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# COMPARISON OF EFFICACY OF INTRAVENOUS DEXMEDETOMIDINE, PETHIDINE AND TRAMADOL FOR PREVENTION OF PERIOPERATIVE SHIVERING IN PATIENTS UNDERGOING SPINAL ANAESTHESIA FOR UROLOGICAL SURGERIES

Anaesthesiology

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KEYWORDS

## INTRODUCTION

Perioperative shivering is a common complication during and after surgical procedures, particularly under regional anaesthesia such as spinal anaesthesia. It is defined as involuntary, oscillatory muscle activity that increases oxygen consumption by approximately 100% to 600% potentially leading to increased carbon dioxide production and metabolic stress in patients [1]. In addition to physiological implications, shivering is often distressing for patients, causing discomfort and exacerbation of postoperative pain. Its prevalence ranges from 40% to 70% in patients under spinal anaesthesia [2].

The primary mechanism behind perioperative shivering is multifactorial including core-to-peripheral redistribution of body heat, the inhibitory effect of anaesthesia on thermoregulation and exposure to a cold operating room environment. Spinal anaesthesia impairs vasoconstriction below the level of the block, resulting in significant heat loss, particularly in surgeries of longer duration [3].

Shivering not only disrupts patient comfort but also affects the surgical outcome. Increased oxygen demand can exacerbate complications in patients with limited cardiorespiratory reserve. It also complicates perioperative monitoring by interfering with electrocardiogram (ECG) and pulse oximetry readings. Consequently, effective prevention and management of perioperative shivering is essential to improve overall patient care [4].

Various pharmacological agents have been investigated for the prevention and treatment of perioperative shivering. These agents act on different pathways involved in thermoregulation, including α2-adrenergic agonists, opioids, and serotonergic agents [5]. Among these dexmedetomidine, pethidine and tramadol have demonstrated notable efficacy. While these agents have been studied individually, there is a paucity of comparative data on their relative efficacy, onset of action, and side-effect profile in preventing perioperative shivering during spinal anaesthesia in urological surgeries.

Urological surgeries, especially those performed under spinal anaesthesia, present unique challenges for thermoregulation. These procedures are often of intermediate to long duration, and patients are exposed to significant fluid loss and irrigating fluids at sub-physiological temperatures further increasing the risk of hypothermia and subsequent shivering [6]. Moreover, many patients undergoing urological surgeries are elderly or have comorbidities such as diabetes or hypertension, making them particularly vulnerable to the adverse effects of shivering [7].

The prevention of shivering in this population is critical for optimizing outcomes. Effective control of shivering reduces metabolic stress, improves patient satisfaction and facilitates faster recovery. Additionally, it minimizes the potential for complications such as hypoxemia, wound dehiscence, and delayed discharge from the post-anaesthesia care unit (PACU) [8] This study aimed to fill the gap in existing literature by comparing the efficacy and safety profiles of intravenous dexmedetomidine, pethidine, and tramadol in preventing perioperative shivering during urological surgeries.

## AIMS AND OBJECTIVES

1) To compare the efficacy of intravenous Dexmedetomidine, Pethidine, & Tramadol in preventing the onset of peri-operative shivering
2) To assess and compare the level of sedation caused by these three study drugs
3) To study and compare the adverse effects caused by these three study drugs

## MATERIALS AND METHODS

The study had been conducted over a period of two years from January 2023 to November 2024 in the Department of Anaesthesiology in association with the Department of Urology. Institutional clearance had been obtained from the Institutional ethical committee (IEC) and Institutional research committee (IRC).

All adult patients aged between 18-70 years who had been admitted under Department of Urology and posted for urological surgery under spinal anaesthesia during the stipulated study period were included after they fulfilled the given criterion

### Inclusion Criteria

- American Society of Anaesthesiologists (ASA) physical status 1 and 2
- Patient Age 18-70 years.
- Patients posted for urological surgery.
- Undergoing Spinal Anaesthesia

### Exclusion Criteria

- Patient not giving written informed consent
- Immunocompromised patients
- Local site infection
- Known allergy to local Anaesthesia and study drug
- Cardio-pulmonary, renal or hepatic impairment
- Known history of substance (except tobacco) or alcohol abuse
- An initial axillary temp >37.5°c or <35.5°c
- Blood transfusion during surgery
- Hypo or hyperthyroidism
- Convulsion or psychiatric disorder
- PT (INR) >1.5

### Sample Size

Sample size was calculated using G Power [28] Version 3.1.9.4 Software. From a previous study conducted by Lim Fern et al. [21] calculated effect size for total 48 samples for the 3 groups( considering mentioned power of 80% and 95% confidence interval) is 0.463. Now considering similar effect size, 95% confidence interval and 99% precision for 3 groups final total sample size was 105. So, each group contained 35 patients.

The sample size of 105 subjects in each group was taken as,
Group D (n = 35) – received Inj Dexmedetomidine in 100 ml of NS
Group P (n = 35) – received Inj Pethidine in 100 ml of NS
Group T (n = 35) – received Inj Tramadol in 100 ml of NS

### Study Technique and Data Collection Procedure

Three groups of DCGI approved intravenous drugs Dexmedetomidine (D), Pethidine (P) and Tramadol (T) were used in the study. The study drugs Dexmedetomidine (0.5µcg/kg), Tramadol (0.5mg/kg) and Pethidine (0.5mg/kg) were prepared by the researcher prior in 100 ml of NS and labelled as D, T, P respectively. Patients aged between 18 to 70 years of ASA physical status grade 1 & 2 of either sex, undergoing urological surgery (except nephrectomy) were included in the study.

All the necessary investigations according to the patients' profile and institutional protocol were carried out. Preoperative evaluation of the patients was carried out and after explaining the procedure written and informed consent was obtained. The weight of the patients was noted before surgery. Data was collected with the help of a pre-designed and pre-tested structured questionnaire.

On arrival in the preoperative room, the patients were divided into three groups (D, P, T) by block randomization. Venous access was secured with 18G cannula and infusion of Ringer's Lactate was given at 10 ml/kg over 15 mins. In the operation theatre, monitors were attached (ECG, non-invasive arterial blood pressure, temperature and pulse oximetry). Operation room temperature was set to 22°C. Patients were administered 100 ml NS (infused with the respective study drugs) over 10 minutes through syringe pump. IV fluids were used at operation room temperature.

All the patients were placed in sitting position bending forward for lumbar puncture, which was performed by on duty anaesthesiologist using a midline approach at third lumbar interspace that is between L3 and L4 under strict aseptic condition. A 25G Quincke needle was inserted intrathecally with the distal end facing laterally. After confirmation of free flow of CSF, 15 mg of 0.5% hyperbaric Bupivacaine (3ml) was injected over 10-15 sec. Then the patients were made to lie in supine position. All the patients were covered by single layer of surgical drape, exposing only the surgical site. IV fluid was administered at 6ml/kg/hr. Oxygen via face mask at 5L/min was administered to all the patients. Inj. Ondansetron 4mg IV was given to all the patients. Surgery was commenced when the level of sensory block reached T8. Patients were monitored for a period of 120 minutes or the end of the surgery whichever was longer.

Shivering was monitored by a grading system as described by WRENCH

- **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

Sedation was Assessed by a Four-point Scale as per Filos et al

- **Grade 1:** Awake and alert,
- **Grade 2:** Drowsy, responsive to verbal stimuli,
- **Grade 3:** Drowsy, arousable to physical stimuli,
- **Grade 4:** Unarousable

**Parameters Observed**

- Pulse rate, systolic, diastolic, mean blood pressure, Spo2 and temperature were monitored continually and recorded for every 5 minutes after spinal anaesthesia till 15 minutes and then every 15 minutes till 120 minutes or the appearance of shivering (grade 3 or more) whichever was earlier. Shivering and sedation score was also noted at the mentioned intervals.
- Patients who developed shivering (Grade 3 or more) during the study period were given Inj.Tramadol 1mg/kg IV bolus as rescue drug. If shivering did not cease within 15 mins the patient was treated by non-pharmacological methods or other drugs and was excluded from the study. Any other adverse effects during the study period were noted.
- Hypotension was defined as a systolic blood pressure of less than 90 mm of Hg or a diastolic blood pressure of less than 60 mm of Hg and was treated with Inj. Mephentermine 6 mg IV bolus. Bradycardia was defined as a heart rate of less than 50 beats per minute and was treated with Inj.Atropine 0.6 mg IV bolus. The episodes of nausea and vomiting were also noted. The data were observed and noted by the on duty anaesthesiologist and analyzed by an independent researcher.

## RESULTS

Data were analysed using Microsoft excel 2019 and Statistical Package for Social Sciences software (SPSS Inc. Chicago II, version 23.0 for Windows).

- There were no significant differences among the three groups in terms of age, sex, weight, ASA classification, Bromage score, or comorbidities.The groups were well-matched and comparable, ensuring that any differences in study outcomes (such as shivering incidence or drug efficacy) were due to the intervention rather than baseline patient characteristics.

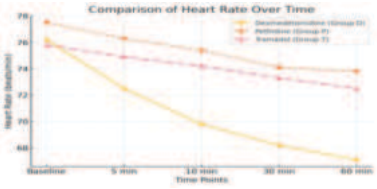


**Figure 1 Line Graph for Heart Rate Trends Across Different Time Points for the Three Groups.**

- It was found that Dexmedetomidine significantly lowered heart rate at 10, 30, and 60 minutes ($p < 0.05$).Pethidine and tramadol have a more stable heart rate effect. It was found that Dexmedetomidine significantly lowered blood pressure at 5 min, 10 min, and 30 min ($p < 0.05$).Pethidine and tramadol maintained a more stable hemodynamic profile. Pethidine causes a significant reduction in respiratory rate at 60 minutes ($p = 0.04$). Dexmedetomidine and tramadol have a more stable respiratory effect.

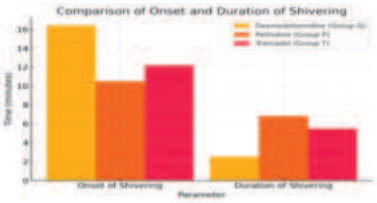


**Figure 2: Bar Chart Comparing the Onset and Duration of Shivering for the Three Groups**

- Dexmedetomidine significantly delays the onset of shivering compared to pethidine and tramadol ($p = 0.001$).Duration of shivering is shortest with dexmedetomidine ($p < 0.001$), confirming its superior anti-shivering effect

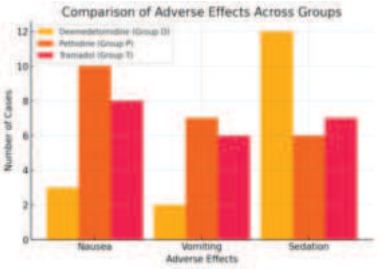


**Figure 3: Bar Chart Comparing Adverse Effects (Nausea, Vomiting, and Sedation)**

- Nausea and vomiting were significantly more common in pethidine and tramadol groups ($p < 0.05$).Dexmedetomidine had a higher incidence of sedation ($p = 0.01$), which may be beneficial in some patients.

## DISCUSSION

Perioperative shivering is a common and distressing complication of spinal anaesthesia. It is associated with increased oxygen consumption, metabolic rate, and patient discomfort, posing significant concerns, especially in individuals with pre-existing cardiopulmonary conditions. Various pharmacological agents, including dexmedetomidine, pethidine, and tramadol have been used to prevent and manage shivering. This study aimed to compare the efficacy and safety of these three drugs in preventing perioperative shivering in patients undergoing urological surgeries which are at more prone to perioperative shivering.

**Comparison of the Incidence and Onset of Shivering**

Our study demonstrated that dexmedetomidine was the most effective agent in preventing perioperative shivering, followed by tramadol and pethidine. The onset of shivering was significantly delayed in the dexmedetomidine group (16.4 ± 4.1 min) compared to pethidine (10.5 ± 3.8 min) and tramadol (12.2 ± 4.0 min). These findings are in line with previous studies that have shown dexmedetomidine to be superior to pethidine and tramadol in delaying shivering onset and reducing overall shivering incidence [1,2].Sessler et al. [3] found that α2-adrenergic agonists like dexmedetomidine suppress thermoregulation centrally(the concentration of alpha 2 receptors are more in hypothalamus), reducing the shivering threshold more effectively than opioids like pethidine and without producing respiratory depression.

Dexmedetomidine also decreases the sympathetic tone and attenuates the neuroendocrine and haemodynamic responses to surgery and anaesthesia. Our study aligns with this observation, as dexmedetomidine provided the longest delay in shivering onset. This effect is beneficial in long-duration surgeries, where prolonged thermoregulation control is essential. However, some studies have reported that pethidine has a faster onset of action in controlling shivering due to its dual mechanism involving μ-opioid and κ-receptor activation [4]. While our study also observed pethidine's rapid onset, it was associated with a higher incidence of adverse effects such as nausea and respiratory depression, making dexmedetomidine a safer choice in most cases.

**Comparison of Shivering Duration**

The duration of shivering was shortest in the dexmedetomidine group (2.5 ± 1.1 min) compared to pethidine (6.8 ± 2.4 min) and tramadol (5.5 ± 2.0 min). These results confirm findings from Elvan et al. [5], who reported that dexmedetomidine significantly reduces the duration of shivering compared to opioids. The shorter shivering duration with dexmedetomidine can be attributed to its ability to act on both central and peripheral thermoregulatory pathways and mitigating the vasoconstriction and sympathoadrenal response whereas pethidine and tramadol predominantly act on opioid and serotonergic mechanisms [9].

**Heart Rate**

Our study found that dexmedetomidine significantly lowered heart rate compared to pethidine and tramadol, particularly at 10, 30, and 60 minutes post-administration. This is consistent with previous studies showing that dexmedetomidine causes dose-dependent bradycardia due to central sympathetic inhibition [10]. Although bradycardia is a concern, it is generally well tolerated unless severe.

**Blood Pressure:** Dexmedetomidine was also associated with a significant reduction in blood pressure, with a mean systolic pressure decrease of approximately 12–15 mmHg compared to pethidine and tramadol. This finding aligns with Bajwa et al. [11], who reported that dexmedetomidine reduces systemic vascular resistance, leading to mild hypotension. While this effect is usually well tolerated, caution is needed in patients with baseline hypotension or volume depletion.

**Respiratory Rate and Oxygen Saturation**

Unlike pethidine, which significantly reduced respiratory rate, dexmedetomidine and tramadol maintained stable respiratory function throughout the study. This confirms findings from Kranke et al. [8], who reported that pethidine can cause dose-dependent respiratory depression by attaching to the mu receptor in the brainstem and targeting the pre Botzinger complex. In contrast, dexmedetomidine has minimal effects on respiration, making it safer for patients at risk of hypoventilation.

**Adverse Effects**

The safety profile of the three drugs was an important consideration in our study.

- **Nausea and Vomiting:**
  - The highest incidence was observed with pethidine (28.6% nausea, 20% vomiting), followed by tramadol (22.9% nausea, 17.1% vomiting).Dexmedetomidine had the lowest rates (8.6% nausea, 5.7% vomiting), consistent with studies indicating that opioids, particularly pethidine, increase nausea and vomiting due to direct chemoreceptor trigger zone stimulation [7].
- **Sedation:**
  - Dexmedetomidine had the highest sedation incidence (34.3%), compared to pethidine (17.1%) and tramadol (20.0%).While sedation is often desirable in perioperative settings, excessive sedation requires monitoring, especially in elderly patients [8].

Given these findings, dexmedetomidine offers a better balance between efficacy and safety, though careful monitoring of bradycardia and sedation is required.

Compared to these agents, dexmedetomidine remains one of the most effective choices due to its strong anti-shivering properties and hemodynamic stability.

**LIMITATIONS AND CONCLUSION**

This study did not consider the onset of the three drugs and their peak effect. Dexmedetomidine was found to be the preferred agent in patients at high risk of shivering, particularly those undergoing long-duration surgeries or those with a history of severe perioperative shivering. Pethidine may be useful for short-duration cases but should be avoided in patients prone to nausea, vomiting, or respiratory depression. Tramadol can be an alternative when opioids are contraindicated, but its anti-shivering effects are slightly weaker than dexmedetomidine. Careful monitoring of hemodynamic is necessary when using dexmedetomidine, particularly in patients with baseline bradycardia or hypotension.

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