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Comparative study of Prophylactic Intravenous Granisetron vs Ondansetron for reducing Hypotensive episodes during Spinal Anaesthesia for Lower Abdominal Surgeries: A Randomised Concurrent Parallel study

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KEYWORDS

Post-spinal hypotension, Granisetron, Ondansetron, Spinal anaesthesia, Hemodynamic stability, Vasopressor requirement

ABSTRACT:

Background: Post-spinal hypotension is a frequent complication of spinal anaesthesia, requiring effective management to maintain hemodynamic stability. Ondansetron and granisetron, commonly used as antiemetics, have been explored for their potential to mitigate spinal-induced hypotension.

Objectives: To compare the efficacy of prophylactic intravenous granisetron versus ondansetron in reducing the incidence of hypotensive episodes during spinal anaesthesia for lower abdominal surgeries.

Methods: This was a hospital based, single centre, double blinded, randomised controlled, concurrent, parallel study conducted in the Department of Anaesthesiology, Aarupadai Veedu Medical College and Hospital, Puducherry, India between July 2023 and June 2025.

Results: A total of 186 patients having lower abdominal surgery under spinal anaesthesia were randomly assigned into two groups: Group O (Ondansetron, 4 mg) and Group G (Granisetron, 2 mg), with 93 patients each. Baseline characteristics, including age, gender, height, weight, ASA grading, and surgical duration, were comparable between groups ($P > 0.05$). Group O exhibited a significantly faster onset of sensory blockade ($P = 0.034$) and a prolonged duration before sensory regression to T8 ($P < 0.001$). Hemodynamic parameters showed no significant differences in systolic blood pressure (SBP) at any time point ($P > 0.05$). Diastolic blood pressure (DBP) was significantly lower in Group G at 20 and 25 minutes ($P = 0.032$, $P = 0.001$, respectively). Mean arterial pressure (MAP) was consistently higher in Group G from 2 minutes onward ($P < 0.05$), while heart rate was significantly lower in Group G from 15 to 30 minutes ($P < 0.05$). No patients experienced intraoperative or postoperative nausea and vomiting. Ephedrine use was significantly higher in Group O, with 16.1% requiring intervention compared to 7.5% in Group G ($P = 0.039$), and the mean dose was also significantly higher ($P = 0.006$). No patients required atropine or metoclopramide.

Conclusion: These findings suggest that while both drugs effectively prevent nausea and vomiting, Granisetron is associated with greater hemodynamic stability and a lower requirement for ephedrine.

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Introduction

Spinal anaesthesia is a widely used technique for lower abdominal surgeries, providing effective analgesia and muscle relaxation. However, it is commonly associated with certain adverse effects, primarily hypotension and bradycardia, which result from sympathetic blockade induced by the procedure.(1) The occurrence of hypotension during spinal anaesthesia can lead to significant complications, including nausea and vomiting, which are triggered by stimulation of the chemoreceptor trigger zone (CTZ) in the medulla.(2, 3) Bradycardia, another side effect, is due to a shift in the cardiac autonomic balance toward the parasympathetic system following spinal block.(4-6) These hemodynamic disturbances often complicate the perioperative management,(7) leading to the need for effective interventions to prevent or mitigate their impact.

Granisetron and Ondansetron, both 5-hydroxytryptamine 3 (5-HT3) receptor antagonists,(8) have been identified as potential agents in addressing the hypotensive episodes associated with spinal anaesthesia. These drugs block the action of serotonin at the 5-HT3 receptors, which play a critical role in the Bezold–Jarisch reflex (BJR), a mechanism that contributes to the hypotension observed after spinal anaesthesia.(9) “A systematic review and meta-analysis by Heesen et al.(10) aimed to see if 5-HT3 receptor antagonists can reduce hypotension when given before spinal anaesthesia. The analysis of 17 trials showed a significant decrease in hypotension risk with a relative risk (RR) of 0.54. In obstetric patients, the risk dropped more (RR 0.52), with a number needed to treat of 4. The treatment also reduced bradycardia and use of phenylephrine.(10) The BJR is a reflexive response involving vasodilation and bradycardia, which can significantly exacerbate hypotensive events, especially when spinal anaesthesia is employed in patients undergoing lower abdominal surgeries.(11)

Given the potential benefits of 5-HT3 receptor antagonists in reducing spinal anaesthesia-induced hypotension, this study primarily aimed to compare the effectiveness of prophylactic intravenous Granisetron versus Ondansetron in reducing hypotensive episodes during spinal anesthesia for lower abdominal surgeries, while also assessing hemodynamic parameters, incidence of nausea and vomiting, and the need for rescue vasopressors.

Materials and Methods

This was a hospital based, single centre, double blinded, randomised controlled, concurrent, parallel study conducted in the Department of Anaesthesiology, Aarupadai Veedu Medical College and Hospital, Puducherry, India for a duration of 18 months (CTRI/2024/01/062002). The study was approved by the Institutional Human Ethics Committee (IHEC) with reference number AV/IHEC/2023/034 dated 25/05/2023. The participants were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Enrolment into the study proceeded upon receipt of written informed consent. Patients between 18 and 60 years of age, of both gender, ASA I or II, undergoing lower abdominal surgeries were included. However, patients allergic to ondansetron and granisetron; with preexisting cardiac pathology; contraindications for spinal anaesthesia; severe dehydration; and with body mass index more than 30 kg/m2 were excluded.

The sample size was calculated to ensure adequate statistical power to detect a significant difference in hypotension between the two groups. Based on a study by Aksoy et al.,(12) the expected incidence of hypotension was 30% in group 1 and 50% in group 2. Using a 5% significance level (α) and 80% power (1−β), the required sample size was determined to be 93 participants per group, resulting in a total of 186 participants. We enrolled participants using nonprobability sampling technique – purposive sampling/consecutive enumeration. On the day before surgery, the general condition of each patient was examined, and baseline vital signs were recorded. They were instructed to maintain nil per oral status for at least six hours prior to the surgery. On the day of surgery, a peripheral intravenous cannula (18-gauge or 20-gauge) was secured, and baseline vitals were re-evaluated before the procedure. Patients were randomized into two groups – Group O (Ondansetron) and Group G (Granisetron) – using a lot system. Each patient received 500 ml of preloaded Ringer’s lactate intravenously before the administration of the study drug. The anaesthetists

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administered the study drugs 10 minutes prior to the surgery. Patients in Group O received 4 mg of Ondansetron diluted to 10 ml with normal saline, while patients in Group G received 2 mg of Granisetron diluted to 10 ml with normal saline. The drugs were administered intravenously in a double-blinded manner. Spinal anaesthesia was performed in all patients in the lateral position under aseptic precautions. The intervertebral space was identified, and local infiltration of 2% lignocaine was performed. A standard-sized Quincke needle was advanced through the L3-L4 intervertebral space. Once the free flow of cerebrospinal fluid was confirmed, 3 ml of 0.5% hyperbaric bupivacaine was administered. Following the administration of spinal anaesthesia, the patients were placed in the supine position. Sensory block levels were assessed using the pinprick and cold sensation methods, and surgery was initiated when the sensory block reached the T6 dermatome level. Motor block levels were assessed using the modified Bromage scale (0 to 3).

During the intraoperative period, mean arterial pressure (MAP), systolic blood pressure (SBP), and heart rate (HR) were measured every five minutes for the first 30 minutes. Hypotension was defined as a fall in SBP greater than 30% from baseline or MAP less than 60 mmHg. Bradycardia was defined as a heart rate below 50 beats per minute. Intravenous injection of Ephedrine (6 mg) was administered to treat hypotension, while intravenous injection of Atropine (1 mg) was given to treat bradycardia. Nausea and vomiting, both intraoperative and postoperative, were evaluated and treated with intravenous injection of Metoclopramide (10 mg) when necessary. After surgery, the patients' vital signs were recorded and monitored during their transfer to the postoperative ward. Vital parameters were measured at 30-minute intervals for a total of two hours postoperatively. Data on intraoperative and postoperative nausea and vomiting were also documented during this period.

Statistical analysis: The data collected was entered into Microsoft Excel and analyzed using SPSS software version 23. Categorical variables were presented as frequencies and percentages, while continuous variables were summarized using mean with standard deviation, depending on the data's normality, which was checked using the Kolmogorov–Smirnov and Shapiro–Wilk tests. Statistical significance was assessed using the Chi-square test or Fisher's exact test for categorical variables and the independent t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant.

Results

The study enrolled a total of 200 patients, of whom 14 were excluded – 9 for not meeting the inclusion criteria and 5 who declined to participate. The remaining 186 patients were randomly assigned into two groups: Group O (Ondansetron, 4 mg of ondansetron diluted with 10 ml normal saline) and Group G (Granisetron, 2 mg of granisetron diluted with 10 ml normal saline), with 93 patients in each group. All assigned patients received their allocated intervention as per protocol, with no deviations or exclusions. During the follow-up period, there were no cases of loss to follow-up in either group. Consequently, all 93 patients in each group were included in the final analysis, ensuring a complete dataset for statistical evaluation.

The mean age of participants was 41.5 ± 9.6 years in Group O and 41.0 ± 10.3 years in Group G (p=0.735). The majority of participants in both groups were aged above 30 years, accounting for 86.0% in Group O and 83.9% in Group G (p=0.682). Males predominated in both groups, with 71.0% in Group O and 61.3% in Group G (p=0.163). The mean height and weight were also similar between the groups (p=0.685 and p=0.402, respectively). ASA grade I and II distribution was comparable, with no significant difference (p=0.557). The mean duration of surgery was 91.5 ± 16.9 minutes in Group O and 92.4 ± 17.0 minutes in Group G (p=0.723). However, there were significant differences in the time to attain T6 sensory block and the time for regression to T8. Group O achieved T6 sensory level in a mean time of 3.8 ± 0.8 minutes, while Group G took a slightly longer time of 4.0 ± 0.8 minutes (p=0.034). Additionally, regression to T8 was significantly faster in Group G (82.0 ± 21.5 minutes) compared to Group O (98.1 ± 29.1 minutes), with a highly significant p-value of <0.001.

The baseline SBP was 131.6 ± 13.7 mmHg in Group O and 130.0 ± 12.0 mmHg in Group G (p=0.395), and subsequent measurements at 2, 5, 10, 15, 20, 25, 30 minutes, and 2 hours post-spinal anesthesia showed no significant differences (p>0.05). Similarly, the DBP

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showed comparable values between the groups at most time points. However, at 20 minutes and 25 minutes, Group G demonstrated a significantly lower DBP (70.1 ± 9.2 mmHg and 69.8 ± 9.5 mmHg, respectively) compared to Group O (72.5 ± 5.6 mmHg and 73.6 ± 5.7 mmHg, respectively) with p-values of 0.032 and 0.001, indicating a transient reduction in DBP in Group G. Nonetheless, the DBP values at other time points, including baseline and at 2 hours postoperatively, showed no significant differences (p>0.05).

The baseline MAP was comparable between Group O (79.8 ± 7.6 mmHg) and Group G (80.4 ± 9.5 mmHg) (p=0.243). However, from 2 minutes to 2 hours post-spinal anesthesia, Group G consistently demonstrated a significantly higher MAP than Group O. Notably, at 5, 10, 15, 20, 25, 30 minutes, and 2 hours, Group G had a significantly higher MAP (p<0.001 at most time points), indicating better maintenance of blood pressure with Granisetron. Regarding heart rate, the baseline values were similar between Group O (80.4 ± 9.2 bpm) and Group G (80.8 ± 12.3 bpm) (p=0.777). However, Group G showed a significantly lower heart rate at 15, 20, 25, and 30 minutes compared to Group O, with p-values of 0.014, 0.001, 0.042, and 0.044, respectively, suggesting a relative bradycardic effect in Group G. By 2 hours postoperatively, the heart rates between the groups were comparable (p=0.094).

The use of ephedrine for the management of hypotension during spinal anesthesia was significantly lower in Group G compared to Group O. Only 7 patients (7.5%) in Group G required ephedrine, whereas 15 patients (16.1%) in Group O needed it, showing a statistically significant difference (p=0.039). Additionally, the mean dose of ephedrine administered was significantly lower in Group G (6.0 ± 0.0 mg) compared to Group O (9.2 ± 3.8 mg) (p=0.006).

Discussion

This study aimed to compare the efficacy of prophylactic intravenous Granisetron versus Ondansetron in maintaining hemodynamic stability during spinal anaesthesia for lower abdominal surgeries. The study enrolled a total of 200 patients, with 186 completing the trial after the exclusion of 14 patients who did not meet the inclusion criteria or declined to participate. The randomization process ensured an equal distribution of patients in Group O (Ondansetron) and Group G (Granisetron), with 93 patients in each group. No significant differences were observed between the groups in terms of age (P = 0.735), gender distribution (P = 0.163), height (P = 0.685), weight (P = 0.402), ASA grading (P = 0.557), and duration of surgery (P = 0.723). The similarity in baseline characteristics indicates that any observed differences in outcomes can be attributed to the pharmacological effects of the drugs rather than patient-related confounders.(13, 14)

The time taken to achieve the T6 sensory level was significantly shorter in Group O (3.8 ± 0.8 min) compared to Group G (4.0 ± 0.8 min), with a P-value of 0.034. This suggests that Ondansetron may facilitate a slightly faster onset of spinal block. A similar finding was reported by Shukla et al. (2023),(15) who suggested that 5-HT3 receptor antagonists might influence spinal block onset through central serotonin modulation. The findings also corroborate with that reported by Fating et al.(16) Conversely, the time for sensory regression to the T8 level was significantly prolonged in Group O (98.1 ± 29.1 min) compared to Group G (82.0 ± 21.5 min), with a highly significant P-value of <0.001. This prolonged sensory blockade with Ondansetron could be related to its mild vasoconstrictive properties, as proposed by Tatikonda et al. (2019),(17) who found that Ondansetron reduced the spread of local anaesthetic agents in spinal anaesthesia. The findings were supported by Hou et al.(18) and Badeaux et al.(19)

Systolic blood pressure was monitored at multiple time points intraoperatively and postoperatively. No statistically significant differences in SBP were observed between the two groups at baseline, intraoperative, or postoperative measurements (P > 0.05 at all time points). Previous studies have explored the role of 5-HT3 antagonists in mitigating hypotension induced by spinal anaesthesia. Aksoy et al.(12) (2021) found that both Ondansetron and Granisetron attenuate the Bezold-Jarisch reflex, a mechanism that contributes to spinal anaesthesia-induced hypotension by inhibiting vagal-mediated vasodilation. In contrast, DBP exhibited some significant differences, particularly at 20 and 25 minutes, where the granisetron group had lower values compared to the ondansetron group. However, this effect was not sustained postoperatively, as DBP values at 2 hours were similar between the two groups.

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MAP, a critical indicator of tissue perfusion, was consistently higher in the granisetron group from 2 minutes onward, with significant differences observed at all time points. This suggests that ondansetron may have a more pronounced hypotensive effect compared to granisetron, which has been previously documented in studies analyzing serotonin receptor antagonists and their cardiovascular effects.(20) The sustained elevation in MAP in the granisetron group may indicate a lesser degree of vasodilation or a compensatory mechanism preserving blood pressure. Heart rate variations were also observed, with the granisetron group exhibiting a significantly lower HR between 15- and 30-minutes post-intervention. This could imply a stronger vagotonic effect of granisetron compared to ondansetron, potentially mediated through its selective receptor binding properties.(21, 22) While these variations in HR were statistically significant, their clinical relevance remains debatable, as the values remained within the normal physiological range.

A notable finding of the study was the significantly higher requirement for ephedrine in the ondansetron group. Ephedrine is commonly administered to counteract intraoperative hypotension, and the increased usage in the ondansetron group suggests a greater predisposition to hypotensive episodes. This aligns with the observed MAP trends and corroborates previous research indicating that ondansetron may contribute to a greater incidence of intraoperative hypotension.(23, 24) The significantly higher mean dose of ephedrine required in the ondansetron group further substantiates this finding, reinforcing the notion that granisetron may be a preferable alternative in patients at risk of intraoperative hypotension.

The absence of PONV in both groups highlights the efficacy of both ondansetron and granisetron in preventing this common postoperative complication. This result is consistent with prior meta-analyses demonstrating that both agents are highly effective in PONV prophylaxis, with granisetron sometimes showing superior efficacy due to its longer half-life and greater receptor affinity.(25, 26) The lack of need for additional antiemetics such as atropine or metoclopramide further underscores the effectiveness of the prophylactic regimen employed in this study. The results of this study suggest that while both ondansetron and granisetron are effective in preventing PONV, granisetron may offer additional hemodynamic stability by maintaining higher MAP and reducing the need for ephedrine. These findings are particularly relevant for surgical patients who may be predisposed to intraoperative hypotension, such as those undergoing spinal anaesthesia or those with baseline cardiovascular compromise.

The study has several limitations that should be acknowledged. First, it was conducted in a single centre, which may limit the generalizability of the findings to other populations with different demographic and clinical characteristics. Additionally, the study focused only on a single dose of ondansetron and granisetron, without evaluating the potential effects of different dosages or repeated administrations, which could provide a more comprehensive understanding of their hemodynamic impact. The study also did not assess long-term postoperative outcomes, limiting conclusions about the extended effects of these drugs beyond the immediate perioperative period. Furthermore, while the study demonstrated differences in blood pressure, heart rate, and ephedrine requirement, it did not explore the underlying physiological mechanisms responsible for these variations. Another limitation is the lack of stratification based on comorbidities such as hypertension and diabetes, which could influence hemodynamic responses. Lastly, although nausea and vomiting were assessed, patient-reported subjective symptoms, such as dizziness or discomfort related to hemodynamic changes, were not documented, which may have provided additional insights into the clinical relevance of the findings.

Conclusion

The study demonstrated that both ondansetron and granisetron effectively maintained hemodynamic stability in patients undergoing surgery, with no significant differences in systolic blood pressure between the two groups at any time point. However, diastolic blood pressure was significantly lower in the granisetron group at 20 and 25 minutes, while mean arterial pressure remained consistently higher in the granisetron group from 2 minutes onward. Additionally, heart rate was significantly lower in the granisetron group from 15 to 30 minutes post-intervention. Notably, none of the patients in either group experienced intraoperative or

postoperative nausea and vomiting. However, the use of ephedrine was significantly higher in the ondansetron group, suggesting that patients receiving ondansetron may require greater hemodynamic support. Despite these differences, both drugs were well tolerated, and no patients required atropine or metoclopramide. These findings suggest that granisetron may offer better hemodynamic stability compared to ondansetron in this surgical setting, with a reduced need for vasopressor support.

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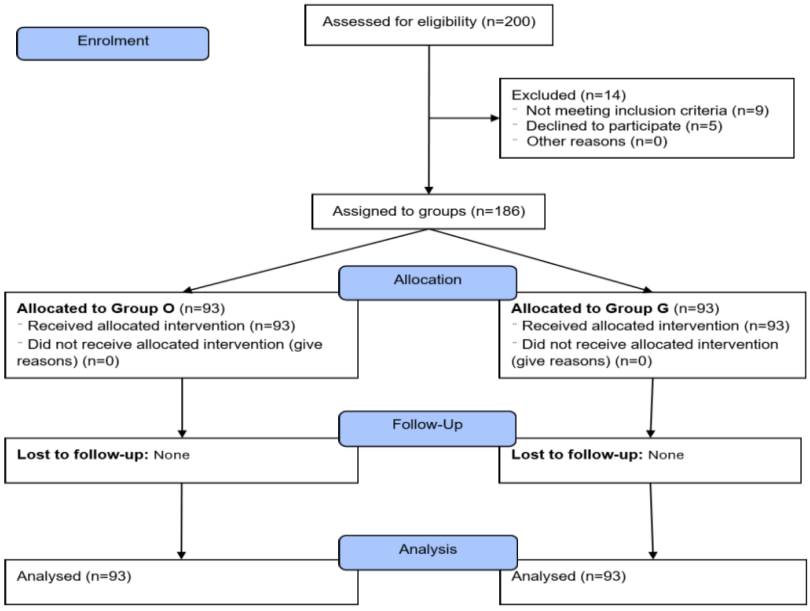

Figure 1: CONSORT flow diagram

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Table 1: Baseline characteristics of the study groups

		Group O N = 93	Group G N = 93	P value
		(n)	(%)	
Age (in years), Mean (SD)		41.5 (9.6)	41.0 (10.3)	0.735
Age (in years)	≤30	13 (14.0)	15 (16.1)	0.682
	>30	80 (86.0)	78 (83.9)	
Gender	Female	27 (29.0)	36 (38.7)	0.163
	Male	66 (71.0)	57 (61.3)	
Height (in cm), Mean (SD)		164.2 (4.6)	163.9 (6.1)	0.685
Weight (in kg), Mean (SD)		66.8 (10.4)	65.6 (9.1)	0.402
ASA grading	I	47 (50.5)	51 (54.8)	0.557
	II	46 (49.5)	42 (45.2)	
Duration of surgery (in minutes), Mean (SD)		91.5 (16.9)	92.4 (17.0)	0.723
Time to attain T6 (in minutes), Mean (SD)		3.8 (0.8)	4.0 (0.8)	0.034*
Time of regression to T8 (in minutes), Mean (SD)		98.1 (29.1)	82.0 (21.5)	<0.001*
*Statistically significant at p<0.05 SD, Standard deviation				

Table 2: Comparison of study groups, by intraoperative and postoperative SBP and DBP

		Group O N = 93	Group G N = 93	P value
		Mean (SD)	Mean (SD)	
Systolic blood pressure	Baseline	131.6 (13.7)	130.0 (12.0)	0.395
	At 2 mins	124.1 (9.4)	124.3 (14.2)	0.874
	At 5 mins	121.1 (9.3)	123.3 (12.9)	0.109
	At 10 mins	116.4 (8.7)	118.4 (13.6)	0.218
	At 15 mins	115.3 (9.6)	116.8 (12.0)	0.330
	At 20 mins	115.3 (8.7)	117.2 (12.3)	0.220
	At 25 mins	115.3 (8.8)	117.9 (12.8)	0.099
	At 30 mins	115.9 (6.9)	117.8 (12.5)	0.206
	At 2 hours	117.8 (7.1)	118.0 (7.2)	0.837
Diastolic blood pressure	Baseline	81.7 (8.5)	79.1 (8.5)	0.119
	At 2 mins	76.5 (7.7)	73.0 (8.7)	0.105
	At 5 mins	74.2 (5.8)	74.0 (8.0)	0.858
	At 10 mins	72.6 (7.1)	71.8 (8.5)	0.460
	At 15 mins	71.7 (7.1)	72.3 (9.1)	0.579
	At 20 mins	72.5 (5.6)	70.1 (9.2)	0.032*
	At 25 mins	73.6 (5.7)	69.8 (9.5)	0.001*
	At 30 mins	72.3 (4.8)	72.9 (8.7)	0.558
	At 2 hours	72.9 (6.6)	72.8 (7.0)	0.923
*Statistically significant at p<0.05				

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SD, Standard deviation

Table 3: Comparison of study groups, by intraoperative and postoperative MAP and HR

		Group O N = 93	**Group G N = 93**	**P value**
		Mean (SD)	**Mean (SD)**	
Mean arterial pressure	Baseline	79.8 (7.6)	80.4 (9.5)	0.243
	At 2 mins	75.9 (8.7)	79.0 (9.0)	0.016*
	At 5 mins	72.2 (6.6)	78.6 (8.5)	<0.001*
	At 10 mins	72.3 (6.7)	78.3 (8.7)	<0.001*
	At 15 mins	71.4 (7.3)	76.4 (9.0)	<0.001*
	At 20 mins	71.8 (6.9)	77.2 (9.8)	<0.001*
	At 25 mins	73.6 (6.9)	78.0 (9.7)	0.001*
	At 30 mins	71.9 (6.4)	77.7 (10.1)	<0.001*
	At 2 hours	72.0 (6.1)	76.3 (6.8)	<0.001*
Heart rate	Baseline	80.4 (9.2)	80.8 (12.3)	0.777
	At 2 mins	82.1 (0.8)	79.4 (13.0)	0.053
	At 5 mins	77.0 (8.6)	78.1 (10.7)	0.437
	At 10 mins	78.2 (9.0)	76.9 (10.9)	0.374
	At 15 mins	77.1 (8.9)	73.4 (11.0)	0.014*
	At 20 mins	77.1 (8.3)	72.1 (11.1)	0.001*
	At 25 mins	77.6 (7.8)	73.5 (14.1)	0.042*
	At 30 mins	76.8 (6.9)	74.0 (11.9)	0.044*
	At 2 hours	78.6 (7.6)	76.5 (9.3)	0.094
*Statistically significant at p<0.05 SD, Standard deviation				

Table 4: Comparison of study groups, by use of Ephedrine and its dose

		Group O N = 93	**Group G N = 93**	**P value**
		(n)	**(%)**	
Ephedrine use	Yes	15 (16.1)	7 (7.5)	0.039*
	No	78 (83.9)	86 (92.5)	
Ephedrine used (mg), Mean (SD)		9.2 (3.8)	6.0 (0.0)	0.006*
*Statistically significant at p<0.05 SD, Standard deviation				

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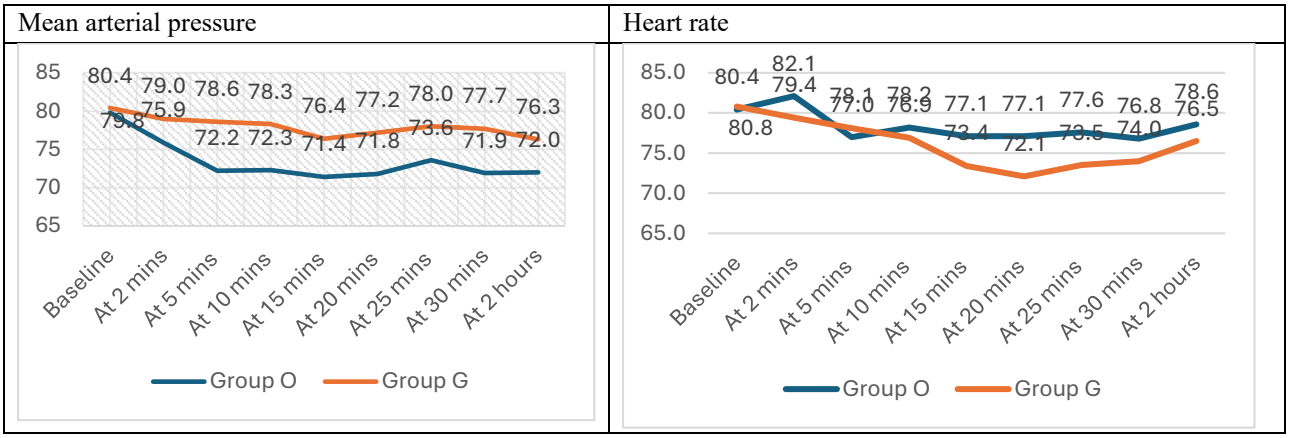

Figure 5: Comparison of study groups, by intraoperative and postoperative MAP and HR