



Original Research Article

Comparing the efficacy of ondansetron vs palonosetron in the prevention of shivering under spinal anaesthesia in patients undergoing transurethral resection of the prostate

Renganathan Sockalingam^{1*}, Indumathy Seeralan², Pavala Kannan Velu³, Ganesh Prabhu S C¹

¹Dept. of Anaesthesiology, Velammal Medical College Hospital and Research Institute, Madurai, Tamil Nadu, India

²Dept. of Anaesthesiology, Government Hospital, Ranipet, Tamil Nadu, India

³Dept. of Urology, Madurai Medical College, Madurai, Tamil Nadu, India

Abstract

Background: Shivering is a common postanaesthetic complication that causes metabolic stress and discomfort. Pharmacological management includes 5-HT₃ receptor antagonists, such as ondansetron and palonosetron; however, their comparative efficacy is unclear. This study compared the efficacy of ondansetron and palonosetron in preventing postanaesthetic shivering (PAS) in patients undergoing transurethral resection of the prostate (TURP) under spinal anaesthesia. **Materials and Methods:** This prospective, double-blind, randomised study involved patients assigned to Group A (ondansetron 8 mg IV) or Group B (palonosetron 0.075 mg IV) 30 min before surgery. A standardised spinal anaesthesia protocol used 0.5% bupivacaine. Patients were monitored for temperature, haemodynamic parameters, and PAS severity at multiple time points up to 120 min postoperatively. The incidence of shivering, vomiting, and temperature variations was assessed and managed.

Results: The incidence of shivering was lower with palonosetron (7.8%) than with ondansetron (21.1%) ($p=0.011$). Vomiting was lower in the palonosetron group (6.7%) versus ondansetron (13.3%) ($p=0.136$). At 120 minutes postoperatively, 91.6% had temperatures $\geq 36^{\circ}\text{C}$, 1.7% were $35.5\text{--}35.9^{\circ}\text{C}$, 5% were $35.0\text{--}35.4^{\circ}\text{C}$, and 1.7% $<35.0^{\circ}\text{C}$. Patients with shivering had higher systolic (144.0 ± 6.1 mmHg) and diastolic (95.0 ± 4.9 mmHg) blood pressures at 120 minutes than non-shivering patients (119.0 ± 5.4 mmHg, 83.2 ± 4.2 mmHg, $p<0.001$). Younger patients (57.0 ± 11.3 years) were more prone to shivering than older ones (62.2 ± 11.8 years, $p=0.027$).

Conclusion: Palonosetron is more effective than ondansetron in preventing PAS, with a lower incidence of shivering and vomiting. Further studies with larger cohorts are required to validate these findings.

Keywords: Postanaesthetic shivering, Ondansetron, Palonosetron, Spinal anaesthesia, 5-HT₃ receptor antagonists.

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1. Introduction

Shivering, characterised as an involuntary and repetitive activity of skeletal muscles, is primarily triggered by hypothermia but has also been documented in normothermic patients. The etiological mechanisms involve hypothesised pathways mediated by uninhibited spinal reflexes, postoperative pain, and hyperactive sympathetic activity. Variations in the frequency and patterns of shivering are observed across different anaesthesia modalities.¹

Shivering not only causes discomfort during the perioperative period but also significantly delays postoperative recovery. Shivering leads to a considerable increase in metabolism, oxygen demand, and cellular-level carbon dioxide production. In severe cases, it may result in lactic acidosis and hypoxaemia, negatively affecting perioperative and postoperative outcomes. With reported incidences ranging from 40% to 60% in various studies,

*Corresponding author: Renganathan Sockalingam
Email: renganathansockalingam@gmail.com

shivering is a not uncommon complication of spinal and general anaesthesia. Factors such as age, type of surgery, duration of surgery, baseline body core temperature, and associated comorbidities independently influence the triggering of shivering and its severity.^{2,3}

Pharmacological treatment of shivering involves lowering the shivering threshold, metabolic heat, and cellular oxygen demand, consumption, and production. Various opioid and non-opioid drugs are commonly employed for the prevention and management of postoperative shivering.⁴ However, they are accompanied by potential side effects such as hypotension, hypertension, sedation, respiratory depression, nausea, and vomiting. Recently, 5-HT₃ receptor antagonists have emerged as potential agents for preventing perioperative and postoperative shivering by inhibiting the neurotransmission involved in thermoregulation in the hypothalamus. But, the conclusive efficacy of these antagonists is still under study.^{5,6}

Ondansetron, a first-generation antiemetic, has a half-life of approximately 5–12 h and functions by blocking the action of serotonin in the brain, thus mitigating nausea, and vomiting post-surgery and preventing shivering in the perioperative and postoperative periods. Palonosetron, a newly introduced 5HT₃ receptor antagonist, exhibits potency with a plasma half-life of approximately 40 h. Particularly, Palonosetron demonstrates a 30 times higher affinity to 5HT₃ receptors compared to older 5HT₃ receptor antagonists.⁷

To compare the efficacy of ondansetron versus palonosetron in preventing shivering under spinal anaesthesia, it is essential to consider the existing literature on the use of ondansetron to prevent post-spinal shivering. Several studies have investigated the efficacy of ondansetron in preventing shivering during various surgical procedures, including caesarean section and inguinal hernia repair surgery.^{8–10} These studies have compared ondansetron with other medications, such as meperidine and pethidine, and have demonstrated its effectiveness in managing postoperative shivering.

Additionally, the studies have highlighted the additional benefit of ondansetron in reducing the incidence of postoperative nausea among patients undergoing caesarean section with spinal anaesthesia.¹¹ Furthermore, the literature includes studies that have evaluated the effect of ramosetron, a serotonin-3 receptor antagonist, on the prevention of shivering during spinal anaesthesia.¹² Although this study does not directly compare ondansetron and palonosetron, it provides valuable insights into the use of serotonin receptor antagonists for preventing shivering, which is relevant to the comparison of ondansetron and palonosetron.

In transurethral resection of the prostate (TURP), it is important to consider the complications and management of TURP, as well as the morbidity, mortality, and early outcomes of the procedure.^{13,14} This study aimed to compare

the efficacy of ondansetron and palonosetron in preventing post-anaesthesia shivering (PAS) in patients undergoing TURP under spinal anaesthesia. The doses of 8 mg ondansetron and 0.075 mg palonosetron were selected based on prior dose-response studies showing their standard efficacy for both antiemetic and anti-shivering effects in perioperative settings.^{6,15,16}

2. Materials and Methods

This prospective observational comparative study was conducted with 180 patients at tertiary care hospital from March 2022 to February 2024. The study began after obtaining ethical clearance from the Institutional Ethics Committee (VMCIEC/74/2022), CTRI – (CTRI/2024/08/073057) and written informed consent was obtained from all patients.

Patients aged 40–80 years with ASA grades I II, and III undergoing elective TURP under spinal anaesthesia were included. Patients with allergies to 5-HT₃ receptor antagonist drugs, psychological disorders, an initial body temperature >38°C or <36°C, those requiring sedation or supplementation with other anaesthetic drugs, and those requiring blood transfusion during the observation period were excluded from the study.

Randomisation was performed using a time-scale method, a type of simple random sampling, with 180 patients scheduled for TURP enrolled and randomly assigned in a double-blind manner into two equal groups using a computer-generated random number table. Group A (n=90) received 8 mg of ondansetron intravenously, whereas Group B (n=90) received 0.075 mg of palonosetron intravenously, both administered in a 4 ml volume within 5 ml syringes 30 min preoperatively. Randomization was performed using a computer-generated random number table in blocks of 10 to ensure balanced allocation, and it was double-blinded. The anaesthesiologist who prepared the study drugs (identical syringes with equal volumes) was not involved in patient care or outcome assessments.

All patients underwent preanesthetic clinic assessments to determine their fitness for anaesthesia and surgery according to established protocols and inclusion criteria. A standard fasting period of 8 h for solids was observed, and preoperative intravenous administration of 50 mg ranitidine and 10 mg metoclopramide was administered before the patient was transferred to the operating room. Upon arrival in the operating room, a subarachnoid block was performed using 2.8 ml of 0.5% bupivacaine (heavy) with a 25/26G Quincke needle, ensuring an adequate block. Patients were dressed in a cotton gown and covered with a single blanket, with surgical drapes used during the procedure, and no active warming was applied.

The operating room temperature was maintained between 22°C and 24°C, and supplemental oxygen was

administered at a rate of 3–4 L/minute via a face mask. Intravenous fluids were at room temperature before administration, and a co-loading regimen with 500 ml of Ringer's lactate solution was implemented during spinal anaesthesia establishment, with no intraoperative anaesthetic supplementation. The operating room temperature was consistently maintained between 22–24°C for all patients. Irrigation fluids used during TURP were at room temperature (22–24°C). All patients were covered with identical cotton blankets, and no active warming methods were applied. These uniform conditions minimized external temperature influences. Monitoring followed ASA standards, including SpO₂, electrocardiography (ECG), and non-invasive blood pressure (NIBP) assessments. Sublingual temperature measurements were taken preoperatively and recorded at 30-minute intervals for 120 min.

The outcomes measured included pulse rate, blood pressure, oxygen saturation, vomiting, temperature, and shivering in both the upper and lower limbs. Perioperative complications such as bradycardia, hypotension, and vomiting were managed using atropine, mephentermine, and metoclopramide in appropriate doses. Severe PAS was treated with intravenous 5 mg boluses of pethidine, as needed. The shivering grading system used was adapted from

the study conducted by Wrench et al., and patients were observed for 120 minutes postoperatively.¹⁷

Shivering was assessed using the Wrench et al. grading system, where Grade 0 indicated no shivering, Grade I represented peripheral vasoconstriction without muscle activity, Grade II involved visible muscle activity limited to one muscle group, and Grade III was characterized by muscular activity involving multiple muscle groups. Observations were made every 30 minutes for 120 minutes postoperatively by trained blinded observers.¹⁷

The sample size was calculated based on an expected reduction in shivering incidence from 24% (ondansetron) to 9% (palonosetron) based on Sharma et al. (15). Using $\alpha = 0.05$ and 80% power, a sample of 86 patients per group was estimated. To account for dropouts, 90 patients were included per group.

Data were presented as mean, standard deviation, frequency, and percentage. Continuable variables were compared using the independent sample t-test and Mann-Whitney U test. Categorical variables were compared using Pearson's chi-square and Fisher's exact tests. Significance was defined by P values < 0.05 using a two-tailed test, and data analysis was performed using IBM-SPSS version 21.0.

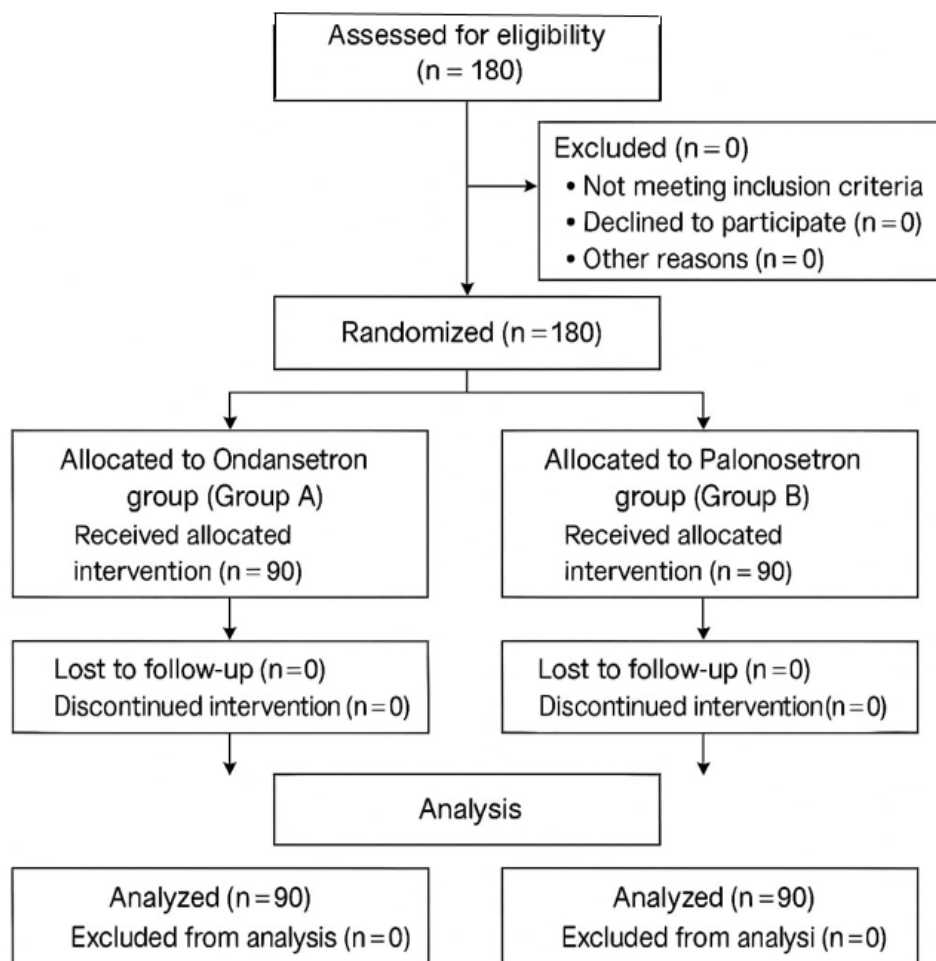


Figure 1: CONSORT flow diagram

3. Results

This randomized controlled trial included 180 patients, with Group A (n=90) receiving 8 mg of ondansetron intravenously and Group B (n=90) receiving 0.075 mg of palonosetron intravenously. The mean age of the patients was 61.5 ± 11.8 years old. The average height was 169 ± 4.46 cm, and the mean weight was 75.2 ± 8.68 kg. The preoperative temperature was recorded as $36.7 \pm 0.3^\circ\text{C}$ (**Table 1**). During the intraoperative period, 95% of the patients maintained a temperature of $\geq 36^\circ\text{C}$ at 60 min, with 1.7% experiencing a drop to 35.0 – 35.4°C . The pulse rate initially averaged 91.8 ± 4.8 bpm, increased to 93.9 ± 6.6 bpm at 30 min, and gradually decreased to 89.7 ± 8.8 bpm at 120 min.

Table 1: Demographic characteristics

	Mean $\pm$ SD
Age (years)	61.5 $\pm$ 11.8
Height (cm)	169 $\pm$ 4.46
Weight (kg)	75.2 $\pm$ 8.68
Pre-operative temperature ($^\circ\text{C}$)	36.7 $\pm$ 0.3

Postoperatively, the pulse rate remained stable, initially at 88.5 ± 5.2 bpm, increased to 89.1 ± 4.5 bpm at 30 min, and decreased to 87.8 ± 5.0 bpm at 120 min. Systolic blood pressure (SBP) was initially measured at 119.0 ± 9.8 mmHg, decreased to 115.0 ± 12.1 mmHg at 30 min, and then increased to 123.0 ± 10.4 mmHg at 120 min. Similarly, the diastolic blood pressure (DBP) was 81.4 ± 5.1 mmHg initially and increased to 84.9 ± 6.0 mmHg at the end of 120 min. At 120 min, 91.6% of the patients maintained a temperature of $\geq 36^\circ\text{C}$, whereas 1.7% experienced a drop below 35.0°C (**Table 2**).

Table 2: Postoperative measurements of vitals

		Mean ± SD	
Pulse Rate (bpm)		0 minutes	88.5±5.2
		30 minutes	89.1±4.5
		60 minutes	87.7±5.2
		90 minutes	87.9±5.3
		120 minutes	87.8±5.0
SBP (mmHg)		0 minutes	119.0±9.8
		30 minutes	115.0±12.1
		60 minutes	121.0±9.3
		90 minutes	123.0±11.1
		120 minutes	123.0±10.4
DBP (mmHg)		0 minutes	81.4±5.1
		30 minutes	82.5±5.4
		60 minutes	84.1±4.4
		90 minutes	83.9±5.2
		120 minutes	84.9±6.0
Temperature (°C)	0 th min	<35.0	3 (1.7%)
		35.0–35.4	0
		35.5–35.9	4 (2.2%)
		≥36	173 (96.1%)
	30 th min	<35.0	0
		35.0–35.4	0
		35.5–35.9	11 (6.1%)
		≥36	169 (93.9%)
	60 th min	<35.0	1 (0.6%)
		35.0–35.4	0
		35.5–35.9	5 (2.8%)
		≥36	174 (96.6%)
	90 th min	<35.0	0
		35.0–35.4	10 (5.6%)
		35.5–35.9	3 (1.7%)
		≥36	167 (92.7%)
	120 th min	<35.0	3 (1.7%)
		35.0–35.4	9 (5%)
		35.5–35.9	3 (1.7%)
		≥36	165 (91.6%)

SBP: Systolic blood pressure; DBP: Diastolic blood pressure

Table 3: ASA grading, surgical duration, and postoperative outcomes

			N (%)
ASA grading	Grade I		52 (28.9%)
	Grade II		66 (36.7)
	Grade III		62 (34.4%)
Duration of surgery (mins)	<60		41 (22.8%)
	60		109 (60.6%)
	90		4 (2.2%)
	>90		26 (14.4%)
Shivering	Absent		154 (85.6%)
	Present	Grade I	11 (6.1%)
		Grade II	10 (5.6%)
		Grade III	5 (2.8%)
Vomiting	Present		18 (10%)
	Absent		162 (90%)
Temperature drop (°C)	1		4 (2.2%)
	2		21 (11.7%)
	3		1 (0.6%)
	NIL		154 (85.6%)

ASA: American Society of Anesthesiologists

Table 4: Comparison of postoperative shivering by antiemetic group and temperature

			Shivering N (%)		p-value
			Absent	Present	
P/O group	Ondansetron		71(78.9%)	19(21.1%)	0.011
	Palonosetron		83(92.2%)	7(7.8%)	
Temperature (°C)	0 th min	<35.0	0	3(100%)	<0.001
		35.0–35.4	0	0	
		35.5–35.9	0	4(100%)	
		≥36	154(89%)	190(11%)	
	30 th min	<35.0	0	0	<0.001
		35.0–35.4	0	0	
		35.5–35.9	1(9.1%)	10(90.9%)	
		≥36	153(90.5%)	16(9.5%)	
	60 th min	<35.0	0	1(100%)	<0.001
		35.0–35.4	0	0	
		35.5–35.9	0	5(100%)	
		≥36	154(88.5%)	20 (11.5%)	
	90 th min	<35.0	0	0	<0.001
		35.0–35.4	1(10%)	9(90%)	
		35.5–35.9	0	3(100%)	
		≥36	153(91.6%)	14(8.4%)	
	120 th min	<35.0	0	3(100%)	<0.001
		35.0–35.4	0	9(100%)	
		35.5–35.9	0	3(100%)	
		≥36	154(85.6%)	26(14.4%)	
Incidence of temperature drop (°C)	Nil		154(100%)	0	<0.001
	1		0	4(100%)	
	2		0	21(100%)	
	3		0	1(100%)	

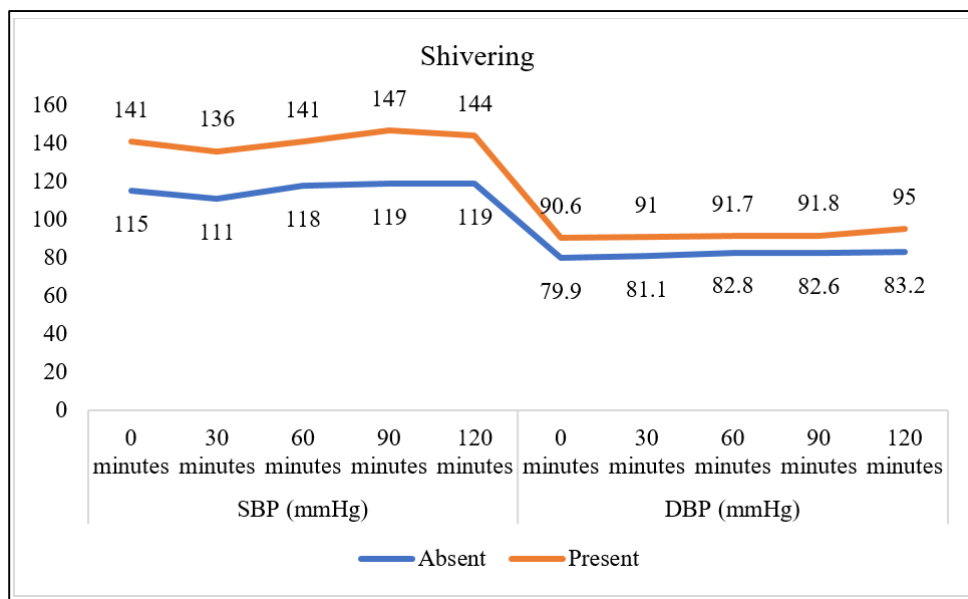


Figure 2: Distribution of hemodynamic parameters with shivering

Table 5: Temperature drop and vomiting incidence

		P/O group		p-value
		Ondansetron	Palonosetron	
Incidence of temperature drop (°C)	1	3 (75%)	1 (25%)	0.079
	2	15 (71.4%)	6 (28.6%)	
	3	1 (100%)	0	
	Nil	71 (46.1%)	83 (53.9%)	
Vomiting	Present	12 (13.3%)	6 (6.7%)	0.136
	Absent	78 (86.7%)	84 (93.3%)	

Regarding ASA grading, 28.9% of patients were classified as Grade I, 36.7% as Grade II, and 34.4% as Grade III. Most surgeries lasted 60 min (60.6%), whereas 14.4% exceeded 90 min. Postoperative shivering was observed in 14.4% of patients, with 6.1%, 5.6%, and 2.8% experiencing Grade I, II, and III shivering. Vomiting occurred in 10% of the patients, and temperature drops were noted in 14.5% of patients, with 11.7% showing a 2°C drop and 0.6% experiencing a 3°C drop (**Table 3**).

Systolic BP was significantly higher in patients with shivering (144.0 ± 6.1 mmHg) than in those without shivering (119.0 ± 5.4 mmHg) ($p < 0.001$). Similarly, Diastolic BP was significantly higher in patients with shivering (95.0 ± 4.9 mmHg) than in those without shivering (83.2 ± 4.2 mmHg) ($p < 0.001$) (**Figure 1**). The mean age of patients with shivering was 57.0 ± 11.3 years, significantly lower than 62.2 ± 11.8 years in those without shivering ($p = 0.027$).

The incidence of shivering was lower in the palonosetron group (7.8%) than in the ondansetron group (21.1%), with a significant difference ($p = 0.011$). All patients with temperatures below 35.0°C experienced shivering ($p < 0.001$), and all patients with a temperature drop of 1°C, 2°C, or 3°C developed shivering ($p < 0.001$) (**Table 4**). The relative risk

reduction for shivering incidence was 63% in the palonosetron group compared to the ondansetron group (RR 0.37; 95% CI: 0.16–0.85; $p = 0.011$). The absolute risk reduction was 13.3%, yielding a number needed to treat of approximately 8.

There was no significant difference in the incidence of a temperature drop ($p = 0.079$) or vomiting ($p = 0.136$) between the ondansetron and palonosetron groups (**Table 5**).

4. Discussion

This prospective, double-blind, randomized study involved patients who were assigned to receive either ondansetron (8 mg IV) in Group A or palonosetron (0.075 mg IV) in Group B, 30 minutes before surgery. A standard spinal anaesthesia protocol using 0.5% bupivacaine was followed, and patients were closely monitored for temperature, blood pressure, heart rate, and the severity of post-anaesthesia shivering up to 120 minutes after the procedure. The study also focused on assessing and managing the incidence of shivering, vomiting, and any temperature changes.

In our study, pulse recordings throughout the surgery demonstrated a typical distribution pattern, with mild

bradycardia observed in a subset of patients during the 120th-minute recording. Most participants showed normal temperatures at all measurement points; however, hypothermia was notably observed. Instances of temperatures falling below 35°C were documented at 0-, 60-, and 120-minute intervals, warranting further investigation. A considerable 14% of patients experienced shivering, with participants who experienced shivering exhibiting almost equal proportions in grades 1 and 2, and a noteworthy proportion in grade 3.

The incidence of shivering was significantly higher in the ondansetron group than in the palonosetron group ($p=0.011$). Patients who experienced shivering were relatively younger compared to others. The mean systolic and diastolic blood pressures of patients with shivering were higher than those of patients without shivering. Most patients with hypothermia experienced shivering. In the group of patients administered palonosetron, the incidence of temperature drop was comparatively lower, and the incidence of vomiting was also lower in the palonosetron group than in the ondansetron group, with no significant difference.

In the investigation conducted by Lakhe et al., the observed incidence of post-anaesthesia shivering (PAS) was approximately 16.7% (5 out of 30 patients) when administering a prophylactic intravenous ondansetron dose of 4 mg in surgeries performed under spinal anaesthesia.¹⁸ In a study by Sharma et al., a similar dose of intravenous ondansetron resulted in an incidence of shivering of 23.8% and concluded that their study exclusively focused on pregnant women with a distinctive haemodynamic milieu undergoing lower segment caesarean section (LSCS), which likely contributed to a higher rate of PAS.¹⁵ These variations in PAS rates may be attributed to the specific patient population characteristics, emphasising the need for tailored approaches in managing shivering based on clinical context and patient demographics.

The effectiveness of palonosetron in preventing PAS following neuraxial block has not been well explored. In Jo et al. study, the incidence of PAS was found to be 21% when administering prophylactic 0.075 mg palonosetron IV. It is noteworthy that their research focused on laparoscopic cholecystectomy under general anaesthesia in the 65-80 age group, potentially contributing to a higher PAS incidence than in our study. This study observed an incidence of approximately 27% when using prophylactic palonosetron in patients undergoing gynaecological laparoscopic surgery with propofol-remifentanyl total intravenous anaesthesia. However, this increased incidence may be linked to general anaesthesia with remifentanyl, a known factor associated with PAS. This study did not reveal a discernible beneficial effect of palonosetron on PAS.¹⁹

A prior regression analysis conducted by Rojas determined that advanced age was independently correlated with a decreased chance of experiencing PAS (odds ratio

0.59, $p < 0.001$). Elderly individuals tend to experience more pronounced and prolonged hypothermia due to diminished thermoregulatory capacity. Moreover, they typically exhibit reduced sensitivity to temperature changes and are less prone to shivering compared to younger individuals.⁷

A randomised double-blind prospective study by Ruku et al. reported no significant differences between the groups in terms of the duration of surgery or sublingual temperature. However, statistically significant difference was recorded for PAS (23.8% in ondansetron group, 9.5% in palonosetron group, $p=0.012$). This distinction remained significant at the 60-minute interval ($p = 0.044$). The prophylactic use of palonosetron demonstrated a considerable reduction in the incidence of PAS compared to ondansetron.²⁰

Bhaskar et al. reported that antiemetic prophylaxis reduced the overall incidence of nausea and vomiting. However, Palonosetron had a lower incidence of nausea and vomiting as compared to dexamethasone and ondansetron.¹⁶ A study by Kim et al. concluded prophylactic administration of palonosetron did not show a superior effect over ondansetron in mitigating hemodynamic changes in patients undergoing spinal anaesthesia with bupivacaine and fentanyl for caesarean section.²¹ A randomised controlled trial by Pradeep et al. concluded the prophylactic administration of Palonosetron is effective in attenuating the incidence of spinal anaesthesia-induced hypotension and bradycardia and a lower incidence of Postoperative Nausea and Vomiting.²²

These findings support the superior efficacy of palonosetron in preventing post-spinal shivering during TURP procedures. Although palonosetron has higher acquisition cost compared to ondansetron, its extended half-life, lower vomiting incidence, and reduced rescue therapy needs may offer favorable cost-benefit in high-risk surgical settings.

Our study also had few limitations. It was conducted at a single medical centre, potentially limiting the generalisability of the results to different patient populations and practices. Additionally, the study population consisted of patients undergoing elective TURP surgeries under spinal anaesthesia, which may introduce selection bias and limit the applicability to other surgical procedures or anaesthesia techniques. The absence of active warming protocols (e.g., forced-air warming, pre-warming) may have influenced the incidence of perioperative shivering, representing a limitation in isolating pharmacological effects.

5. Conclusion

Palonosetron is more effective than ondansetron in preventing postanaesthetic shivering (PAS), temperature drop, and vomiting incidence in patients undergoing TURP under spinal anaesthesia. However, due to the study's limited sample size and specific patient population, further research with larger cohorts and diverse surgical procedures is needed

to confirm and generalize the effectiveness of palonosetron in preventing PAS across various surgical settings.

6. Source of Funding

None.

7. Conflict of Interest

None.

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