International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

Effect of Different Doses of Ondansetron on Hemodynamic Status in Patients Undergoing Elective Caesarean Section Under Spinal Anaesthesia: A Randomized Controlled Trial

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Abstract: ***Background: Spinal anaesthesia for elective caesarean section is associated with hypotension (incidence up to 80%), bradycardia, nausea-vomiting, and shivering. Ondansetron, a 5-HT3 receptor antagonist, attenuates the Bezold-Jarisch reflex and may reduce these complications. This study compares prophylactic ondansetron 4 mg (O4) vs 6 mg (O6) vs normal saline (control) on haemodynamic parameters and complication rates. Methods: A prospective, double-blind, randomized controlled trial was conducted at PannaDhai Zanana Hospital, RNT Medical College, Udaipur from April 2022 to June 2022. 150 ASA I-II pregnant females undergoing elective caesarean section were randomized equally into three groups (n=50 each). The intervention was administered IV 20 minutes before spinal anaesthesia. Primary outcome: MAP changes. Secondary outcomes: hypotension incidence, vasopressor requirement, bradycardia, shivering, nausea-vomiting. Results: Baseline demographics were comparable. Mean SBP and MAP were significantly higher in O4 and O6 groups vs control at 6, 8, 10, and 12 minutes ($p<0.05$). Hypotension incidence: Control 40%, O4 16%, O6 14% ($p<0.05$). Vasopressor requirement: Control 38%, O4 12%, O6 10% ($p<0.05$). Bradycardia: Control 24%, O4 10%, O6 8%. Shivering: Control 38%, O4 4%, O6 4%. Nausea-vomiting: Control 42%, O4 8%, O6 6%. No significant difference between O4 and O6 for any parameter ($p>0.05$). Conclusion: Prophylactic ondansetron (4 mg or 6 mg IV) significantly reduces hypotension, bradycardia, shivering, and nausea-vomiting after spinal anaesthesia for caesarean section. No significant difference exists between 4 mg and 6 mg doses; hence ondansetron 4 mg is recommended as the optimal prophylactic dose.***

Keywords: Ondansetron, Spinal Anaesthesia, Caesarean Section, Hypotension, Bezold-Jarisch Reflex, Haemodynamic Stability

1. Introduction

The proportion of caesarean sections performed under regional anaesthesia has increased greatly over the last two decades. The Royal College of Anaesthetists (UK) recommends that >95% of elective and >85% of emergency caesarean deliveries be performed under regional techniques. Regional anaesthesia avoids the risks of difficult airway management, reduces maternal mortality, and allows the mother to remain awake during delivery.

Despite these advantages, spinal anaesthesia is associated with significant haemodynamic instability. Hypotension occurs in 50–80% of parturients and results from preganglionic sympathetic block causing venodilation, reduced preload, and decreased venous return. The Bezold-Jarisch reflex (BJR) further contributes by triggering paradoxical bradycardia and hypotension via mechanoreceptors in the inferoposterior left ventricle, particularly in hypovolaemic states. Intraoperative nausea and vomiting (IONV) occurs in up to 80% of parturients under spinal anaesthesia, often as a direct consequence of hypotension.

Ondansetron, a selective 5-HT3 receptor antagonist, is widely used as an antiemetic. Cardiac 5-HT3 receptors play a central role in triggering the BJR; ondansetron's blockade of these receptors may attenuate hypotension and bradycardia in addition to preventing nausea-vomiting. Several studies have explored ondansetron for prophylaxis, but optimal dosing remains debated. This study was designed to compare the haemodynamic effects and complication profiles of two prophylactic doses- 4 mg and 6 mg- against placebo.

2. Aims & Objectives

Primary Objective

To measure the effect of ondansetron administration 20 minutes prior to spinal anaesthesia on haemodynamic status (SBP, DBP, MAP, HR, SpO2) in patients undergoing elective caesarean section.

Secondary Objectives

- To quantify vasopressor dose requirement for correction of hypotension.
- To determine the incidence of complications: bradycardia, shivering, intraoperative nausea-vomiting (IONV), pruritus, and transient hearing loss.
- To compare the efficacy and safety of ondansetron 4 mg vs 6 mg vs placebo.

3. Material & Methods

Study Design & Setting

A prospective, parallel-group, double-blind, randomized controlled trial was conducted at the Department of Anaesthesiology, Obstetric Operation Theatre, PannaDhai Zanana Hospital, RNT Medical College, Udaipur (Rajasthan) from April 2022 to June 2022.

Participants

Inclusion criteria: ASA physical status I or II pregnant females aged 18–40 years, full-term gestation (≥37 weeks), single term pregnancy, scheduled for elective caesarean section under spinal anaesthesia, BMI <35 kg/m². Exclusion criteria: Emergency caesarean, contraindication to spinal anaesthesia, known allergy to ondansetron, haemodynamic instability at baseline, pre-eclampsia/eclampsia, multiple gestation, coagulopathy, hepatic/renal impairment, or use of serotonergic drugs.

Sample Size & Randomization

Sample size was calculated using a superiority trial formula for continuous outcomes with σ=13 mmHg (from Samarah et al.), $Z_{1-\alpha}$=1.28 (one-tailed, α=5%), $Z_{1-\beta}$=1.65 (one-tailed, β=10%), yielding n=47 per group; rounded to 50 per group (total N=150). Randomization was performed using a computer-generated random number table with sequentially numbered sealed opaque envelopes.

Intervention Protocol

Group Control (n=50): 10 mL normal saline IV bolus 20 min before spinal anaesthesia. Group O4 (n=50): Ondansetron 4 mg in 10 mL normal saline IV 20 min before. Group O6 (n=50): Ondansetron 6 mg in 10 mL normal saline IV 20 min before. Spinal anaesthesia was administered at L3-L4 with hyperbaric bupivacaine 0.5% (2 mL) + fentanyl 25 mcg. Vasopressor (ephedrine 6 mg bolus) was given for hypotension (SBP <90 mmHg or >20% fall from baseline).

Outcome Measurements

Haemodynamic parameters (SBP, DBP, MAP, HR, SpO2) were recorded at baseline and every 2 minutes for 30 minutes post-spinal, then every 5 minutes until end of surgery. Complications (hypotension, bradycardia, shivering, IONV, pruritus, transient hearing loss) were recorded by a blinded observer. Statistical analysis: ANOVA, Chi-square/Fisher's exact test, post-hoc Tukey test; significance p<0.05.

4. Observations & Results

Table 1: Baseline Demographics

Parameter	Control (n=50)	O4 (n=50)	O6 (n=50)	p-value
Age (years), Mean±SD	22.74±2.52	23.52±3.28	22.98±2.97	0.399
Weight (kg), Mean±SD	58.2±6.1	57.9±5.8	58.6±6.4	0.812
Height (cm), Mean±SD	155.4±4.2	154.9±3.8	155.7±4.5	0.621
ASA I / II	38/12	40/10	39/11	0.872
Baseline SBP (mmHg)	118.6±8.4	119.2±7.9	118.1±8.7	0.784
Baseline MAP (mmHg)	88.4±6.2	89.1±5.8	88.7±6.5	0.891

All baseline parameters were comparable between the three groups (p>0.05). Mean time to T6 sensory blockade, median Bromage score, and mean duration of surgery were also comparable.

Table 2: Haemodynamic Outcomes & Complications

Outcome	Control	O4	O6	p-value (Control vs O4/O6)	p-value (O4 vs O6)
Hypotension incidence	40% (20/50)	16% (8/50)	14% (7/50)	<0.05*	0.754
Vasopressor requirement	38% (19/50)	12% (6/50)	10% (5/50)	<0.05*	0.648
Bradycardia	24% (12/50)	10% (5/50)	8% (4/50)	<0.05*	0.721
Shivering	38% (19/50)	4% (2/50)	4% (2/50)	<0.05*	1
Nausea-Vomiting (IONV)	42% (21/50)	8% (4/50)	6% (3/50)	<0.05*	0.695
Pruritus	2% (1/50)	4% (2/50)	4% (2/50)	0.612	1
Transient Hearing Loss	0% (0/50)	2% (1/50)	2% (1/50)	0.315	1

Statistically significant. Mean SBP and MAP were significantly higher in O4 and O6 groups vs control at 6, 8, 10, and 12 minutes post-spinal (p<0.05). Mean DBP was significantly higher in ondansetron groups at 12 minutes (p<0.05). No clinically or statistically significant difference was observed between O4 and O6 groups for any haemodynamic parameter or complication at any time interval (p>0.05).

5. Summary

In the present study, mean age, weight, and height were comparable between the three intervention groups. Baseline SBP, DBP, MAP, HR, and SpO2 were comparable among all three groups. No significant difference was found in mean time to T6 sensory blockade, median Bromage score, or mean duration of surgery.

Reduction in SBP, DBP, and MAP was observed after spinal anaesthesia in all three groups. At most time intervals no significant difference was observed in mean haemodynamic values between the three groups. However, mean SBP was significantly higher in ondansetron groups (O4 and O6) compared to the control group at 6, 8, and 10 minutes (p<0.05). Mean DBP was significantly higher in ondansetron groups at 12 minutes (p<0.05). MAP was significantly higher in ondansetron groups at 6, 8, 10, and 12 minutes (p<0.05).

On post-hoc intergroup analysis, no clinically or statistically significant difference was found in mean SBP, DBP, or MAP between O4 and O6 groups (p>0.05). Consistent increment in HR was observed up to 16 minutes followed by a reduction in all groups; HR was comparable between all three groups at all time intervals. SpO2 was comparable across all groups throughout.

Intraoperative incidence of hypotensive episodes was significantly higher in the normal saline (control) group than in the ondansetron groups (O4 and O6). Both the frequency and duration of hypotensive episodes were significantly reduced in ondansetron groups. Vasopressor (ephedrine) requirement was significantly lower in O4 and O6 groups. Bradycardia, shivering, and IONV were all significantly less frequent in ondansetron groups. No significant difference in any complication rate was observed between O4 and O6.

6. Conclusion

In the present study it is concluded that prophylactic use of ondansetron (either 4 mg or 6 mg IV) prevents significant reduction in MAP after spinal anaesthesia in caesarean cases and also significantly reduces:

- Incidence, frequency, and duration of intraoperative hypotensive episodes
- Vasopressor (ephedrine) requirement
- Incidence of bradycardia
- Incidence of intraoperative shivering
- Incidence of intraoperative nausea and vomiting (IONV)

Different doses of ondansetron (4 mg and 6 mg) do not have significantly different effects on haemodynamic status or on the incidence of complications including bradycardia, shivering, nausea-vomiting, pruritus, and transient hearing loss. Therefore, ondansetron 4 mg IV administered 20 minutes before spinal anaesthesia is recommended as the optimal prophylactic dose for elective caesarean section-being equally effective to 6 mg while offering a better safety margin and cost advantage.

Acknowledgements
The authors sincerely thank the faculty, residents, nursing staff, and patients of the Department of Anaesthesiology and Obstetric Operation Theatre, PannaDhai Zanana Hospital, RNT Medical College, Udaipur for their support and cooperation during this study.

Conflict of Interest: None declared. Funding: None. Ethical Approval: Obtained from Institutional Ethics Committee, RNT Medical College, Udaipur.

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