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REDUCTION IN SPINAL-INDUCED HYPOTENSION WITH ONDANSETRON IN PARTURIENTS UNDERGOING CAESAREAN SECTION.

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ABSTRACT

Background
Spinal anesthesia is the predominant technique utilized for caesarean sections, owing to its quick onset, straightforward administration, and efficacy.
Objective: The aim is to evaluate how well intravenous ondansetron reduces spinal-induced hypotension in parturients who underwent elective cesarean delivery under spinal anaesthesia.

Methods
Patna Medical College & Hospital conducted this prospective, randomized, double-blind trial over a 12-month period. Randomized into two groups (n=46 each), ninety-two ASA I/II parturients booked for elective lower segment cesarean delivery under spinal anesthesia were:
Group O (ondansetron group): Five minutes before spinal anesthesia, 8 mg of ondansetron intravenously.
Group C (Control group) received 10 mL of normal saline intravenuously.
Using 2 mL of 0.5% hyperbaric bupivacaine, all patients underwent spinal anesthesia. Baseline and consistent interval documentation of hemodynamic measurements—systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR)—was recorded for thirty minutes following the block. There were reports of hypotension, vasopressors (ephedrine), and side effects included nausea and vomiting.

Results
The occurrence of hypotension was markedly reduced in Group O (26.1%) in contrast to Group C (63%). The ondansetron group required a much lower overall dose of ephedrine. Moreover, Group O saw a reduced incidence of intraoperative nausea and vomiting. The hemodynamic parameters exhibited greater stability in the ondansetron group during the monitoring period. No negative effects were observed in either group.

Conclusion
The prophylactic injection of intravenous ondansetron markedly diminishes the occurrence and intensity of spinal-induced hypotension in parturients having cesarean section. Its use also diminishes the necessity for vasopressors and enhances intraoperative mother comfort by alleviating nausea and vomiting. Ondansetron, a secure and easily accessible medication, may be regarded as a beneficial addition in the therapy of spontaneous intracranial hypotension during obstetric anesthesia.

Keywords: *Spinal anaesthesia, Hypotension, Ondansetron, Caesarean section, Parturients, Vasopressors, Maternal hemodynamics.*
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INTRODUCTION

Spinal anesthesia is widely accepted as the preferred anesthetic technique for cesarean section due to its rapid onset, profound sensory and motor blockade, and minimal fetal exposure to systemic medications (Lee et al., 2002). However, spinal-induced hypotension (SIH) remains its most common and clinically significant adverse effect, occurring in approximately 70–80% of parturients (Ortiz-Gómez, 2012). SIH can lead to maternal discomfort, dizziness, nausea, vomiting, and, more critically, impaired uteroplacental perfusion that may result in fetal acidosis and low Apgar scores (Liao et al., 2004; Klöhr et al., 2010).

Current strategies for preventing or managing SIH include intravenous fluid preloading, co-loading, and vasopressor administration—typically ephedrine or phenylephrine (Saravanan et al., 2006). However, these measures are not consistently effective and may have undesirable effects.

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Ephedrine, for instance, is associated with maternal tachycardia and fetal acidosis, whereas phenylephrine may cause reflex bradycardia and reduce cardiac output (Ngan Kee et al., 2005; Stewart et al., 2010).

Recently, attention has turned toward ondansetron, a selective 5-HT_3 receptor antagonist widely used to manage nausea and vomiting, as a promising prophylactic agent against SIH. The proposed mechanism involves the attenuation of the Bezold-Jarisch reflex—an inhibitory cardiovascular reflex triggered by decreased venous return and serotonin release, leading to profound hypotension and bradycardia (Owczuk et al., 2008; Sahoo et al., 2012). Ondansetron is thought to blunt this reflex through its serotonin antagonism, thereby stabilizing cardiovascular responses during spinal anesthesia.

Numerous studies have supported this hypothesis. Wang et al. (2015) and Ortiz-Gómez et al. (2014) demonstrated significant reductions in the incidence and severity of SIH following pre-anesthetic ondansetron administration. Similarly, Rashad and Farmawy (2013) showed decreased vasopressor requirements in parturients receiving ondansetron. Nonetheless, variations in patient demographics, drug dosages, and monitoring protocols necessitate region-specific validation of these findings.

In the Indian obstetric population, data on the effectiveness of ondansetron in mitigating SIH remain limited. Given its excellent safety profile, wide availability, and dual benefit as an antiemetic, evaluating ondansetron's prophylactic role in cesarean sections within a high-volume tertiary care setting is clinically relevant. This study aims to assess the efficacy of intravenous ondansetron in reducing the incidence and severity of SIH in parturients undergoing elective cesarean delivery under spinal anesthesia, with a focus on vasopressor requirement, maternal comfort, and neonatal well-being.

MATERIALS AND METHODS

Research Design

Designed in the Department of Anaesthesiology at Patna Medical College & Hospital, this prospective, randomized, double-blind, placebo-controlled experiment ran from January 2023 to January 2024. The study was authorized by the institutional ethics committee, and each participant signed written informed permission.

Analysis Cohort and Sample Scale

Enrolled in the study were ninety-two parturient aged 18 to 35 years who planned an elective lower segment caesarean section under spinal anaesthesia after singleton pregnancies at term (37 to 40 weeks). Every patient fell into either physical state I or II according to American Society of Anesthesiologists (ASA).

Eligibility Criteria

- Individuals aged 18 to 35 years
- ASA physical status I or II
- Single gestation term pregnancy
- Elective lower segment cesarean section with spinal anesthesia
- No known drug allergies or concomitant conditions

Criteria for Exclusion

- Emergency cesarean delivery
- Multiple gestation or premature labor
- Preeclampsia or eclampsia
- History of cardiovascular illness or arrhythmias
- Contraindications to spinal anesthesia
- Administration of antiemetic or serotonergic drugs within 24 hours preceding surgery

Randomization and Blinding

Using computer-generated random numbers and a sealed envelope technique, participants were evenly divided into two groups:

Group O (ondansetron group) received 8 mg of intravenuous ondansetron diluted in 10 mL of normal saline.
Administered as a placebo 10 mL of intravenuous normal saline, Group C (Control group).

An anesthesiologist not involved in patient monitoring or data collecting made both solutions ready and given to preserve blindness.

Anesthetic Protocol

Standard monitoring—which included ECG, non-invasive blood pressure (NIBP), and pulse oximetry—was started upon arrival into the surgery room. Documented were baseline blood pressure (systolic, diastolic, and mean arterial pressure), as well as heart rate (HR). Every patient had a preload of 10 mL/kg of Ringer's lactate given over 15 minutes after an expanded bore intravenous line was set up.

Two mL (10 mg) of 0.5% hyperbaric bupivacaine was injected in the L3–L4 interspace using a 25G Quincke needle five minutes following delivery of the research medicine spinal anesthesia. Patients were then positioned supine with a left lateral inclination to lessen aortocaval pressure.

Data Acquisition and Hemodynamic Surveillance

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Hemodynamic parameters (SBP, DBP, MAP, and HR) were recorded at subsequent time intervals:
Pre-spinal basis
For the first 10 minutes every two minutes.
Every five minutes after delivery.

Either a systolic blood pressure below 100 mmHg or a drop more than 20% from baseline defined hypotension. Bradycardia is typified by a heart rate fewer than 60 beats per minute. Six mg increments of intravenous ephedrine helped control hypotension; intravenous atropine at 0.6 mg helped treat bradycardia.
Supplementary results encompassed:

- Total usage of ephedrine
- Prevalence of nausea and emesis
- Requirement for intraoperative antiemetics
- Apgar scores for neonates at 1 and 5 minutes

Statistical Examination

Data were entered into Microsoft Excel and subjected to SPSS version 25 analysis. Mean ± SD presentation of continuous variables was examined using Student's t-test. Fisher's exact test or Chi-square test looked at categorical variables. Considered statistically significant was a p-value less than 0.05.

RESULTS

A total of 92 parturients were examined, including 46 in each cohort. The two groups were equivalent regarding age, weight, gestational age, and baseline hemodynamic parameters (data omitted for conciseness).

Incidence of Hypotension and Vasopressor Requirement

The occurrence of spinal-induced hypotension was markedly reduced in Group O (ondansetron group) at 26.1% against 63.0% in Group C (control group) ($p < 0.001$). The average dose of ephedrine needed to manage hypotension was considerably reduced in the ondansetron group (4.2 ± 1.8 mg) compared to the control group (10.7 ± 2.4 mg, $p < 0.001$). This suggests that the preventive use of ondansetron enhanced hemodynamic stability.

Incidence of Nausea and Vomiting

The ondansetron group demonstrated a notable decrease in intraoperative nausea (10.9%) and vomiting (4.3%) relative to the control group, which exhibited a 30.4% incidence of nausea and 15.2% of vomiting ($p < 0.05$ for both). The symptoms were addressed conservatively, and no patients necessitated further antiemetics beyond the initial study medication.

Neonatal Outcomes

The neonatal welfare, evaluated using Apgar ratings, was slightly superior in the ondansetron group. The average Apgar score at 1 minute was 8.3 for Group O and 7.6 for Group C. At the five-minute mark, the scores were 9.6 and 9.3, respectively. Despite the lack of statistical significance ($p > 0.05$), these differences indicate consistent neonatal outcomes in both cohorts.
The Table 1 and Figure 1 demonstrates significantly lower rates of adverse outcomes in the ondansetron group compared to control.

Table 1: Comparison of Clinical Outcomes Between Groups

Parameter	*Group O (Ondansetron)*	*Group C (Control)*
Incidence of Hypotension (%)	26.1	63.0
Mean Ephedrine Dose (mg)	4.2	10.7
Incidence of Nausea (%)	10.9	30.4
Incidence of Vomiting (%)	4.3	15.2
Apgar Score at 1 min (mean)	8.3	7.6
Apgar Score at 5 min (mean)	9.6	9.3

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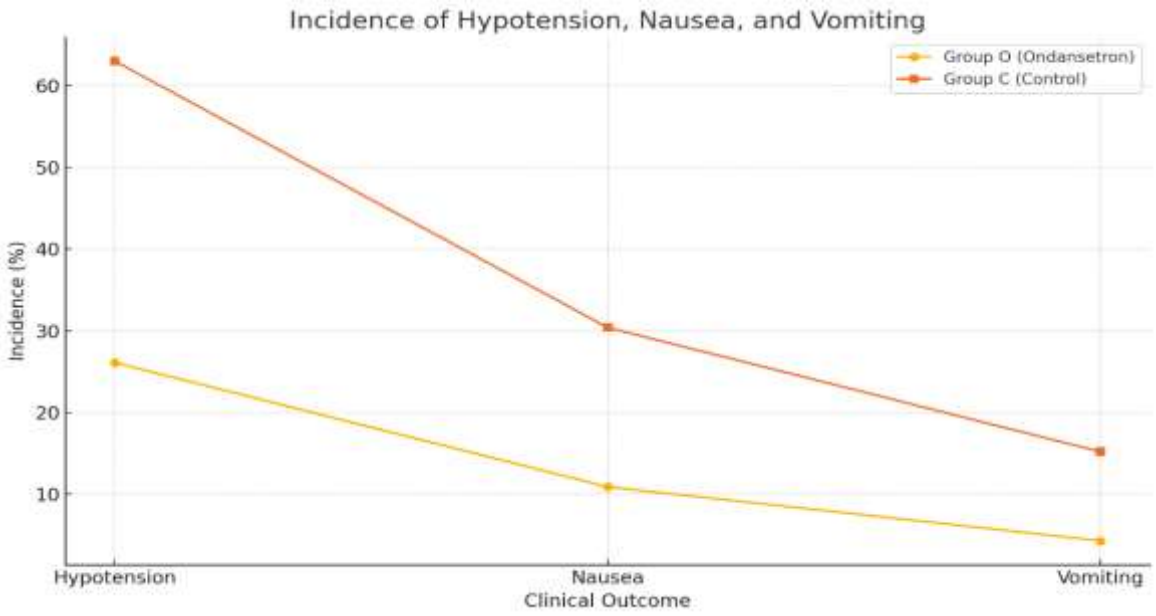

Figure 1: Incidence of Hypotension, Nausea, and Vomiting

DISCUSSION

The study assessed the impact of intravenous ondansetron on spinal-induced hypotension (SIH) in parturients undergoing elective cesarean section. The results clearly demonstrate that pre-spinal ondansetron administration significantly reduces the incidence and severity of hypotension, decreases vasopressor requirements, and lowers the prevalence of intraoperative nausea and vomiting.

These findings agree with previous investigations. Ortiz-Gómez et al. (2014) and Wang et al. (2015) reported that ondansetron not only stabilizes maternal hemodynamics but also reduces the total dose of ephedrine administered during cesarean delivery. The attenuation of the Bezold-Jarisch reflex is considered the primary mechanism by which ondansetron acts—by blocking serotonin-induced vagal stimulation, thus preventing vasodilation and bradycardia (Owczuk et al., 2008; Sahoo et al., 2012). Our results validate this mechanism in the Indian obstetric population.

The use of ondansetron in our study resulted in a 36.9% absolute reduction in SIH incidence compared to placebo, aligning closely with prior reports from Liao et al. (2004) and Rashad & Farmawy (2013). Furthermore, the mean ephedrine dose was significantly lower in the ondansetron group, corroborating earlier studies suggesting reduced vasopressor dependency (Stewart et al., 2010; Saravanan et al., 2006). These outcomes are particularly important in minimizing maternal side effects and optimizing fetal perfusion.

Ondansetron also contributed to a significant reduction in intraoperative nausea and vomiting, a finding that mirrors earlier trials by Ngan Kee et al. (2005) and Trabelsi et al. (2015), who emphasized the dual role of ondansetron in improving maternal comfort and maintaining cardiovascular stability.

Neonatal Apgar scores in both groups were comparable and within normal limits, suggesting that ondansetron use does not adversely affect neonatal outcomes, as previously observed by Wang et al. (2015) and Ortiz-Gómez et al. (2014). While the differences in scores were not statistically significant, the slightly better outcomes in the ondansetron group indicate a possible trend that may be confirmed in larger cohorts.

Although promising, this study is not without limitations. It was conducted at a single center with a modest sample size and did not assess long-term neonatal outcomes or maternal satisfaction scores. Moreover, optimal ondansetron dosage and timing remain areas for future investigation, particularly in the context of varied patient profiles and spinal anesthetic techniques (El Sayed et al., 2016; Ali et al., 2018).

In conclusion, our findings substantiate the clinical utility of ondansetron as a prophylactic agent against SIH in cesarean sections. Its cost-effectiveness, safety, and additional antiemetic benefit make it a viable adjunct in obstetric anesthetic protocols, especially in high-risk or high-volume surgical settings.

CONCLUSION

This randomized, double-blind trial indicates that intravenous ondansetron given before spinal anesthesia significantly decreases the occurrence and severity of spine-induced hypotension (SIH) in parturients

undergoing elective cesarean section. In comparison to the control group, patients administered 8 mg ondansetron exhibited more stable hemodynamic parameters, necessitated significantly reduced doses of vasopressors (ephedrine), and reported fewer occurrences of intraoperative nausea and vomiting. The medication was well-tolerated, with no adverse effects observed in maternal or neonatal outcomes.

Ondansetron's advantageous function is ascribed to its capacity to inhibit 5-HT_3 receptors implicated in the Bezold-Jarisch reflex, considered a crucial mechanism in spinal-induced hypotension. Moreover, ondansetron's recognized antiemetic qualities significantly improve maternal satisfaction and comfort during surgical procedures.

Clinically, ondansetron is deemed safe, cost-effective, easily accessible, and has been incorporated into standard perioperative protocols for its antiemetic properties. The findings of this study endorse its wider use as a preventive drug for SIH, particularly in high-volume obstetric centers where sustaining maternal hemodynamic stability is essential for both maternal and fetal outcomes.

Nonetheless, more multicenter trials involving varied populations are necessary to validate these results, investigate optimal dosing strategies, and evaluate long-term effects for both neonates and mothers. This study provides significant evidence for the regular preventive administration of ondansetron in spinal anesthesia procedures for cesarean sections.

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