05 vs 4.20 ± 5.98 minutes ($p = 0.0026$). These values, combined with incidence and grade distribution, indicate a substantially higher shivering burden with tramadol prophylaxis.

3.3 Rescue Medication, Haemodynamics and PONV

Rescue anti-shivering medication was required in 1/50 patients (2%) in Group D and 17/50 (34%) in Group T ($p < 0.001$). Hypotension occurred in 9/50 (18%) vs 11/50 (22%; $p = 0.803$) and bradycardia in 8/50 (16%) vs 9/50 (18%; $p = 1.000$), with similar mepentermine (9 vs 9) and atropine (8 vs 6; $p = 0.774$) use in Groups D and T.

PONV in the first 2 hours was more frequent in the tramadol group: 20/50 (40%) vs 8/50 (16%) in the dexamethasone group ($p = 0.0279$), with more moderate-to-severe episodes. Ondansetron was required in 20 vs 8 patients ($p = 0.0135$).

4. DISCUSSION

This trial demonstrates that IV Dexamethasone 4mg is more effective than Tramadol 50mg for the prevention of post spinal shivering in adult infraumbilical and lower limb surgeries, both being used as single doses for preemptive treatment with standard warming. All patient, surgical, and thermal variables were similar at baseline, suggesting that the effect can be attributed to the drug.

In the current study, dexamethasone reduced the incidence of shivering from 40% to 16% and reduced the need for rescue therapy from 34% to 2%, with reduced severity and the absence of grade 4 shivering. This is consistent with previous studies in the neuraxial environment, in which dexamethasone reduced clinically significant shivering compared with placebo or pethidine and fitted well into the precision routine (Entezariasl & Isazadehfar, 2013; Esmat et al., 2021). This is also consistent with the meta-analysis data supporting the use of dexamethasone peri-operatively for the reduction of shivering and PONV in all surgery (Tu et al., 2023).

Tramadol has been found to be a potent anti-shivering drug and has been found to be effective in comparison to a placebo, ketamine, and ondansetron in spinal anesthesia (Lema et al., 2017; Lakhe et al., 2017; Fenta et al., 2022). However, in this study, it has been found to increase shivering and has a significantly higher incidence of PONV, similar to other studies in which tramadol has been found to require a higher antiemetic requirement than other methods of prophylaxis (Nnacheta et al., 2020).

There was no significant difference in haemodynamic events or treatment, indicating that low-dose dexamethasone did not increase cardiovascular risk, similar to other reviews of the use of steroids in the perioperative period. For the ERAS spinal technique, the improved shivering and reduced PONV make dexamethasone the first choice of drug, in comparison to other drugs, for spinal anesthesia (Tu et al., 2023; Amsalu et al., 2022).

The limitations include the design, which is a single-centre study, and the population, which is only ASA I and II, with a short duration of follow-up. The results might not be applicable to other risk groups or obstetrics. Ambient and warming practices, although standardized, might be different in other areas. Further studies, possibly with a larger

population, might be needed to confirm the generalization and evaluate other doses and combinations.

5. CONCLUSION

In adult ASA I-II patients who underwent infra-umbilical and lower limb surgeries with spinal anesthesia, the use of IV dexamethasone 4mg was found to be better than tramadol 50mg for the prevention of post-spinal shivering, which reduces the incidence and severity of shivering, almost completely eliminates the need for anti-shivering measures, and reduces the incidence of early PONV without increasing the risk of hypotension and bradycardia. Dexamethasone 4mg IV can be recommended for the prevention of post-spinal shivering, while tramadol can be reserved for the treatment of shivering, especially when corticosteroids are contraindicated (Tu et al., 2023; Amsalu, 2022).

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