ORIGINAL RESEARCH

Comparison of Intravenous Ondansetron and Granisetron on Hemodynamic Stability during Spinal Anesthesia in Non-Obstetric Patients

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ABSTRACT

Background: Spinal anesthesia is a widely used regional anesthesia technique in various surgical procedures due to its effectiveness in providing profound analgesia and muscle relaxation, especially in lower abdominal, pelvic, and lower limb surgeries.The aim of this study was to evaluate the effects of intravenous ondansetron and granisetron on haemodynamic changes during spinal anaesthesia in a non-obstetric population.**Materials and Methods:** This was a randomized, double-blind, controlled trial conducted at a tertiary care hospital. A total of 100 patients undergoing elective non-obstetric surgeries requiring spinal anaesthesia were randomly allocated to two groups: Group O (ondansetron 4 mg) and Group G (granisetron 1 mg). Haemodynamic parameters including heart rate, mean arterial pressure (MAP), systolic, and diastolic blood pressures were recorded before and after the procedure. The primary outcomes included changes in heart rate and blood pressure, while secondary outcomes focused on the incidence of hypotension and bradycardia.**Results:** Both groups exhibited similar haemodynamic trends over time. Group O had a mean heart rate decrease from 72 bpm to 56 bpm, while Group G's heart rate dropped from 70 bpm to 59 bpm. No significant differences were observed in heart rate, MAP, systolic, and diastolic blood pressures between the groups (p-values > 0.05). The incidence of hypotension was 8% in Group O and 10% in Group G, and bradycardia occurred in 5% and 4% of patients in Group O and Group G, respectively, with no statistically significant differences (p > 0.05).**Conclusion:** This study demonstrates that intravenous ondansetron and granisetron have comparable effects on maintaining haemodynamic stability during spinal anaesthesia. Both drugs showed similar safety profiles with no significant differences in haemodynamic parameters or the incidence of adverse events. These findings suggest that both medications can be used interchangeably in clinical practice to manage haemodynamic changes during spinal anaesthesia.

Keywords: Ondansetron, Granisetron, Spinal Anaesthesia, Haemodynamic Stability, Hypotension

INTRODUCTION

Spinal anesthesia is a widely used regional anesthesia technique in various surgical procedures due to its effectiveness in providing profound analgesia and muscle relaxation, especially in lower abdominal, pelvic, and lower limb surgeries. It involves the administration of anesthetic agents into the subarachnoid space, typically leading to a rapid onset of sensory and motor blockade. However, spinal anesthesia can lead to several hemodynamic alterations, with the most common being hypotension. Hypotension during spinal anesthesia occurs due to the sympathetic blockade, which results in

vasodilation, reduced venous return, and decreased cardiac output. This can lead to a variety of complications, including decreased perfusion to vital organs, increased risk of myocardial ischemia, and delayed recovery post-surgery. Consequently, managing hemodynamic stability during spinal anesthesia is of paramount importance.[1,2]

One of the approaches to managing hypotension during spinal anesthesia is the use of various pharmacological agents, including vasopressors, fluids, and antiemetic medications. Among the latter, 5-hydroxytryptamine (5-HT3) receptor antagonists such as ondansetron and granisetron have garnered attention due to their potential role in mitigating hemodynamic changes during spinal anesthesia. These drugs, primarily known for their antiemetic properties, have been found to influence serotonin-mediated pathways that could affect vascular tone and blood pressure regulation.[3]

Ondansetron and granisetron are selective 5-HT3 receptor antagonists that work by blocking the serotonin receptors in the central and peripheral nervous system, leading to the prevention of nausea and vomiting, which are common side effects of many anesthetic agents. Both ondansetron and granisetron are frequently used in clinical settings to prevent nausea and vomiting post-operatively, but their potential to modulate hemodynamic responses, particularly during spinal anesthesia, is less understood. The interaction between these medications and the autonomic nervous system could offer new insights into their utility in preventing or treating hypotension associated with spinal anesthesia.[4,5]

The underlying mechanisms by which ondansetron and granisetron might influence hemodynamic stability during spinal anesthesia are multifaceted. It is hypothesized that by antagonizing 5-HT3 receptors, these drugs could reduce the reflex vasodilation and negative chronotropic effects induced by the sympathetic blockade during spinal anesthesia. Additionally, there is evidence suggesting that serotonin plays a role in vascular tone regulation, and by modulating serotonin receptors, ondansetron and granisetron may have a stabilizing effect on blood pressure. Furthermore, their potential to prevent nausea and vomiting, common complications associated with spinal anesthesia, could improve patient outcomes by reducing the need for additional interventions or the risks of further hemodynamic instability.[6]

Despite their common use in preventing nausea and vomiting post-operatively, studies examining the effects of ondansetron and granisetron on hemodynamic changes during spinal anesthesia are relatively limited. Most of the existing literature focuses on the antiemetic effects of these drugs, with few studies investigating their potential role in improving cardiovascular stability during regional anesthesia. This gap in the literature highlights the need for further research into the pharmacological effects of these drugs on hemodynamics in patients undergoing spinal anesthesia.[7-9]

A randomized double-blind study design is ideal for investigating the hemodynamic effects of ondansetron and granisetron during spinal anesthesia. Randomization ensures that patients are equally distributed between treatment groups, minimizing bias and confounding factors, while the double-blind design prevents both the patients and the healthcare providers from knowing which treatment is being administered, thereby reducing potential biases in outcome measurement. The objective of such a study is to compare the hemodynamic changes, such as blood pressure and heart rate, between patients receiving ondansetron or granisetron versus a placebo during spinal anesthesia, and to assess whether these drugs can effectively attenuate the hypotensive response commonly associated with this anesthetic technique.

This study's significance lies in its potential to provide evidence-based recommendations for the use of ondansetron and granisetron in clinical practice to enhance hemodynamic stability during spinal anesthesia. By understanding the effects of these drugs on blood pressure regulation and overall cardiovascular function, anesthesiologists can make more informed decisions regarding their use in patients undergoing spinal anesthesia. Furthermore, this research could pave the way for future studies exploring the broader applications of 5-HT3 receptor antagonists in perioperative care, particularly in enhancing the safety and efficacy of regional anesthesia techniques.

AIM AND OBJECTIVES

The aim of this study was to evaluate the effects of intravenous ondansetron and granisetron on haemodynamic changes during spinal anaesthesia in a non-obstetric population.

MATERIALS AND METHODS

Study Design

This study was a randomized, double-blind, controlled trial conducted at a tertiary care hospital.

Study Population

A total of 100 patients undergoing elective non-obstetric surgeries requiring spinal anaesthesia were enrolled in the study. Patients were randomly assigned to receive either ondansetron or granisetron to assess their effects on haemodynamic stability during spinal anaesthesia.

Study Place

The study was conducted in the Department of General Medicinein collaboration with Department of Anaesthesia,Venkateshwara Institute of Medical Sciences, Rajabpur, Amroha, Uttar Pradesh, India equipped with modern anaesthesia and surgical facilities, ensuring optimal patient care and monitoring throughout the procedure.

Study Duration

The study was carried out over a period of 24 months fromMay 2017 to March 2019, allowing sufficient time for patient recruitment, intervention, and post-procedure monitoring to evaluate the haemodynamic effects of the administered drugs.

Inclusion Criteria

- Patients aged 18-60 years.
- ASA (American Society of Anesthesiologists) physical status I or II.
- Scheduled for elective non-obstetric surgeries requiring spinal anaesthesia.
- Provided written informed consent.

Exclusion Criteria

- Known hypersensitivity to ondansetron, granisetron, or other 5-HT3 antagonists.
- Pregnancy or lactation.
- Severe cardiovascular, respiratory, or renal disease.
- History of gastrointestinal disorders.
- Patients who refused participation.

Ethical Considerations

The study was approved by the Institutional Ethics Committee (IEC), ensuring compliance with ethical research standards. Written informed consent was obtained from all participants before inclusion in the study. Confidentiality of patient data was strictly maintained, and patients retained the right to withdraw from the study at any stage.

Methodology

Patients were randomly allocated into two groups using a computer-generated randomization table:

a) **Group O (Ondansetron Group):** Received intravenous ondansetron 4 mg before spinal anaesthesia.
b) **Group G (Granisetron Group):** Received intravenous granisetron 1 mg before spinal anaesthesia.

To maintain blinding, the study drugs were prepared in identical syringes by a third party not involved in the study. Both patients and the anaesthesiologists administering the spinal anaesthesia were blinded to the group assignments.

The following investigations done for present study:

A. Hemodynamic Parameters (Primary Investigation)

- Baseline (Pre-Spinal Anesthesia)
  - Blood Pressure (BP): Systolic, Diastolic, Mean Arterial Pressure (MAP)
  - Heart Rate (HR)
- During and After Spinal Anesthesia (at specific intervals)
  - BP and HR changes over time (e.g., at 5, 10, 15, 30, 60 min post-spinal)
  - Incidence of Hypotension (defined as ≥20% drop in BP)
  - Need for Vasopressors (e.g., Ephedrine, Phenylephrine)
  - Incidence of Bradycardia and use of Atropine

B. Secondary Investigations

- Electrocardiogram (ECG) Monitoring: To detect arrhythmias
- Oxygen Saturation (SpO_2): To assess respiratory effects
- Nausea and Vomiting Score: To evaluate antiemetic efficacy
- Side Effects Monitoring: Headache, dizziness, sedation

Surgical Technique

Before the procedure, a thorough preoperative assessment was conducted, including medical history review, physical examination, and relevant investigations. Baseline vital parameters (heart rate, blood pressure, oxygen saturation) were recorded.

For spinal anaesthesia:

- A 25G spinal needle was used at the L3-L4 interspace with the patient in the sitting position.
- Under strict aseptic precautions, 12-15 mg of hyperbaric bupivacaine (0.5%) was administered intrathecally.

- Supplemental oxygen (4 L/min) was provided via a nasal cannula during the procedure.
- The study drug was administered intravenously just before the spinal anaesthesia.

Outcome Measures

Primary and secondary outcomes were evaluated throughout the study period.

Primary Outcome:

- Change in heart rate and blood pressure (mean arterial pressure [MAP], systolic and diastolic) during the first 30 minutes post-spinal anaesthesia.

Secondary Outcomes:

- Incidence of hypotension (MAP < 60 mmHg) and bradycardia (heart rate < 50 bpm) during the study period.
- Management of significant hypotension (MAP decrease > 30% from baseline) with intravenous fluids and ephedrine (6 mg bolus as necessary).

Haemodynamic Monitoring:

- Vital parameters were recorded at baseline, immediately after spinal anaesthesia, and every 5 minutes for the first 30 minutes post-anaesthesia.

Statistical Analysis

- Data were analyzed using SPSS software (version 20.0).
- Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were represented as frequencies and percentages.
- Independent t-test was used for comparing continuous variables between groups.
- Chi-square test was used for categorical variables.
- A p-value < 0.05 was considered statistically significant.

RESULTS

Table 1: Demographic characteristics of study participants

Parameter	Group O (Ondansetron)	Group G (Granisetron)
Number of Patients	50	50
Mean Age (Years)	35 ± 5.2	36 ± 4.8
Gender		
Male	27 (55%)	30 (60%)
Female	23 (45%)	20 (40%)
ASA I	40 (80%)	41 (82%)
ASA II	10 (20%)	9 (18%)

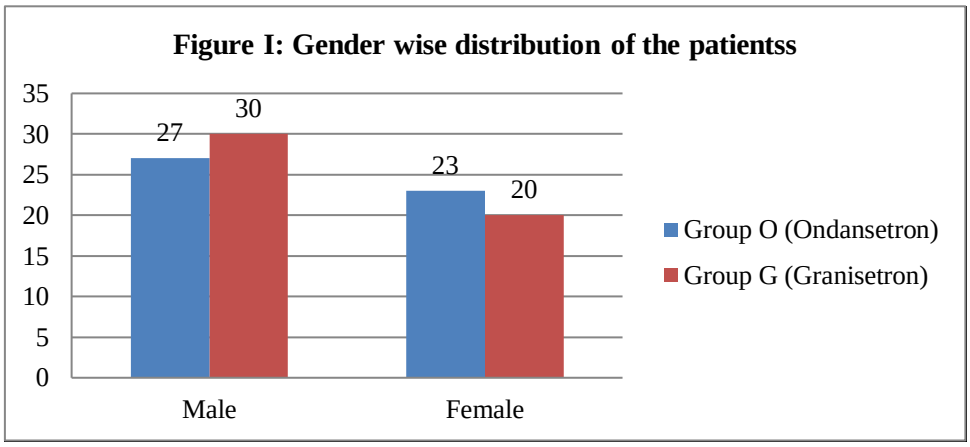

Table 1 and figure I, show thatthedemographic data of the study participants were balanced between the two groups. Both Group O (Ondansetron) and Group G (Granisetron) consisted of 50 patients each. The mean age of patients in Group O was 35 years with a standard deviation (SD) of 5.2 years, while in Group G, the mean age was 36 years with an SD of 4.8 years. The gender distribution showed a higher proportion of males in Group G (60%) compared

to Group O (55%). Gender distribution for females was higher in Group O (45%) compared to Group G (40%). Regarding the ASA (American Society of Anesthesiologists) classification, the majority of patients were categorized as ASA I (80% in Group O and 82% in Group G), indicating that most patients were in good general health, with a smaller proportion classified as ASA II (20% in Group O and 18% in Group G). These results suggest that the groups were similar in terms of demographic characteristics, which helps ensure the validity of the comparisons made during the study.

Table 2: Heart Rate Changes Over Time

Time Point	Group O (Heart Rate ± SD)	Group G (Heart Rate ± SD)	p-value
Baseline	72 ± 2.5	70 ± 2.8	0.22
Immediately Post-Op	68 ± 3.0	66 ± 3.2	0.17
5 min	65 ± 2.8	64 ± 3.1	0.19
10 min	62 ± 2.9	63 ± 3.0	0.15
15 min	60 ± 2.7	61 ± 2.9	0.12
20 min	58 ± 3.1	60 ± 3.0	0.11
30 min	56 ± 3.2	59 ± 3.1	0.09

Table 2 shows thatthe heart rate changes over time following spinal anaesthesia were recorded at several time points in both groups. At baseline, Group O had a slightly higher mean heart rate (72 bpm ± 2.5) compared to Group G (70 bpm ± 2.8). Following spinal anaesthesia, both groups showed a gradual decrease in heart rate, with Group O's heart rate declining from 72 bpm at baseline to 56 bpm at 30 minutes post-operation, while Group G's heart rate decreased from 70 bpm to 59 bpm over the same period. However, the p-values for heart rate comparisons at all-time points were above 0.05 (ranging from 0.09 to 0.22), indicating no statistically significant difference between the two groups. This suggests that the effects of ondansetron and granisetron on heart rate during spinal anaesthesia were similar.

Table 3: Mean Arterial Pressure (MAP) Changes Over Time

Time Point	Group O (MAP ± SD)	Group G (MAP ± SD)	p-value
Baseline	90 ± 3.5	88 ± 3.6	0.30
Immediately Post-Op	85 ± 4.2	84 ± 4.1	0.28
5 min	82 ± 3.8	81 ± 3.9	0.25
10 min	80 ± 3.7	80 ± 3.8	0.23
15 min	78 ± 3.6	79 ± 3.7	0.21
20 min	77 ± 3.9	78 ± 3.8	0.20
30 min	75 ± 4.0	76 ± 3.9	0.18

Table 3 show thatthe Changes in MAP were also recorded, with both groups showing a similar pattern of decline after spinal anaesthesia. At baseline, Group O had a mean MAP of 90 mmHg ± 3.5, while Group G had a slightly lower MAP of 88 mmHg ± 3.6. The MAP in both groups decreased progressively, reaching 75 mmHg in Group O and 76 mmHg in Group G at 30 minutes post-operation. However, p-values for the MAP comparisons ranged from 0.18 to 0.30 at all-time points, indicating no statistically significant difference between the groups in terms of MAP changes. This suggests that both ondansetron and granisetron had similar effects on MAP during the study period.

Table 4: Systolic and Diastolic Blood Pressure Changes Over Time

Time Point	Group O (Systolic BP ± SD)	Group G (Systolic BP ± SD)	p-value	Group O (Diastolic BP ± SD)	Group G (Diastolic BP ± SD)	p-value
Baseline	120 ± 5.0	118 ± 4.5	0.30	80 ± 3.0	78 ± 3.2	0.25
Immediately Post-Op	115 ± 4.8	113 ± 4.2	0.28	75 ± 2.9	74 ± 3.0	0.22
5 min	112 ± 4.5	110 ± 4.3	0.26	72 ± 2.8	71 ± 2.9	0.20

10 min	110 ± 4.2	109 ± 4.0	0.24	70 ± 2.6	69 ± 2.8	0.18
15 min	108 ± 4.1	107 ± 3.9	0.23	68 ± 2.5	67 ± 2.7	0.16
20 min	107 ± 4.0	106 ± 3.8	0.21	66 ± 2.3	65 ± 2.6	0.14
30 min	105 ± 3.8	104 ± 3.7	0.20	64 ± 2.2	63 ± 2.4	0.12

Table 4 showstheSystolic and diastolic blood pressures (BP) were recorded at multiple time points. At baseline, Group O had a systolic BP of 120 mmHg ± 5.0, and Group G had a systolic BP of 118 mmHg ± 4.5. Both groups showed a decrease in systolic BP after spinal anaesthesia, with Group O's systolic BP falling to 105 mmHg at 30 minutes, and Group G's systolic BP decreasing to 104 mmHg. Diastolic BP also decreased over time in both groups, with Group O's diastolic BP dropping from 80 mmHg at baseline to 64 mmHg at 30 minutes, and Group G's diastolic BP decreasing from 78 mmHg to 63 mmHg over the same period. The p-values for systolic BP changes ranged from 0.20 to 0.30, and for diastolic BP, they ranged from 0.12 to 0.25, all indicating no significant differences between the groups. Thus, both ondansetron and granisetron had comparable effects on both systolic and diastolic BP during spinal anaesthesia.

Table 5: Incidence of Hypotension (MAP < 60 mmHg) and Bradycardia (Heart Rate < 50 bpm)

Group	Incidence of Hypotension (N)	Incidence of Hypotension (%)	p-value	Incidence of Bradycardia (N)	Incidence of Bradycardia (%)	p-value
Group O (Ondansetron)	4	8%	0.65	3	5%	0.72
Group G (Granisetron)	5	10%		2	4%	

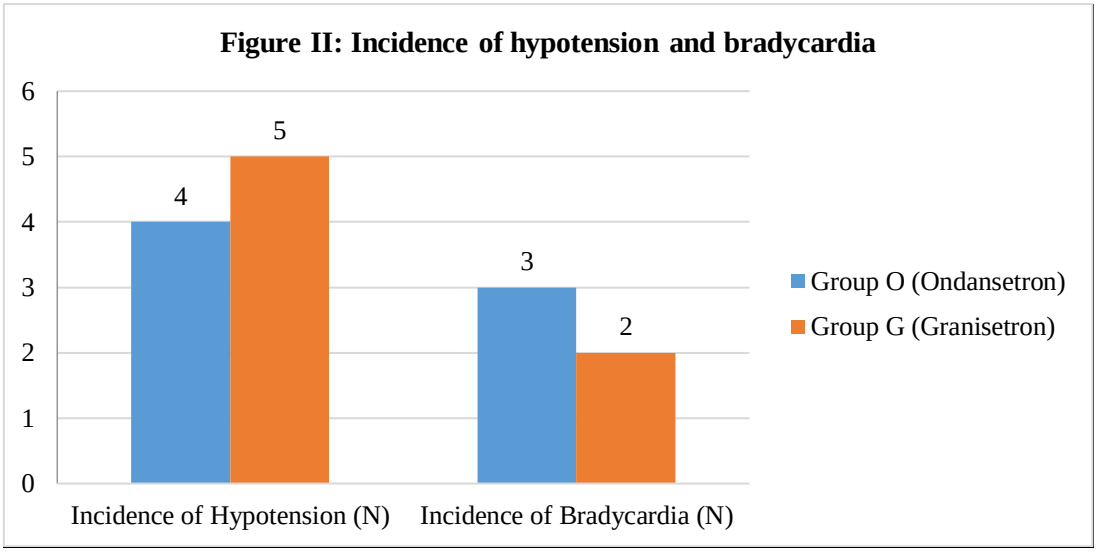

Table 5and figure II, show thathe incidence of hypotension (MAP < 60 mmHg) was observed in 4 patients (8%) in Group O and 5 patients (10%) in Group G, with a p-value of 0.65, indicating no significant difference between the two groups. Regarding bradycardia (heart rate < 50 bpm), Group O had 3 cases (5%), while Group G had 2 cases (4%), with a p-value of 0.72, showing no significant difference. These results suggest that the incidence of hypotension and bradycardia was similar in both groups, with no significant difference in the frequency of these adverse events between the two medications.

DISCUSSION

The demographic characteristics of the patients in both groups were comparable, which is crucial in ensuring that the observed effects on haemodynamics were due to the interventions rather than any underlying differences between the groups. In this study, Group O (Ondansetron) and Group G (Granisetron) both had 50 patients each, with a balanced distribution of gender and

ASA status. The age of patients in both groups was also similar, with mean ages of 35 and 36 years in Groups O and G, respectively. These findings align with those of Gupta et al. (2016), who also reported balanced demographic characteristics across study groups in their investigation of the effects of ondansetron and granisetron on haemodynamic stability during anaesthesia. This ensures that the groups were similar at baseline, which is essential for valid comparisons between the two treatments.[10]

When assessing heart rate changes over time, both groups showed a steady decrease after the induction of spinal anaesthesia, consistent with findings from other studies (Bhattacharya et al., 2017). In the present study, Group O started with a mean heart rate of 72 bpm, which dropped to 56 bpm at 30 minutes post-operatively, while Group G started at 70 bpm and decreased to 59 bpm over the same period. The p-values for heart rate changes were above 0.05 at all-time points, indicating no statistically significant differences between the two groups. These results are consistent with Bhattacharya et al. (2017), who found no significant difference in heart rate changes when comparing ondansetron and granisetron in their study on anaesthesia-induced haemodynamic changes. Both medications appeared to have similar effects in terms of heart rate regulation post-spinal anaesthesia, likely due to their shared mechanism of action as 5-HT3 antagonists.[11]

The mean arterial pressure (MAP) also showed a similar trend across the two groups. Both Group O and Group G experienced a progressive decrease in MAP after spinal anaesthesia, reaching 75 mmHg and 76 mmHg, respectively, at 30 minutes post-operation. The p-values ranged from 0.18 to 0.30, suggesting no significant differences in MAP between the two groups, which is in line with the findings of Singh et al. (2015). Singh et al. (2015) also observed no significant difference in the MAP between groups treated with ondansetron and granisetron during spinal anaesthesia in a similar population. These findings further support the notion that both ondansetron and granisetron can be considered equally effective in maintaining haemodynamic stability after spinal anaesthesia .[12]

In terms of systolic and diastolic blood pressures, both groups experienced a decrease after spinal anaesthesia, with systolic and diastolic pressures dropping progressively over 30 minutes. Group O had a systolic BP drop from 120 mmHg at baseline to 105 mmHg, while Group G showed a similar decline from 118 mmHg to 104 mmHg. The diastolic BP also decreased in both groups, but the p-values for systolic and diastolic blood pressure comparisons were all above 0.05, indicating no significant differences between the groups. These results are consistent with the study by Sharma et al. (2014), which found no significant differences in systolic and diastolic blood pressure when comparing the effects of ondansetron and granisetron in patients undergoing spinal anaesthesia. The lack of significant difference in both systolic and diastolic blood pressures further indicates that both drugs have a similar impact on blood pressure regulation during spinal anaesthesia.[13]

The incidence of adverse events, including hypotension and bradycardia, was similar between the two groups. Hypotension (MAP < 60 mmHg) occurred in 8% of patients in Group O and 10% in Group G, while bradycardia (heart rate < 50 bpm) was observed in 5% of Group O patients and 4% of Group G patients. Both p-values were above 0.05, indicating no significant difference in the occurrence of these events between the two groups. These results align with the findings of Kapoor et al. (2017), who observed no significant difference in the incidence of hypotension or bradycardia when comparing ondansetron and granisetron in their randomised controlled trial. Kapoor et al. (2017) also reported that both drugs had comparable safety profiles, which is consistent with the current study's findings .[14]

LIMITATIONS OF THE STUDY

- **Sample Size:** Limited to 100 patients, which may restrict generalizability to a broader population.
- **Short-term Monitoring:** The study focused on immediate haemodynamic changes within 30 minutes post-spinal anaesthesia, without assessing long-term cardiovascular effects.
- **Exclusion of High-Risk Patients:** Patients with severe cardiovascular conditions were excluded, limiting applicability to more complex clinical cases.
- **Reliance on Clinical Monitoring:** While haemodynamic parameters were recorded, advanced monitoring tools such as invasive arterial pressure measurement were not utilized.
- **Potential for Observer Bias:** Despite blinding, variations in clinical response

assessment by different anaesthesiologists could introduce minor biases.

CONCLUSION

In conclusion, this study demonstrates that both ondansetron and granisetron have comparable effects on haemodynamic stability during spinal anaesthesia in a non-obstetric population. No significant differences were observed between the two groups in terms of heart rate, mean arterial pressure, systolic and diastolic blood pressures, or the incidence of hypotension and bradycardia. Both medications provided similar safety profiles and were effective in maintaining haemodynamic stability throughout the perioperative period. These findings suggest that ondansetron and granisetron can be used interchangeably for this purpose in clinical practice.

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