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Original Research Article

Comparison of Effect of Intravenous Palonosetron Versus Ondansetron for the Prevention of Shivering in Parturients Undergoing Caesarean Section Under Subarachnoid Block

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Abstract

Background and Aims: Shivering is a common complication in patients undergoing spinal anaesthesia for caesarean sections, with an incidence of 40–60%. It increases oxygen demand, hemodynamic stress, and postoperative discomfort. While 5-HT$_3$antagonists like ondansetron are known for antiemetic effects, recent studies suggest they may also reduce shivering. This study aimed to compare the efficacy of intravenous palonosetron (0.075 mg) versus ondansetron (8 mg) in preventing shivering during caesarean sections under subarachnoid block. The primary objective was to determine which drug offers superior shivering prevention with minimal side effects.

Materials and Methods: A randomized, double-blinded study was conducted on 130 ASA I/II parturients undergoing elective caesarean sections under spinal anaesthesia. Participants were divided into two groups: Group A received ondansetron (8 mg IV), and Group B received palonosetron (0.075 mg IV) 10 minutes post-spinal block. Shivering incidence and intensity (graded 0–4using the Tsai & Chu scale), hemodynamic parameters, and neonatal APGAR scores were recorded. Rescue tramadol (25 mg IV) was administered for grade ≥2 shivering. Statistical analysis included chi-square and t-tests.

Results: Palonosetron was significantly more effective, with 9.2% of patients experiencing shivering compared to 26.2% in the ondansetron group ($p = 0.022$). Grade 3 shivering occurred in 1.5% (palonosetron) vs. 7.7% (ondansetron). Only 4.6% of palonosetron patients required tramadol versus 20% in the ondansetron group ($p = 0.016$). Both drugs maintained hemodynamic stability and had no adverse effects on neonatal APGAR scores.

Conclusion: Palonosetron (0.075 mg IV) is more effective than ondansetron (8 mg IV) in preventing perioperative shivering, with lower incidence, reduced severity, and fewer rescue interventions. The study supports palonosetron as a safer, more effective alternative for shivering prophylaxis in caesarean sections under spinal anaesthesia, without compromising maternal or neonatal outcomes.

Keywords: Shivering, Palonosetron, Ondansetron.

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Introduction

Shivering can be defined as repetitive involuntary skeletal muscles activity.[1] Perioperative shivering is a common complication in patients undergoing spinal anaesthesia which has an incidence of around 40-60% [1,2]. Caesarean section is usually done under neuraxial anaesthesia, which commonly causes shivering. Vasodilatation due to internal heat redistribution caused by neuraxial anaesthesia results in decreased core body temperature initially. This promotes ongoing heat loss below the level of blockade and the altered perception of temperature by the hypothalamus in blocked dermatomes results in decreased shivering threshold.[2]

Shivering can cause increased oxygen consumption, catecholamine release, cardiac output, heart rate, blood pressure, intracerebral and intraocular pressure.[3] Long term adverse effects include myocardial infarction, delayed wound healing and increased perioperative mortality.[4] Several opioid and nonopioid drugs, used in the prevention and management of postoperative shivering can causes adverse effects like

hypotension, hypertension, sedation, respiratory depression, nausea and vomiting.[5] Recently it has been found that 5HT3 antagonists, which are well known for postoperative nausea and vomiting could also reduce the postanesthetic shivering after regional anaesthesia.[6] Specific 5HT3 antagonist like ondansetron affects the thermoregulation.[5] The inhibition of 5HT3 (serotonin) reuptake in the preoptic regionof anterior hypothalamus by palonosetron may be accounting for its anti-shivering effect.[2]

Hence, In this study we are comparing the effect of intravenous palonosetron 0.075mg versus ondansetron 8 mg for controlling peri-operative shivering in parturients undergoing caesarean section under subarachnoid block.

Materials and Methods

This double-blind randomised control study was conducted in ESIC Model Hospital, ESIC-MC & PGIMSR Bangalore for 18 months (April 2024 – October 2025) after obtaining institutional ethical committee clearance.

A total of 130 parturients were included in the study who were divided into 2 different groups by a computer-generated random number. A study conducted by CK Banik et al2shows that shivering was observed in 53.3% in controls & 26.7% in palonosetron group. At 95% confidence level & 80% power with an allocation ratio 1:1, the estimated sample size is 60 per group using EZR 2.7.1. To compensate for dropouts, a total of 65 patients will be included in both groups.

Parturients with the age between 21-40 years belonging to ASA physical status 2 with singleton pregnancy who are willing to undergo elective caesarean section were included in this study.

We have excluded Parturients with absolute contraindications to regional anaesthesia, known history of Hypersensitivity to amide local anaesthetics, palonosetron and ondansetron, Parturients belonging to American society of anesthesiologists (ASA) physical status 3 or 4, Excessive haemorrhage needing transfusion, Failure or incomplete spinal block, Febrile illness.

After detailed preanesthetic check-up, Informed written consent was taken from all the parturients. All parturients received oral tab. ranitidine150mg the night before and 150mg on the morning of surgery. 130 parturients planned for caesarean section under spinal anaesthesia was enrolled in this double and were randomly divided into two groups, Group A and Group B of 65 patients each using computer generated random number table. Group A received IV 8 mg ondansetron diluted in 100 ml normal saline 10 minutes after administration of spinal anaesthesia and Group B received IV 0.075 mg palonosetron diluted in 100 ml normal saline 10 minutes after administration of spinal anaesthesia.

Anaesthesiologist who prepared the study drugs for administration was not involved later in the study. Upon patients arrival in the anaesthesia room, 18-gauge intravenous cannula was secured in the upper limband were preloaded with Ringer's lactate solution (10ml/kg). Fluids were stored at room temperature. Basic monitoring including non-invasive blood pressure, electrocardiography and pulse oximetry was connected for all patients andbaseline values were recorded.

Anaesthesiologist who is blinded to the study drugs performed the spinal anaesthesia under aseptic technique with patientin sitting position, at the L3 – L4 or L4-L5 interspace using a 25gauge Quincke tip spinal needle. On confirming free flow of cerebrospinal fluid, 0.5% bupivacaine heavy 2 mlwas injected intrathecally. All patients were turned to the supine position immediately with left uterine displacement, while supplemental oxygen was administered at the rate of 5 L / min through face mask. The level of sensory block (defined as loss of pinprick sensation) was assessed every minute. Once the level reached T6 to T4 level, the surgery proceeded. The peak sensory block level was recorded.

The temperature of the operating room and post-anaesthesia care unit was kept at 22°C to 26°C throughout the study. During the operation, the whole body of the patient, except the head, neck and operation site, was covered with one layer of surgical drapes. In the post-anaesthesia care unit, the patient's body was covered with one cotton blanket.

The incidence and intensity of shivering, as well as axillary temperature, was evaluated by a colleague who has no prior knowledge of the administered drugs. The incidence of shivering was assessed by close observation of the patients during the surgery. The intensity of shivering was graded on a 5 point scale of 0 to 4 by the method of Tsai and Chu:[11]

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, but not generalised
4- Shivering involving the whole body

The time interval from spinal block to shivering occurrence and intensity of shivering was recorded every 5 minutes during surgery for 30 min and thereafter every 30 min till 120 min.

Any patient complaining shivering of grade 2 or more was treated with rescue intravenous 25mg tramadol. The duration of surgery and APGAR score of newborn babies were recorded at 1 and 5

min. Effects of spinal anaesthesia such as hypotension (defined as decrease in mean arterial blood pressure of more than 20% from baseline), bradycardia (defined as decrease in HR < 50 beats/min) were treated with infusion of crystalloid (250ml) fluid as required followed by intravenous ephedrine (6mg), and atropine 0.6mg iv bolus respectively. Any adverse effects like nausea vomiting was recorded. Rescue drug for nausea/ vomiting was intravenous dexamethasone 8mg.

The number of patients requiring rescue drugs in each group were recorded.

The data was collected and compiled in MS Excel. Descriptive statistics has been used to present the data. To analyse the data the Jamovi Project Version 2.6.44 was used. Significance level was fixed as 5% ($\alpha = 0.05$). Qualitative variables are expressed as frequency and percentages, and Quantitative variables are expressed as Mean and Standard Deviation. For Comparison of proportions, Chi-square test was used and to compare data between 2 groups Unpaired t test was used.

Results

The demographic parameters were comparable between Group A and Group B with no significant change as depicted in the following table:

Table 1:

Demographic Variable	Group A (Mean ± SD)	Group B (Mean ±SD)	p-value
Age	27.43 ± 4.54	26.35 ± 4.29	0.1703
Weight	69.22 ± 9.52	70.23 ± 9.54	0.5478
Height	161.75 ± 7.99	162.91 ± 8.08	0.4179
BMI	26.70 ± 4.87	26.65 ± 4.53	0.9558

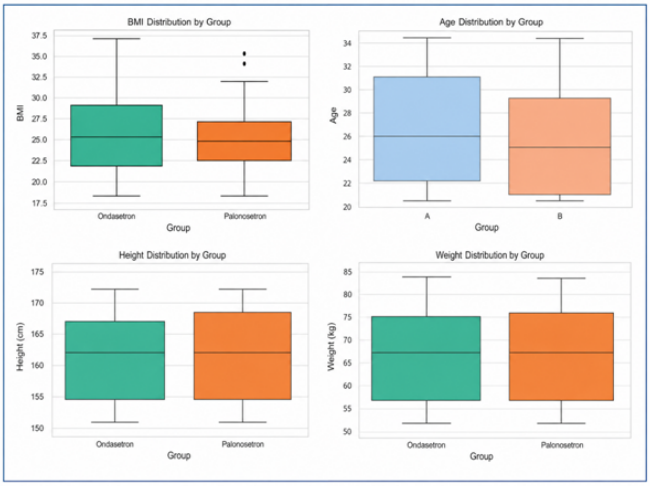

Figure 1:

Duration of surgery: No statistical difference in both the group

Table 2:

Group	Mean Duration	SD	Min	Max	N	p-value
Group A	77.20 min	8.78	60	90	65	0.514
Group B	76.14 min	9.69	60	90	65	0.514

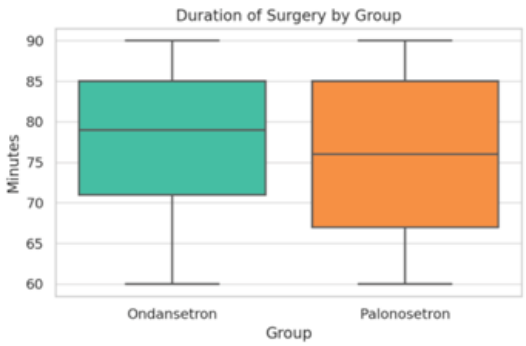

Figure 2:

Level of Sensory Block

Table 3:

Peak Block Level	Group A	Group B	p-value
T4	30 (46.2%)	28 (43.1%)	0.86
T6	35 (53.8%)	37 (56.9%)	

There is no significant difference in peak block level

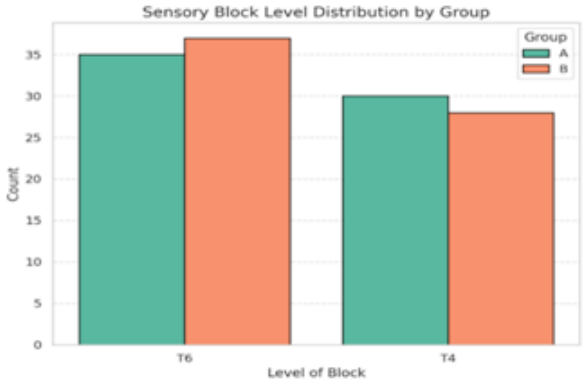

Figure 3:

Incidence of Shivering: The number of patients having shivering in Group A is 18 (26%) and in Group B 6 (9.2%) which was statistically significant (p value 0.022) as depicted

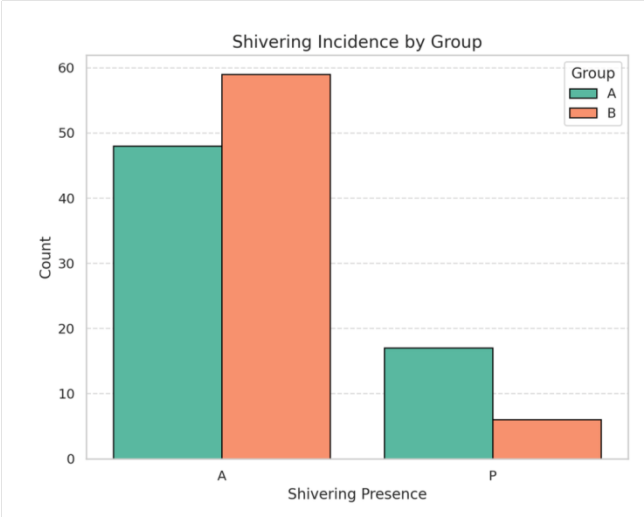

Figure 4:

Table 4:

Shivering	Group A	Group B	P value
Absent	47 (72.3%)	59 (90%)	0.022*
Present	18 (27.7%)	6 (9.2)	

Grade of Shivering: In Group A 18 patients had shivering in which 5(7.7%) patients had grade 1 Shivering, 8 patients (12.3%) had grade 2 shivering and 5 (7.7%) patients had grade 3 shivering. While in group B 6 patients had shivering, in which 3 (4.6%) patients had grade 1 shivering, 2 (3.1%) patients had grade 2 shivering and only 1 (1.5%) patient had grade 3 shivering.

The distribution of grades 1, 2 and 3 of shivering were statistically significant as the p value is 0.016 as depicted.

Table 5:

Grade	Group A	Group B	p-value
0	47 (72.3%)	59 (90.8%)	0.043*
1	5 (7.7%)	3 (4.6%)	
2	8 (12.3%)	2 (3.1%)	
3	5 (7.7%)	1 (1.5%)	
4	0	0	

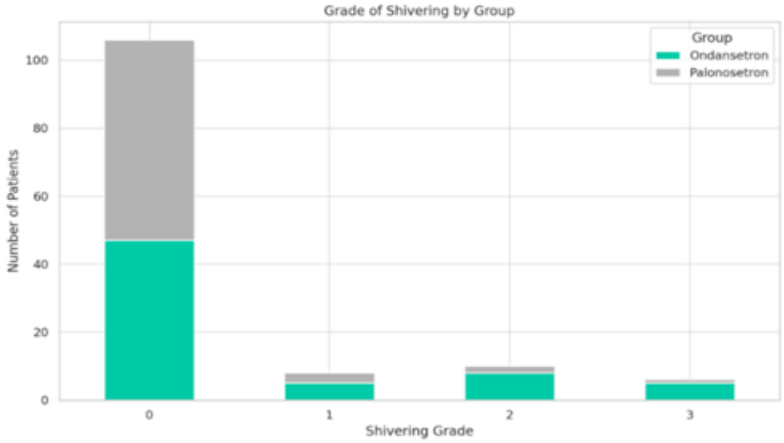

Figure 5:

Rescue Anti-Shivering Drug: In group A 13 (20%) patients out of 65 patients received rescue anti shivering drug which is intravenous tramadol 25mg, while in group B only 3 (4.6%) patients out of 65 received rescue anti shivering drug with a p value of 0.016 which is statistically significant as shown:

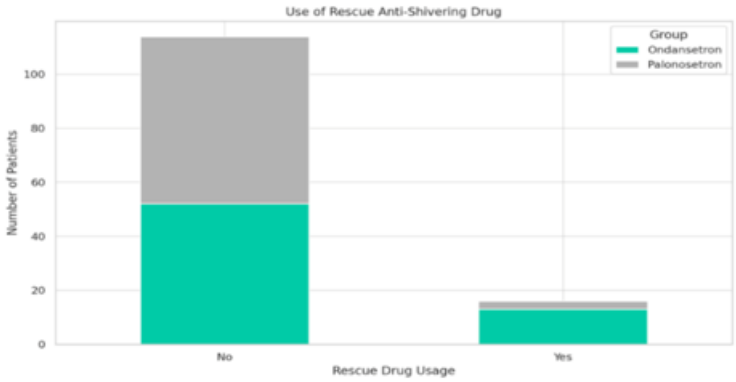

Figure 6:

Table 6:

Rescue Drug	Group A	Group B
No	52 (80.0%)	62 (95.4%)
Yes	13 (20.0%)	3 (4.6%)

Neonatal Outcomes

APGAR Scores: The Apgar score of newborn was comparable between two groups as shown.
There was no clinical and statistical significance between 2 groups.

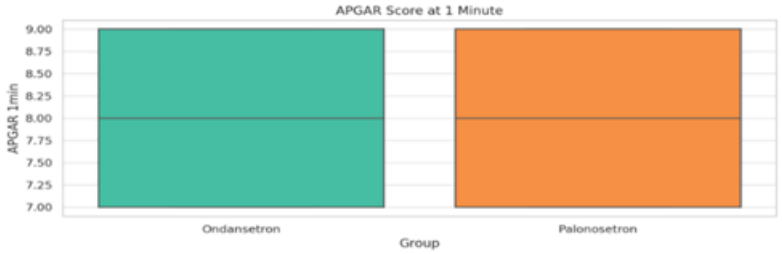

FIGURE 20: Distribution of APGAR at 1 minute by group

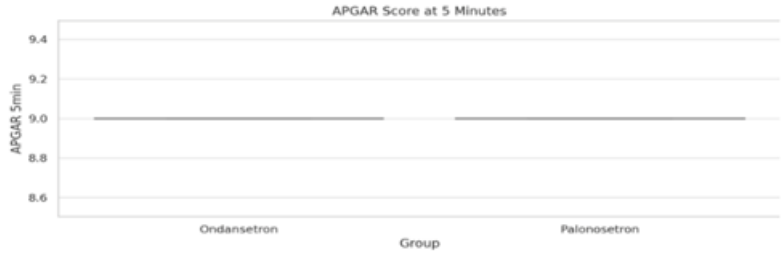

Figure 7:

Table 7:

Group	APGAR 1 min (Mean ± SD)	APGAR 5 min (Mean ± SD)
Group A	8.00 ± 0.77	9.00 ± 0.00
Group B	8.03 ± 0.85	9.00 ± 0.00

Heart Rate (HR) Trend Over Time: The mean heart rate at different time intervals, showed no significant differences between two groups.

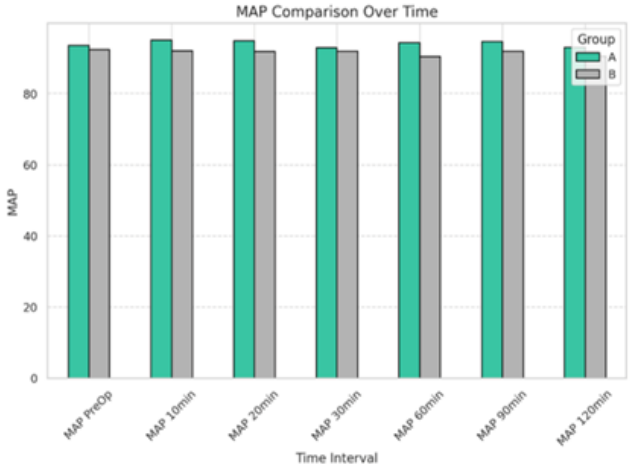

Figure 8:

Table 8:

Time Point	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Pre-Op	81.85 ± 13.13	84.49 ± 13.52	0.2634
10min	84.23 ± 12.77	82.31 ± 11.54	0.3731
20min	84.60 ± 12.10	81.37 ± 13.16	0.1507
30min	83.55 ± 11.69	82.06 ± 12.71	0.4906
60min	83.83 ± 12.75	80.28 ± 12.66	0.1161
90min	83.89 ± 14.20	80.18 ± 12.36	0.1177
120min	83.23 ± 13.14	83.43 ± 11.03	0.9258

Mean Arterial Pressure: Mean arterial pressure during the study showed statistical significance between two groups at 10th, 20th,60th and 90th minute. The p values were 0.0178, 0.0299, 0.0032, 0.0386 at 10, 20, 60 and 90 minutes respectively as shown However, it was not clinically significant.

Table 9:

Time Point	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Pre-Op	93.51 ± 7.13	92.31 ± 7.71	0.3624
10min	95.06 ± 6.73	92.05 ± 7.47	0.0178 *
20min	94.82 ± 8.25	91.82 ± 7.17	0.0299 *
30min	92.89 ± 8.00	91.92 ± 6.59	0.4560
60min	94.25 ± 7.75	90.37 ± 6.84	0.0032 *
90min	94.58 ± 7.75	91.94 ± 6.52	0.0386 *
120min	92.98 ± 7.74	90.48 ± 7.64	0.0674

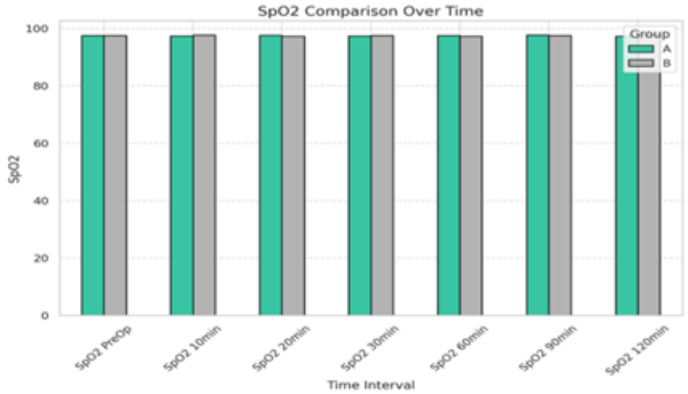

Figure 9:

SpO2: SpO2 during the study showed statistical significance between two groups at 120th minute with p value of 0.0133 as shown. However, it was not clinically significant.

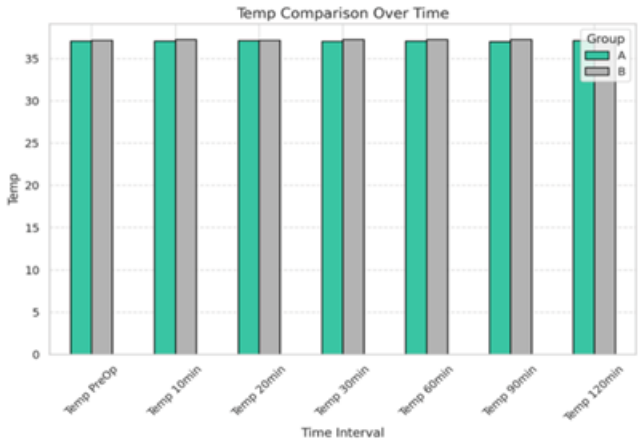

Figure 10:

Table 10:

Time Point	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Pre-Op	97.42 ± 1.08	97.42 ± 1.18	1.0000
10min	97.32 ± 1.11	97.63 ± 1.09	0.1161
20min	97.54 ± 1.14	97.25 ± 1.10	0.1413
30min	97.32 ± 1.11	97.49 ± 1.04	0.3752
60min	97.46 ± 1.11	97.23 ± 0.97	0.2135
90min	97.66 ± 1.11	97.42 ± 1.08	0.2065
120min	97.25 ± 1.11	97.75 ± 1.18	0.0133 *

Temperature: The mean temperature during the study showed statistical significance between two groups at 10th, 30th and 90th minute. The p values were 0.0404, 0.0076, 0.0014 at 10, 30 and 90 minutes respectively. However, it was not clinically significant.

Table 11:

Time Point	Group A (Mean ± SD)	Group B (Mean ± SD)	p-value
Pre-Op	37.04 ± 0.44	37.15 ± 0.46	0.1711
10min	37.05 ± 0.46	37.22 ± 0.42	0.0404 *
20min	37.08 ± 0.43	37.16 ± 0.40	0.2863
30min	37.00 ± 0.47	37.22 ± 0.45	0.0076 *
60min	37.06 ± 0.50	37.21 ± 0.47	0.0902
90min	36.97 ± 0.42	37.23 ± 0.47	0.0014 *
120min	37.10 ± 0.52	37.13 ± 0.48	0.7668

Repeated Measures ANOVA Results: The p-value from ANOVA results for all the hemodynamic parameters were comparable and shows no statistically significant changes in the hemodynamic parameters within the groups as shown**.**

Table 12:

Hemodynamic Variable	F-Value	P-Value
Heart Rate (HR)	0.2753	0.9486
Systolic Blood Pressure (SBP)	0.5164	0.7962
Diastolic Blood Pressure (DBP)	1.2777	0.2650
Mean Arterial Pressure (MAP)	1.1537	0.3293
Respiratory Rate (RR)	0.5533	0.7676
Oxygen Saturation (SpO_2)	0.4668	0.8331
Temperature (Temp)	0.1715	0.9844

Discussion

Our study found that intravenous palonosetron 0.075 mg (diluted in 100 mL normal saline) given 10 minutes after spinal anaesthesia significantly reduced the incidence and intensity of post-spinal shivering compared with intravenous ondansetron 8 mg. We also observed no significant change in newborn APGAR scores, indicating no adverse immediate neonatal effect.

Spinal anaesthesia is preferred for caesarean sections due to its advantages, including lower postoperative pain and avoidance of general anaesthesia–related risks. However, shivering is a common unwanted complication of spinal anaesthesia, with reported incidences up to 57%, and it can adversely affect the parturient's physiology. Although shivering has been managed with various drugs, safe and effective prevention remains important.

Pethidine is considered effective, but it is not recommended for use in nursing mothers, raising ethical and legal concerns. Meta-analyses (e.g., Zhou et al.[9]) suggest that 5-HT3 antagonists such as ondansetron and palonosetron may be effective alternatives with fewer side effects. Ondansetron is widely used as an antiemetic and has anti-shivering properties, while palonosetron—also a 5-HT3 antagonist used for chemotherapy-induced nausea—has demonstrated anti-shivering effects with good tolerability. Based on this, we selected palonosetron 0.075 mg for our study.

We compared ondansetron 8mg and palonosetron 0.075 mg using the Tsai and Chu 5-point scale [11]. The incidence of shivering in the palonosetron group was 9.2%, comparable with Sharma et al. (9.5%). Patients in the ondansetron group had higher shivering grades; in ondansetron group, 72.3%had grade 0 (no shivering), and none had grade 4, consistent with findings from Nallam et al[12]. In contrast, Jo et al [6]. reported higher shivering rates with palonosetron, which may be due to differences in surgical context (laparoscopy with pneumoperitoneum) and smaller sample size. Overall, our results showed palonosetron was more effective than ondansetron, with incidence rates of 9.2% vs 26.2%, aligning with other studies.

We found no significant hemodynamic differences between groups, supporting the safety profile of palonosetron, as similarly reported by Banik et al [2]. For rescue treatment, tramadol 25 mg was used in patients with shivering > grade 2. Rescue requirement occurred in 20% of ondansetron patients and 4.6% of palonosetron patients, which may differ from Nallam et al [12]. (10%) due to variations in sample size.

Conclusion

Administration of intravenous palonosetron 0.075 mg after spinal anaesthesia helps in better prevention of shivering compared to intravenous ondansetron 8mg in parturients undergoing caesarean section under sub arachnoid block with

lesser intensity of shivering without any effect on neonatal APGAR score.

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