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The Effect of Intravenous Ondansetron on Prevention of Hemodynamic Instability in Patients Undergoing Elective Caesarean Surgery: A Double-Blind Randomized Clinical Trial

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ABSTRACT

Background & Objective: Spinal anesthesia for elective cesarean delivery has a high incidence of hypotension (50-80%) caused by sympathetic inhibition and activation of the Bezold-Jarisch reflex. This double-blind randomized study was designed to determine whether preoperative administration of 4 mg of intravenous Ondansetron can stabilize hemodynamics in patients undergoing elective cesarean section.

Materials & Methods: Sixty ASA I pregnant women scheduled for elective cesarean delivery were randomized to receive IV Ondansetron (n=30) or placebo (n=30) 3 minutes before spinal anesthesia (12.5 mg hyperbaric bupivacaine + 2.5 µg sufentanil). Hemodynamic parameters (heart rate and blood pressure trends) were primary outcomes; secondary outcomes included ephedrine requirements and adverse events. Independent t-tests, ANOVA, Mann-Whitney U tests, and Chi-square tests (SPSS v22; $\alpha = 0.05$) were used in the statistical analysis.

Results: Ondansetron was associated with significantly more shivering (46.7% vs. 17.2%; P<0.05). The Ondansetron group maintained a higher total heart rate (93.50 ± 1.742 vs. 88.34 ± 1.673 bpm; P=0.044), with significant increases at 25, 45, and 120 minutes (P<0.05). Although diastolic blood pressure/mean arterial pressure was higher at later periods (75/105 min; P<0.05), systolic blood pressure in the Ondansetron group was lower at 5 minutes (108.81 ± 16.072 vs. 118.86 ± 16.072 mmHg, P<0.01). Overall, there were no net differences in blood pressure. The Ondansetron group required ephedrine more frequently (77.4% vs. 58.6%), although they had the same mean dose (14.16±7.019 vs. 12.35±5.036 mg; P=0.368). Ondansetron caused significantly more shivering (46.7% vs. 17.2%; P<0.05).

Conclusion: Prophylactic Ondansetron raises heart rate and momentarily increases late-phase BP but worsens early hypotension and shivering. It offers no overall hemodynamic benefit and may raise vasopressor requirements, so caution is advised in clinical use.

Keywords: Ondansetron, Caesarean Section, Spinal Anesthesia, Hypotension, Bezold-Jarisch Refle

1. Introduction

Spinal anesthesia has been the primary anesthetic method for elective cesarean birth owing to its swift onset, dependable blockage, and advantageous safety profile relative to general anesthesia (1). Nonetheless, a notable issue associated with neuraxial anesthesia in obstetric surgery is the elevated prevalence

of hemodynamic instability, with maternal hypotension affecting around 50-80% of unmedicated parturient undergoing elective cesarean section (2).

This hemodynamic deficit arises from two main mechanisms: vasodilatation generated by sympathetic blockade and activation of the Bezold-Jarisch reflex (BJR), a cardio-inhibitory parasympathetic response mediated by serotonin type 3 (5-HT3) receptors on intracardiac vagal nerve terminals (3). This study examines the effectiveness of intravenous ondansetron, a 5-HT3 receptor antagonist, in alleviating post-spinal hemodynamic instability in parturient after elective cesarean delivery.

The clinical importance of averting hemodynamic instability generated by spinal anesthetic transcends mother comfort, covering significant maternal and fetal morbidity. Mother hypotension during cesarean birth induces nausea, vomiting, syncope, and altered mental status, all of which contribute to mother morbidity and a suboptimal surgical experience. Reduced arterial blood pressure adversely affects uteroplacental perfusion, resulting in diminished oxygen supply to the fetus (4). This may lead to fetal hypoxia, bradycardia, metabolic acidosis, and impaired newborn outcomes. Thus, the efficient prevention and control of post-spinal hypotension is crucial for enhancing the safety of both mother and neonate. Despite the widespread use of traditional prophylactic measures, including fluid preloading and coloading with crystalloid infusions, lower-limb compression, and vasopressor administration, these methods are often insufficiently effective and frequently necessitate rescue interventions, highlighting the need for supplementary pharmacological agents.

Despite increasing interest in pharmaceutical therapies aimed at the causes of spinal anesthesia-induced hemodynamic instability, considerable questions remain in the scientific literature. Meta-analyses indicate that 5-HT3 receptor antagonists, especially ondansetron, diminish the occurrence of hypotension and bradycardia in cesarean delivery populations, with a number needed to treat around 4. However, conflicting results from individual randomized controlled trials imply that the efficacy may vary and could be influenced by dosage and timing (5). The observed variability in outcomes may be ascribed to methodological discrepancies in ondansetron dosing (ranging from 2 to 12 mg), timing of administration (prior to or following spinal induction, minutes before or at delivery), anesthetic protocols utilized (varying local anesthetic doses, adjuvants), and the patient cohorts examined (6). Moreover, although certain studies indicate that prophylactic ondansetron diminishes vasopressor needs and enhances overall hemodynamic stability, others suggest negligible or no clinically significant hemodynamic advantage, prompting inquiries about the actual extent of its protective effect and its practical relevance in standard obstetric anesthetic practice.

This randomized, double-blind clinical investigation aimed to fill the knowledge gaps concerning the hemodynamic effects of intravenous ondansetron in the obstetric population. The main aim was to assess if a fixed dose of 4 mg intravenous ondansetron given 3 minutes prior to spinal anesthesia induction effectively stabilizes maternal hemodynamics and diminishes the occurrence of hypotension in women undergoing elective cesarean delivery with spinal anesthesia using hyperbaric bupivacaine (7). This investigation's innovation resides in its systematic evaluation of temporal hemodynamic alterations, thorough characterization of the hemodynamic profile (including systolic and diastolic blood pressures, mean arterial pressure, and heart rate trends), and extensive assessment of secondary outcomes such as vasopressor requirements and adverse events. This work enhances the comprehension of 5-HT3 antagonism in obstetric anesthesia by offering further evidence on the dose-response relationship and possible clinical ramifications of ondansetron use in this susceptible group.

2. Materials and Methods

2.1 Study Design and Participants

This double-blind randomized clinical trial (IRCT20191015045121N1 at 2019-10-26) received approval from the Ethical Committees of Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1398.415). After obtaining informed consent, 60 ASA physical status 1 pregnant women admitted to Imam Khomeini hospital, Ahvaz, Iran (2019–2020) were enrolled and equally randomized to two groups. Exclusion criteria included hypertension, cardiovascular disease, contraindications to spinal anesthesia, and allergy to Ondansetron.

Sample size determination: Sample size was determined a priori using G*Power software (v3.1.9.7) based on hypotension incidence data from previous studies (α=0.05, β=0.2, effect size=0.8), yielding 27 participants per group. Accounting for potential dropouts, 30 participants were enrolled in each group.

Randomization and blinding: Participants were randomly allocated in a 1:1 ratio to one of two groups: the Ondansetron group (n = 30), which received 4 mg of intravenous Ondansetron diluted in 2 mL of normal saline, or the Placebo group, which received 2 mL of normal saline. The study solutions were prepared by a nurse anesthetist who was not involved in the intraoperative management. Both the patients and the healthcare providers responsible for intraoperative and postoperative care were blinded to the group assignments.

Procedure: Upon arrival in the operating room, all patients received an initial infusion of 500 ml 0.9% saline or Ringer's lactate. Baseline hemodynamic parameters (HR, SBP, DBP, MAP, and SpO_2) were recorded. Participants were randomized to receive either 4 mg intravenous Ondansetron or an equivalent volume of 0.9% saline as a placebo. Spinal anesthesia was administered 3 minutes later at L3-L4/L4-L5 using 12.5 mg hyperbaric bupivacaine 0.5% (Exir Pharmaceutical

Co., Iran) and 2.5 µg sufentanil (DarouPakhsh Pharmaceutical Co., Iran).

At predetermined times—immediately after spinal anesthesia (baseline), then at 1-minute intervals from 1-5 minutes, 3-minute intervals from 6-15 minutes, and 5-minute intervals from 20-30 minutes post-spinal anesthesia, hemodynamic variables were measured. Measurements were taken postoperatively every 15 minutes for two hours (started 15 minutes following the conclusion of the surgery).

2.2 Outcome Measures

Primary outcome: Changes in heart rate and blood pressure over time.

Secondary outcomes: Ephedrine requirements and adverse events (pruritus, chills, nausea, vomiting). Hypotension (SBP <90 mmHg) was treated with 5–10 mg IV ephedrine; nausea/vomiting with 10 mg IV metoclopramide.

2.3 Statistical Analysis

Data were analyzed using SPSS v22. Continuous data were compared via Student's t-test (normally distributed) or Mann-Whitney U-test (non-parametric). Categorical data were compared via Chi-square/Fisher's exact test. Significance threshold: $p \leq 0.05$ (two-tailed).

3. Result

3.1 Baseline Characteristics of the Study Population

The demographic and preoperative hemodynamics were comparable in terms of Mean age, sex, BMI, and Baseline SBP &DBP between the groups (Table 1).

3.2 Primary Outcome

Changes in heart rate over time: Heart rate (HR) trends indicated consistently higher values in the Ondansetron group. Significant differences were found at 25, 45, and 120 minutes post-induction (P<0.05 at each point). Over the full duration, HR decreased significantly in both groups (P< 0.001), but the Ondansetron group maintained a higher overall HR compared to controls (93.50 ± 1.742 vs. 88.34 ± 1.673 bpm; P=0.044), suggesting a possible effect of Ondansetron in mitigating bradycardia (Table 2 & Figure 1).

Changes in heart rate and blood pressure over time: Following anesthesia induction, a significant initial drop in systolic blood pressure (SBP) was observed in both the Ondansetron and control groups. Notably, the SBP was significantly lower in the Ondansetron group compared to the control group as early as 5 minutes post-induction (108.81 ± 16.072 mmHg vs. 118.86 ± 16.072 mmHg; P<0.01).

Although SBP in the Ondansetron group surpassed that of the control group around the 50-minute mark, this trend did not reach statistical significance over time (P=0.827). Overall, while time-related changes in SBP were significant in both groups (P<0.001), they were not attributed to Ondansetron administration (Table 2).

Diastolic blood pressure (DBP): It followed a similar trajectory, initially decreasing in both groups. Statistically significant differences emerged at the 75-minute mark, where DBP was higher in the Ondansetron group (73.48 ± 13.834 mmHg vs. 66.21 ± 11.684 mmHg; P <0.05). Although DBP varied significantly over time in both cohorts (P <0.001), these changes were not linked to the study drug (P=0.822) (Table 2 & Figure 2).

Mean arterial pressure (MAP): It showed an early decline in both groups, with the Ondansetron group temporarily falling below the control group, then exceeding it around the 20-minute mark. Significant differences in MAP were noted at 75 and 105 minutes, favoring the Ondansetron group (P<0.05 for both time points). However, neither time nor group effects were statistically significant overall (P=0.174 and P=0.254, respectively), and Ondansetron had no significant impact (P=0.970) (Table 2 & Figure 2).

3.3 Secondary Outcomes

Ephedrine Use: A total of 57 doses of ephedrine were administered, with more interventions required in the Ondansetron group (35 doses; 77.41%) compared to the control group (22 doses; 58.62%). However, the mean dose of ephedrine used did not differ significantly between the two groups (14.16 ± 7.019 mg vs. 12.35 ± 5.036 mg; P=0.368).

Adverse Events: Adverse events such as shivering, nausea, and itching were more common in the Ondansetron group. Shivering was significantly more frequent (46.7% vs. 17.2%; P<0.05), while differences in nausea (23.3% vs. 20.7%; P=0.782) and pruritus (26.7% vs. 10.3%; P=0.132) were not statistically significant (Table 2).

Table 1. Baseline Characteristics of Study Participants.

Variable	Ondansetron Group (n=30)	Control Group (n=30)	*P*-Value
Age(years)	29.5 ± 4.2	30.1 ± 3.8	0.56
BMI (kg/m²)	28.4 ± 2.1	27.9 ± 2.3	0.38
Baseline SBP (mmHg)	129.42±13.96	128.2±18.78	0.836
Baseline DBP (mmHg)	81.08± 7.33	80.4 ± 17.82	0.874
Baseline HR (bpm)	96 ±13.53	95.9 ± 9.21	0.983

Continuous variables are presented as mean ± standard deviation. Group comparisons were performed using independent samples t-tests. All p-values >0.05 indicate no statistically significant differences between groups at baseline.

Table 2. Hemodynamic Parameters and Adverse Events comparison between groups.

Parameter	Ondansetron Group (n=30)	Control Group (n=30)	*P*-Value
SBP (overall mean ± SE) mmHg	115.90 ± 1.891	116.49 ± 1.955	0.827
SBP at 5 min mmHg	108.81 ± 16.072	118.86 ± 16.072	<0.01
DBP (overall mean ± SE) mmHg	69.51 ± 1.583	68.99 ± 1.637	0.822
DBP at 75 min mmHg	73.48 ± 13.834	66.21 ± 11.684	<0.05
MAP (overall mean ± SE) mmHg	83.83 ± 2.143	83.71 ± 2.215	0.970
MAP at 75 min mmHg	87.02 ± 14.814	80.41 ± 10.016	<0.05
MAP at 105 min mmHg	88.92 ± 10.474	81.69 ± 11.982	<0.05
HR (overall mean ± SE) bpm	93.50 ± 1.742	88.34 ± 1.673	0.044
HR at 25, 45, 120 min	Higher at each point	Multiple time points	<0.05
Ephedrine use (n doses)	35 (77.4%)	22 (58.6%)	—
Mean ephedrine dose (mg)	14.16 ± 7.019	12.35 ± 5.036	0.368
Shivering incidence	46.7%	17.2%	<0.05
Nausea incidence	23.3%	20.7%	0.782
Itching incidence	26.7%	10.3%	0.132

Continuous variables are presented as mean ± standard error (SE) unless otherwise specified. Between-group comparisons: Independent samples t-tests for continuous hemodynamic parameters; Mann-Whitney U tests for ephedrine dose (non-normal distribution); Chi-square tests for adverse event frequencies. Time-point analyses used Bonferroni-adjusted t-tests. SD = standard deviation.

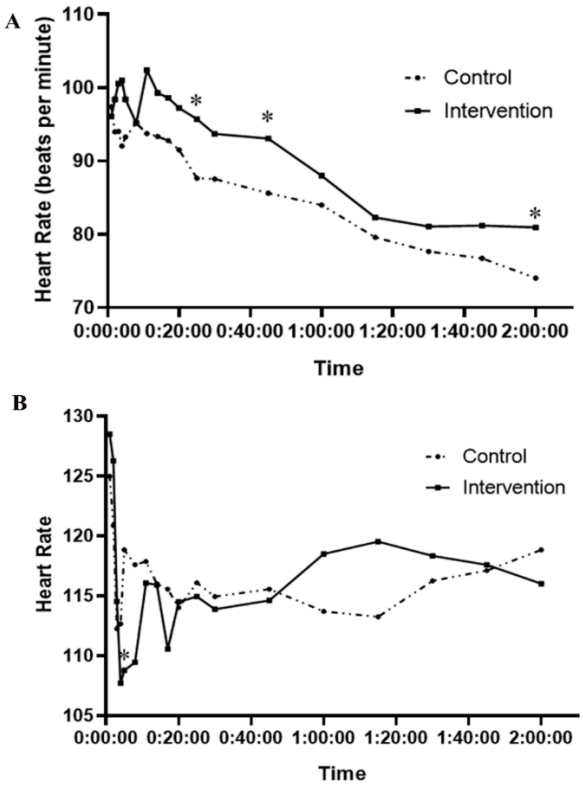

Figure 1. Comparison of heart rate changes between control and intervention groups over 2 hours. **(A)** Illustrates the sustained heart rate reduction in the intervention group compared to the control, with significant differences observed at indicated time points. **(B)** Demonstrates distinct heart rate patterns for the intervention and control groups, with initial variations and later convergence/divergence. (**Prepared by Authors, 2025**).

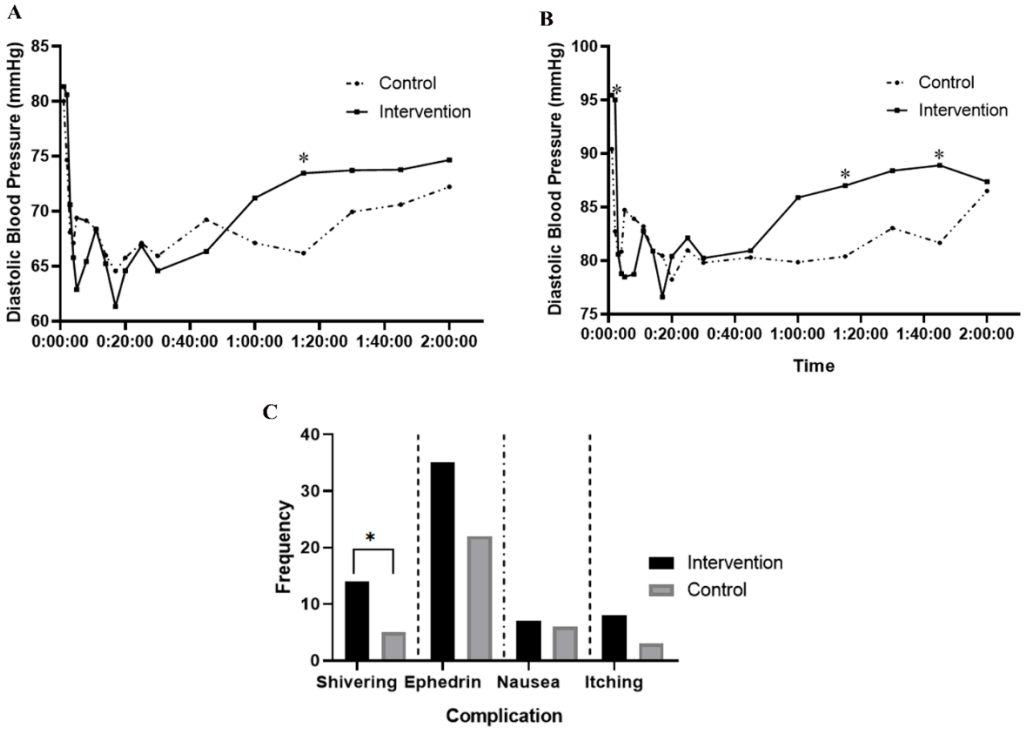

Figure 2. Differential physiological responses to intervention in control and treated groups. **(A)** Illustrates the sustained difference in heart rate between the intervention and control groups over 2 hours, with significant differences at indicated time points (*). **(B)** Shows distinct heart rate patterns for the intervention and control groups, with initial fluctuations followed by divergence or convergence. **(C)** Presents the frequency of reported complications, including shivering, ephedrine effects, nausea, and itching, experienced by intervention and control groups, with a significant difference in the frequency of shivering (*). (**Prepared by Authors, 2025**).

4. Discussions

The primary objective of this study was to assess the effect of prophylactic intravenous Ondansetron administration on hemodynamic stability in patients undergoing elective cesarean section under spinal anesthesia. Our findings contribute to the growing body of evidence exploring the cardiovascular effects of 5-HT_3 antagonists in obstetric anesthesia.

In this investigation, patients in the Ondansetron group exhibited distinctive hemodynamic responses compared to those in the control group. Notably, a sustained elevation in heart rate (HR) was observed in the Ondansetron group, with statistically significant differences emerging at several time intervals following spinal anesthesia. This suggests a potential chronotropic effect of Ondansetron, possibly mediated by its interaction with serotonin receptors in the central and peripheral nervous systems that regulate autonomic function and cardiovascular control (8).

While both groups experienced an initial drop in systolic blood pressure (SBP) following anesthesia induction, the reduction was more pronounced in the Ondansetron group within the first 5 minutes-a difference that reached statistical significance. However, SBP in the Ondansetron group gradually surpassed that of the control group by approximately 50 minutes post-induction. This biphasic pattern indicates that Ondansetron may initially contribute to transient hypotension, but potentially supports hemodynamic recovery during the later intraoperative period. Diastolic blood pressure (DBP) and mean arterial pressure (MAP) followed similar trajectories, with the Ondansetron group exhibiting higher values in the latter half of the intraoperative period, although not consistently reaching statistical significance.

The mechanisms underlying these findings remain incompletely understood. It is hypothesized that ondansetron's modulation of 5-HT_3 receptors alters autonomic tone, resulting in vascular and cardiac effects (9). Prior studies have posited similar mechanisms, particularly regarding ondansetron's vasodilatory potential and its influence on vagal reflexes (9). The trends observed in our study—early hypotension followed by hemodynamic stabilization—are consistent with prior reports but also highlight the complex and possibly dose- and time-dependent nature of these effects.

Our findings diverge in part from previous research. For instance, Sahoo et al (10) reported that prophylactic Ondansetron significantly reduced the incidence of hypotension and bradycardia and decreased the need for vasopressors during cesarean section, which contrasts with the early hypotensive response observed in our study (10). Conversely, Wang et al (11) found no significant effect of 4 mg Ondansetron on hemodynamic outcomes, aligning more closely with our overall results (11). Terkawi et al (12) and Ortiz et al (13). Similarly, reported negligible hemodynamic benefits from Ondansetron at higher doses. Interestingly, Marashi et al (14), in a study involving non-pregnant surgical patients, observed a clear hemodynamic benefit of Ondansetron in reducing hypotension (14). These discrepancies may be attributed to differences in patient populations, anesthetic regimens, and Ondansetron administration timing, underscoring the need for population-specific evaluation.

In our study, the incidence of complications, particularly shivering, was significantly higher in the Ondansetron group. Although other adverse events, such as nausea and pruritus, were more common in this group, these differences did not achieve statistical significance. The increased need for ephedrine in the Ondansetron group, though not statistically significant, may reflect a clinical trend that warrants further exploration. Notably, Ondansetron failed to mitigate opioid-induced pruritus in our cohort, which differs from findings in studies using morphine or fentanyl, possibly due to our use of sufentanil and bupivacaine.

The study's strengths include its randomized, double-blind design, which enhances internal validity. However, several limitations must be acknowledged. The modest sample size and single-center design restrict generalizability. Furthermore, the short follow-up period precludes evaluation of long-term effects. The timing of Ondansetron administration may also have influenced outcomes; administering the drug just before spinal anesthesia, as done here, differs from other studies recommending administration closer to surgical closure.

Future research should aim to address these limitations by conducting larger, multicenter trials with extended follow-up and varying timing and dosages of Ondansetron. Mechanistic studies investigating the precise cardiovascular effects of 5-HT_3 antagonism in pregnant populations are also warranted.

5. Conclusion

This study demonstrates that prophylactic Ondansetron administration in patients undergoing elective cesarean section is associated with transient early hypotension, increased heart rate, and a higher incidence of certain adverse events. These findings highlight the complex hemodynamic profile of Ondansetron and underscore the need for cautious clinical application. Further research is essential to fully elucidate the therapeutic and potentially adverse cardiovascular implications of Ondansetron in this setting.

6. Declarations

6.1 Acknowledgments

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Hospital Clinical Research Development Unit, Ahvaz, Iran, for their cooperation.

6.2 Ethical Considerations

This study was approved under the ethics committee of Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran (IR.AJUMS.REC.1398.415). Chairman Prof M. Badavi. Written informed consent was obtained from all participants following the Declaration of Helsinki**.** Clinical Trial Registration Code is IRCT20191015045121N1 at 2019-10-26.

6.3 Authors' Contributions

K.B. contributed to clinical studies; A.M. contributed to concept, study design, the definition of intellectual content, and literature search. A.G. and S.N. participated in clinical and experimental studies. A. G. and M.G. contributed to Project administration, Software review and editing, and Final approved experimental studies. A.M.A. contributed to data collection, Software, and editing; O.A.J.A.Q. and F.J. contributed to manuscript preparation. All authors participated in reviewing the manuscript and its revision, and they were involved in research, interpretation, and finalizing the manuscript.

6.4 Conflict of Interest

The authors have no conflict of interest.

6.5 Fund or Financial Support

Financial support for this study was provided by Ahvaz Jundishapur University of Medical Sciences.

6.6 Using Artificial Intelligence Tools (AI Tools)

The authors were not utilized AI Tools.

6.7 Availability of Data and Materials

The dataset presented in the study is available on request from the corresponding author during submission or after its publication.

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