International Journal of Medical and Pharmaceutical Research

Online ISSN-2958-3683 | Print ISSN-2958-3675
Frequency: Bi-Monthly
Available online on: https://ijmpr.in/

Original Article

A Comparative Study of Prophylactic Intravenous Ondansetron on Spinal Anaesthesia-Induced Hypotension Versus Placebo

Dr Bandini Singhal[1], Dr. Pranav Pujari[2], Dr Ajay Kumar Sinha[3]

[1] MD Anaesthesia Department of Anaesthesiology, Critical Care, Pain and Palliative Medicine, GMC Haldwani, Nainital, Uttarakhand.
[2] Assistant Professor, Department of Anaesthesiology, Critical Care, Pain and Palliative Medicine, GMC Haldwani, Nainital, Uttarakhand.
[3] Professor, Department of Anaesthesiology, Critical Care, Pain and Palliative Medicine, GMC Haldwani, Nainital, Uttarakhand.

Corresponding Author:

Dr Bandini Singhal

MD Anaesthesia Department of Anaesthesiology, Critical Care, Pain and Palliative Medicine, GMC Haldwani, Nainital, Uttarakhand.

Received: 18-09-2025
Accepted: 09-10-2025
Available online: 12-11-2025

ABSTRACT

Background: Spinal anaesthesia is widely used for lower abdominal and lower limb surgeries but is frequently complicated by hypotension and bradycardia, leading to significant perioperative morbidity. The Bezold–Jarisch reflex, mediated via serotonin (5-HT_3) receptors, is implicated in this response. Ondansetron, a 5-HT_3 antagonist routinely used for prophylaxis of postoperative nausea and vomiting.

Aim: To evaluate the efficacy of prophylactic intravenous ondansetron in reducing the incidence of spinal anaesthesia-induced hypotension compared with placebo.

Materials and Methods: This prospective, randomised, double-blind, comparative study was conducted on 76 ASA I–II patients aged 18–60 years undergoing elective non-obstetric surgeries under spinal anaesthesia. Patients were randomised into two groups: Group A (Control, n=38) received 10 ml of normal saline, while Group B (Ondansetron, n=38) received 4 mg ondansetron diluted in 10 ml saline, administered five minutes before spinal anaesthesia. All patients were preloaded with Ringer's Lactate (20 ml/kg). Spinal anaesthesia was performed with 3.0 ml of 0.5% hyperbaric bupivacaine at L3–L4. Hemodynamic parameters (SBP, DBP, MAP, HR, SpO_2) were recorded at baseline and at regular intervals up to 30 minutes.

Results: The incidence of hypotension was significantly lower in the ondansetron group (28.9%) compared with controls (55.3%, p=0.02). Bradycardia (7.9% vs. 26.3%, p=0.03), nausea (7.9% vs. 34.2%, p=0.005), and mephentermine requirement (21.1% vs. 47.4%, p=0.01) were also reduced. SBP, DBP, and MAP were consistently better maintained with ondansetron. No significant differences were observed in vomiting or shivering.

Conclusion: Prophylactic intravenous ondansetron (4 mg) significantly reduces the incidence of spinal anaesthesia-induced hypotension, bradycardia, and nausea while improving hemodynamic stability and reducing vasopressor use. Ondansetron may serve as a safe and effective adjunct in routine anaesthetic practice.

Keywords: *Spinal anaesthesia, Hypotension, Ondansetron, Bezold–Jarisch reflex, Bradycardia.*

INTRODUCTION

Spinal anaesthesia has remained one of the most frequently employed regional anaesthesia techniques worldwide since its introduction by August Bier in 1898. It is considered safe, cost-effective, and reliable, providing profound analgesia and muscle relaxation for surgeries involving the lower abdomen, pelvis, and lower extremities. Compared to general anaesthesia, it offers advantages such as rapid onset, minimal drug requirement, superior postoperative pain relief,

decreased risk of aspiration, early ambulation, and reduced opioid consumption. These factors contribute to its widespread use across various surgical specialties.[1]

However, spinal anaesthesia is not without complications. The most significant and common hemodynamic disturbances associated with it are **hypotension and bradycardia**. Reported incidences range from 30–40% in non-obstetric surgical populations to nearly 60% in obstetric patients. Hypotension is typically defined as either a decrease in systolic blood pressure (SBP) ≥20% from baseline or an absolute SBP <100 mmHg. It arises primarily due to sympathetic blockade leading to systemic vasodilatation, decreased venous return, and reduced cardiac output. Additionally, activation of the **Bezold-Jarisch Reflex (BJR)**—a cardioinhibitory response mediated by serotonin (5-HT_3) receptors in the heart—further contributes to the triad of hypotension, bradycardia, and vasodilation.[2]

The clinical implications of spinal anaesthesia-induced hypotension (SAIH) are considerable. Even transient hypotension can compromise organ perfusion, potentially resulting in myocardial ischaemia, cerebral hypoperfusion, acute kidney injury, or increased perioperative morbidity. The elderly, patients with cardiovascular comorbidities, and parturients are particularly vulnerable. Therefore, strategies to prevent or attenuate SAIH have been the focus of continuous research.[3]

Preventive measures include preloading and co-loading with crystalloids or colloids, pharmacologic support with vasopressors such as phenylephrine or ephedrine, physical measures like leg wrapping or Trendelenburg positioning, and pharmacological adjuvants targeting the pathophysiology of SAIH. In this regard, **ondansetron**, a selective 5-HT_3 receptor antagonist widely used for prophylaxis of postoperative nausea and vomiting (PONV), has gained interest.[4]

The rationale stems from its ability to block 5-HT_3 receptors implicated in the BJR. Serotonin released in the left ventricle during reduced venous return activates these receptors, inducing bradycardia and vasodilation. Ondansetron antagonises these receptors, potentially blunting the reflex and stabilising hemodynamics. Several studies have explored this concept. Marashi et al.[5] (2013) showed that ondansetron significantly reduced hypotension and bradycardia. Similarly, Shah et al. (2016)[6] demonstrated a lower incidence of hypotension and vasopressor requirement with prophylactic ondansetron in elderly patients. More recently, Bhiwal et al.[7] (2021) reported favourable outcomes in parturients undergoing caesarean delivery.

Despite encouraging evidence, results remain inconsistent. For example, Salih et al.[8] (2021) found no significant difference in hypotension rates but reported reduced shivering with ondansetron. Variability in patient populations, drug dosages, timing of administration, and definitions of hypotension contribute to these discrepancies. Furthermore, data from non-obstetric Indian populations are limited, particularly from the Kumaon region.

Given the high prevalence of SAIH and the potential dual benefit of ondansetron (hemodynamic stability and antiemesis), this study was undertaken to evaluate the prophylactic effect of intravenous ondansetron compared with placebo in adult patients undergoing elective non-obstetric surgeries under spinal anaesthesia.

The primary outcome was the incidence of hypotension. Secondary outcomes included incidence of bradycardia, vasopressor requirement, nausea, vomiting, and shivering. By analysing these parameters, the study aimed to clarify ondansetron's role in routine anaesthesia practice and its possible integration into standard preventive strategies for SAIH.

AIM AND OBJECTIVES

Aim

To evaluate the effect of **prophylactic intravenous ondansetron** on the incidence of spinal anaesthesia-induced hypotension in adult patients undergoing elective non-obstetric surgeries, as compared with placebo.

Objectives

Primary Objective:

- To determine the effectiveness of intravenous ondansetron (4 mg) in preventing **spinal anaesthesia-induced hypotension**.

Secondary Objectives:

1. To assess the impact of ondansetron on the incidence of **bradycardia** during spinal anaesthesia.
2. To evaluate the requirement of **vasopressor support (mephentermine)** in patients receiving ondansetron versus placebo.
3. To compare the occurrence of **nausea, vomiting, and shivering** between the two groups.

MATERIALS AND METHODS

Study Design and Setting

This was a **prospective, randomised, double-blind comparative study** conducted at the Department of Anaesthesiology, Critical Care, Pain and Palliative Medicine, Government Medical College and Dr. Sushila Tiwari Government Hospital,

Haldwani (Uttarakhand). The study duration was 18 months following approval from the Institutional Ethics Committee (IEC Reg. No. 744/IEC/R-06-09-2023) and registration with the Clinical Trials Registry of India (CTRI/2024/03/063398).

Sample Size

A total of **76 patients** fulfilling the eligibility criteria were enrolled and randomised into two equal groups (n=38 each).

Inclusion Criteria

- Adult patients aged 18–60 years
- American Society of Anesthesiologists (ASA) physical status I or II
- BMI 18.5–24.9 kg/m²
- Elective non-obstetric surgeries under spinal anaesthesia

Exclusion Criteria

- Patient refusal
- Pregnancy
- Contraindications to spinal anaesthesia (e.g., spinal deformities, infection at puncture site)
- Known hypersensitivity to ondansetron
- Comorbidities (hypertension, diabetes, asthma, conduction blocks, tuberculosis)
- Conversion to general anaesthesia

Randomisation and Blinding

Group allocation was achieved using opaque sealed envelopes. Patients were randomly assigned into:

- **Group A (Control):** 10 ml of 0.9% normal saline IV
- **Group B (Ondansetron):** 4 mg ondansetron diluted in 10 ml normal saline IV

Both the patient and the assessing anaesthesiologist were blinded to group allocation.

Procedure

All patients enrolled in the study were admitted to the preoperative area after confirming fasting status of at least eight hours and fitness for anaesthesia. An 18-gauge intravenous cannula was secured in a peripheral vein under aseptic precautions. Each patient was preloaded with **Ringer's Lactate solution at a dose of 20 ml/kg** over 15–20 minutes prior to the initiation of spinal anaesthesia to counteract the anticipated reduction in venous return and to minimise the risk of spinal anaesthesia-induced hypotension. Standard monitoring devices were attached, including a non-invasive blood pressure (NIBP) cuff, continuous electrocardiography (ECG), and a pulse oximeter (SpO_2), and baseline readings were recorded for all parameters.

The study drug was prepared by an independent anaesthesia assistant not involved in patient assessment. It was administered intravenously as a slow bolus injection over 10 seconds, five minutes before initiation of spinal anaesthesia. Patients in the ondansetron group received **4 mg ondansetron diluted in 10 ml of normal saline**, while those in the control group received **10 ml of normal saline** only.

Spinal anaesthesia was administered with the patient in a sitting position. After strict aseptic preparation and draping, a midline lumbar puncture was performed at the **L3–L4 intervertebral space** using a 25G Quincke spinal needle. Once free flow of cerebrospinal fluid (CSF) was obtained, **3.0 ml of 0.5% hyperbaric bupivacaine** was injected intrathecally over 10–15 seconds. The needle was withdrawn, and patients were immediately positioned supine to ensure uniform cephalad spread of the local anaesthetic.

Hemodynamic parameters, namely **systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), and oxygen saturation (SpO_2)**, were continuously monitored and documented at predefined intervals. Readings were taken at baseline (prior to spinal injection), then every three minutes for the first 15 minutes, and subsequently at five-minute intervals until 30 minutes post-block.

Adverse hemodynamic events were managed according to standard protocol. **Hypotension**, defined as a fall in SBP of ≥20% from baseline, was promptly treated with intravenous boluses of **mephentermine 6 mg**. **Bradycardia**, defined as HR <50 beats per minute, was managed with **intravenous atropine 0.6 mg**. Incidences of **nausea, vomiting, and shivering** were also recorded throughout the perioperative period and documented for comparison between groups.

Statistical Analysis

All collected data were compiled, coded, and entered into a Microsoft Excel spreadsheet and subsequently analysed using Statistical Package for Social Sciences (SPSS) version 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables such as age, weight, height, body mass index (BMI), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR) were expressed as mean ± standard deviation (SD). The comparison of these continuous parameters between the two study groups (ondansetron vs. control) was performed using the unpaired Student's t-test after confirming normal distribution of data. Categorical variables, including sex distribution, ASA physical status,

incidence of hypotension, bradycardia, nausea, vomiting, shivering, and requirement of vasopressors, were expressed as numbers and percentages. These were analysed using the Chi-square test or Fisher's exact test, as appropriate, depending on the expected frequency of values in contingency tables. For all statistical tests, a p-value <0.05 was considered to indicate statistical significance.

RESULTS

Table 1. Demographic and baseline characteristics

Parameter	Ondansetron Group (n=38)	Control Group (n=38)	p-value
Age (years, mean ± SD)	38.9 ± 11.8	38.0 ± 11.5	0.73
Sex (M/F)	25/13	27/11	0.64
ASA Grade I/II	8/30	7/31	0.73
BMI (kg/m²)	20.52 ± 1.83	20.53 ± 1.68	0.98

The demographic and baseline characteristics of patients in the two groups were comparable, ensuring proper randomisation and eliminating selection bias. The mean age of participants in the ondansetron group was 38.9 ± 11.8 years, while in the control group it was 38.0 ± 11.5 years, with no statistically significant difference (p = 0.73). The sex distribution also showed similarity between groups, with a male-to-female ratio of 25:13 in the ondansetron group and 27:11 in the control group (p = 0.64). Most patients in both groups belonged to ASA physical status II (78.9% in the ondansetron group vs. 81.6% in the control group), while the remainder were ASA I; this difference was not significant (p = 0.73). The mean body mass index (BMI) was almost identical between the groups (20.52 ± 1.83 vs. 20.53 ± 1.68, p = 0.98). These findings confirm that both groups were well matched in terms of baseline demographic and clinical characteristics, thus allowing a valid comparison of outcomes without confounding due to patient variability.

Table 2. Systolic blood pressure trends (mmHg)

Time	Ondansetron (mean ± SD)	Control (mean ± SD)	p-value
Baseline	121.3 ± 18.9	121.4 ± 11.6	0.98
6 min	112.9 ± 14.7	96.6 ± 24.1	0.001*
12 min	111.1 ± 13.1	96.5 ± 23.7	0.002*
20 min	109.3 ± 14.0	95.2 ± 22.2	0.001*
30 min	110.6 ± 14.0	94.0 ± 20.9	<0.001*

Systolic blood pressure (SBP) remained significantly better maintained in the ondansetron group compared to controls throughout the observation period. At baseline, SBP values were nearly identical between groups (121.3 vs. 121.4 mmHg, p = 0.98), confirming comparability. However, beginning at 6 minutes post-spinal block, the control group exhibited a marked and persistent decline in SBP, with mean values significantly lower than those in the ondansetron group at all subsequent time points (p < 0.01). By 30 minutes, mean SBP in the ondansetron group was 110.6 ± 14.0 mmHg, whereas it fell to 94.0 ± 20.9 mmHg in controls (p < 0.001). These results indicate that ondansetron provided greater hemodynamic stability by attenuating the fall in systolic blood pressure following spinal anaesthesia.

Table 3. Mean arterial pressure (MAP, mmHg)

Time	Ondansetron (mean ± SD)	Control (mean ± SD)	p-value
Baseline	91.1 ± 15.9	93.4 ± 7.9	0.42
6 min	85.5 ± 14.6	72.2 ± 13.5	<0.001*
15 min	81.9 ± 13.6	71.7 ± 12.9	0.001*
30 min	83.4 ± 13.9	70.6 ± 12.3	<0.001*

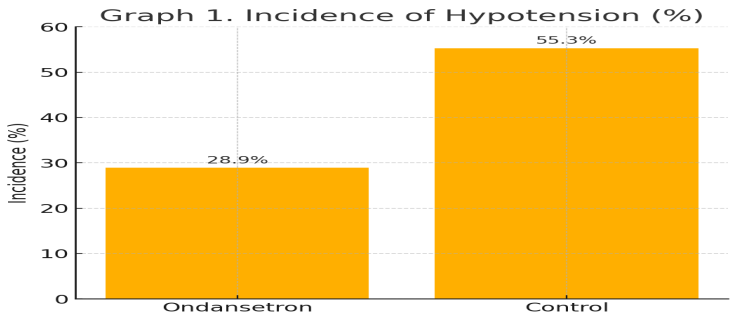
The mean arterial pressure (MAP) values at baseline were comparable between the two groups (91.1 vs. 93.4 mmHg, p = 0.42). Following spinal anaesthesia, patients in the control group experienced a more pronounced decline in MAP compared to those who received ondansetron. At 6 minutes, MAP dropped significantly in the control group (72.2 ± 13.5 mmHg) versus the ondansetron group (85.5 ± 14.6 mmHg, p < 0.001). This trend persisted throughout the monitoring period, with ondansetron consistently maintaining higher MAP values at 15 minutes (81.9 vs. 71.7 mmHg, p = 0.001) and 30 minutes (83.4 vs. 70.6 mmHg, p < 0.001). These findings clearly demonstrate that prophylactic ondansetron contributed to improved maintenance of perfusion pressure and overall hemodynamic stability compared to placebo.

Table 4. Incidence of hypotension, bradycardia, and adverse effects

Variable	Ondansetron Group (%)	Control Group (%)	p-value
Hypotension	28.9	55.3	0.02*
Bradycardia	7.9	26.3	0.03*
Nausea	7.9	34.2	0.005*

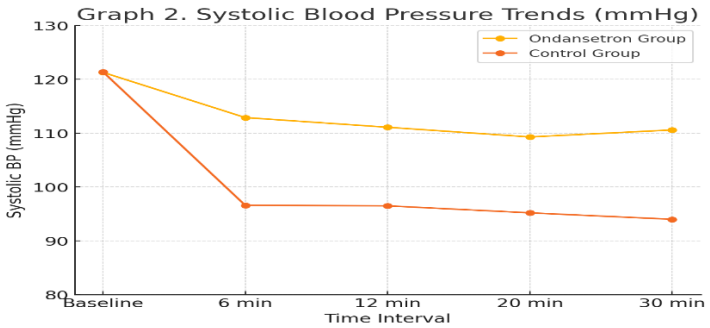
Vomiting	5.3	10.5	0.47
Shivering	13.2	18.4	0.56
Mephentermine use	21.1	47.4	0.01*

The incidence of adverse hemodynamic and perioperative events was notably lower in the ondansetron group compared to controls. Hypotension occurred in 28.9% of patients receiving ondansetron versus 55.3% in the control group (p = 0.02), while bradycardia was also significantly reduced (7.9% vs. 26.3%, p = 0.03). Similarly, the incidence of nausea was markedly lower with ondansetron (7.9% vs. 34.2%, p = 0.005). No significant differences were observed for vomiting (5.3% vs. 10.5%, p = 0.47) or shivering (13.2% vs. 18.4%, p = 0.56). Importantly, the requirement for vasopressor support with mephentermine was significantly reduced in the ondansetron group (21.1% vs. 47.4%, p = 0.01). These findings demonstrate that prophylactic ondansetron not only reduced the incidence of spinal anaesthesia-induced hypotension and bradycardia but also improved patient comfort by lowering nausea and decreasing vasopressor requirement.



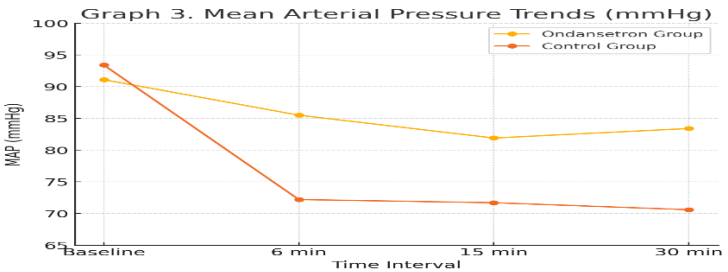
Graph 1. Incidence of Hypotension (%)

The incidence of hypotension was significantly lower in patients who received prophylactic ondansetron compared to the control group (28.9% vs. 55.3%). This demonstrates that ondansetron effectively reduced the occurrence of spinal anaesthesia-induced hypotension by nearly half, highlighting its protective role in maintaining perioperative hemodynamic stability.



Graph 2. Systolic Blood Pressure Trends (mmHg)

At baseline, systolic blood pressure (SBP) was almost identical between the two groups (**121.3 mmHg in the ondansetron group vs. 121.4 mmHg in the control group; difference 0.1 mmHg**), confirming comparability. However, following spinal anaesthesia, the control group showed a marked and sustained decline in SBP, while the ondansetron group maintained relatively stable values. By 30 minutes, the mean SBP remained above **110 mmHg** in the ondansetron group compared to only **94 mmHg** in controls, indicating that ondansetron effectively attenuated the fall in systolic pressure and preserved hemodynamic stability.



Graph 3. Mean Arterial Pressure Trends (mmHg)

DISCUSSION

The present study demonstrated that prophylactic intravenous ondansetron significantly reduced the incidence of spinal anaesthesia-induced hypotension (SAIH), bradycardia, and nausea while lowering vasopressor requirement. Hemodynamic stability, reflected by higher SBP, DBP, and MAP values, was better maintained in the ondansetron group compared to placebo.

Baseline demographic characteristics, including age, sex, ASA grading, and BMI, were comparable between the two groups, ensuring that outcome differences could be attributed to the intervention rather than confounding factors. Similar findings of balanced baseline demographics have been reported in studies by **Raghu et al.[9] (2019)** and **Bhiwal et al.[7] (2021)**, both of which also highlighted the importance of proper randomisation in trials evaluating ondansetron's prophylactic role.

In our study, the incidence of hypotension was significantly lower in the ondansetron group (28.9%) compared to controls (55.3%, $p = 0.02$). These findings are consistent with **Marashi et al.[5] (2013)**, who reported that none of the patients receiving ondansetron developed hypotension, compared to 12% in the placebo group. Similarly, **Shah et al.[6] (2016)** demonstrated reduced hypotension in elderly patients (46% with ondansetron vs. 68% with placebo). Bradycardia was also significantly reduced in our study (7.9% vs. 26.3%, $p = 0.03$). This aligns with **Raghu et al.[9] (2019)**, who reported fewer cases of bradycardia in the ondansetron group (4 patients) compared to controls (13 patients, $p = 0.0176$).

Regarding nausea, the ondansetron group showed a markedly lower incidence (7.9% vs. 34.2%, $p = 0.005$). This antiemetic effect is well documented in literature; **Baig et al.[10] (2017)** similarly observed a significant reduction in nausea and vomiting with ondansetron compared to placebo. Vomiting and shivering, however, were not significantly different between groups in our study. This finding is comparable to **Salih et al.[8] (2021)**, who also reported no significant effect of ondansetron on vomiting but observed reduced shivering. Conversely, **Devkota et al[11] (2021)** demonstrated significant reduction in shivering among obstetric patients, highlighting possible population-specific differences.

The requirement for mephentermine was significantly lower in the ondansetron group (21.1% vs. 47.4%, $p = 0.01$), which is comparable to findings by **Mendonça et al.[12] (2021)**, who reported significantly lower ephedrine requirements among patients receiving ondansetron.

Our study showed that systolic blood pressure was significantly better maintained in the ondansetron group from 6 minutes onwards, with mean values consistently above 110 mmHg compared to <100 mmHg in controls ($p < 0.01$ at all time points). These results are supported by **Shah et al.[6] (2016)**, who also demonstrated that SBP was significantly higher in the ondansetron group at multiple intervals post-spinal anaesthesia. Similarly, **Devkota et al.[11] (2021)** observed that SBP values were significantly preserved with ondansetron, particularly between 3–18 minutes after spinal anaesthesia in caesarean section patients.

Mean arterial pressure (MAP) was also significantly higher in the ondansetron group at 6, 15, and 30 minutes compared with controls. At 30 minutes, mean MAP was **83.4 mmHg** in the ondansetron group versus **70.6 mmHg** in controls ($p < 0.001$). These results are in agreement with **Baig et al.[10] (2017)**, who reported significantly fewer episodes of hypotension and higher MAP values in the ondansetron group. In contrast, **Owczuk et al.[13] (2015)** found no significant reduction in the incidence of hypotension with ondansetron in elderly patients, although they noted a smaller decline in SBP and MAP, suggesting at least partial benefit.

Taken together, the results of our study reinforce the evidence that prophylactic ondansetron reduces the incidence and severity of spinal anaesthesia-induced hypotension and bradycardia, decreases the need for vasopressor support, and provides the added benefit of reducing nausea. The mechanism is attributable to antagonism of serotonin-mediated **Bezold–Jarisch Reflex (BJR)**, preventing vagally mediated bradycardia and vasodilation.

Limitations

Our study had some limitations. The relatively small sample size ($n = 76$) limited the power of subgroup analyses. High-risk groups such as elderly patients >60 years, obstetric patients, and those with comorbidities were excluded, which may restrict generalisability. Monitoring was limited to 30 minutes, whereas spinal anaesthesia-induced hypotension may persist beyond this period. Future large-scale, multicentric studies including diverse populations are required to confirm the general applicability of these findings.

CONCLUSION

Prophylactic administration of **4 mg intravenous ondansetron** significantly reduced the incidence of **spinal anaesthesia-induced hypotension, bradycardia, and nausea**, while improving hemodynamic stability and decreasing vasopressor requirement compared with placebo. No major adverse effects were observed. Given its widespread availability, safety

profile, and additional antiemetic benefits, ondansetron represents a simple and effective strategy to mitigate SAIH in routine anaesthesia practice. Larger, multicentric studies including diverse patient groups are recommended to further validate these findings.

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