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Evaluation of The Efficacy of Ondansetron in preventing post spinal Anesthesia Hypotension in Cesarean Sections

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Abstract
Background: Spinal anesthesia-induced hypotension (SAIH) is a common complication during Cesarean sections. The prophylactic use of ondansetron has been suggested as a potential intervention to prevent SAIH. This study purposed to assess ondansetron efficacy in SAIH prevention and its impact on ephedrine consumption, as well as the incidence of adverse effects such as maternal bradycardia, postdural puncture headache, pruritus, and shivering. **Methods:** This prospective double-blind, placebo-controlled, randomized study was performed on female patients aged 18-35 years undergoing Cesarean Section under spinal anesthesia. The sample size was estimated using data from earlier research, with a total of 90 cases divided equally into two groups: the ondansetron group (Group O) and the placebo group (Group P). Baseline data, intraoperative monitoring, and postoperative assessments were conducted, and statistical comparison was conducted between the results of the two groups. **Results:** No substantial changes were seen between two groups regarding demographic data, anthropometric measures, American Society of Anesthesia (ASA) scores, and duration of surgery. However, the ondansetron group demonstrated a substantially lower hypotension incidence compared to the placebo group at various time points after spinal anesthesia. Additionally, the ondansetron group exhibited significantly higher systolic blood pressure and diastolic blood pressure readings, as well as a lower incidence of shivering, nausea, and vomiting. **Conclusion:** The prophylactic use of ondansetron was effective in reducing the incidence of spinal anesthesia-induced hypotension during Cesarean sections. It also resulted in less ephedrine consumption and a lower occurrence of shivering, nausea, and vomiting.

Keywords: Spinal Anesthesia, Hypotension, Ondansetron,Cesarean Section, Prophylaxis, Shivering, Nausea, Vomiting.

1. Introduction

Post-spinal anesthesia hypotension (SAIH) is a common complication observed during cesarean sections, potentially leading to adverse maternal and fetal outcomes. Despite numerous preventive strategies, such as intravenous fluids, vasopressors, and left uterine displacement, SAIH remains a significant concern [1].

Ondansetron, a selective 5-hydroxytryptamine 3 (5-HT3) receptor antagonist often used as an antiemetic, has shown potential in avoiding SAIH. By modulating the release of serotonin and reducing sympathetic outflow, ondansetron may mitigate the hypotensive response related to spinal anaesthesia. This study aims to evaluate the efficacy of prophylactic ondansetron administration in preventing SAIH during cesarean sections, while also assessing its impact on ephedrine consumption and potential adverse effects [2].

Cesarean sections are commonly performed under spinal anesthesia due to its advantages over general anesthesia, such as rapid onset, better maternal respiratory function, and minimal fetal exposure to anesthetic agents. However, the sympathetic blockade caused by spinal anesthesia often leads to a decrease in systemic vascular resistance, resulting in hypotension [3]. SAIH can compromise uteroplacental perfusion, leading to fetal acidosis, hypoxia, and adverse neonatal outcomes. Additionally, maternal hypotension may result in maternal discomfort, nausea, vomiting, and impaired organ perfusion. Thus, effective prevention and management of SAIH are crucial to ensure the well-being of both mother and fetus [4].

Ondansetron, primarily known for its antiemetic properties in the management of nausea and vomiting, has demonstrated additional physiological effects that make it a potential candidate for SAIH prevention. As a 5-HT3 receptor antagonist, ondansetron inhibits serotonin-mediated vasodilation and attenuates the Bezold-Jarisch reflex, a vagal reflex associated with hypotension [5]. Several studies have explored the use of ondansetron as a prophylactic agent for SAIH, with promising results. However, the available evidence is still limited, warranting further investigation to establish its efficacy and safety in the context of cesarean sections [6, 7].

The prevention of SAIH traditionally relies on intravenous fluid administration, vasopressors, or both. However, these strategies may have limitations, such as fluid overload, reduced cardiac output, and adverse effects of vasopressors. Ondansetron, as an adjunctive therapy, could offer an alternative approach with potential benefits. By modulating serotonin receptors, it may provide a more

targeted and mechanism-based intervention to prevent SAIH without the aforementioned drawbacks. Furthermore, it is a well-tolerated drug commonly used in obstetric practice, making it an attractive option for prophylaxis during cesarean sections [8].

This research aimed to determine the impact of prophylactic ondansetron administration on the incidence of spinal anesthesia-induced hypotension (SAIH), ephedrine intake, and side effects such as maternal bradycardia, postdural puncture headache, itching, and shivering.

2. Methods

This prospective double-blind, placebo-controlled, randomized study was conducted at the Surgical Hospital of Benha University after obtaining approval from the medical ethical committee. Participants in the research were 18- to 35-year-old females having caesarean section under spinal anaesthesia. The research was conducted from January 2022 to January 2023 after receiving clearance from the Institutional Review Board of the Faculty of Medicine at Benha University. After describing the technique to every patient, written informed permission was acquired.

Sample Size:

The sample size was determined using the STATA program, with an alpha error set at 5% and power at 80%. A prior research by Marashi et al. (2014) revealed that none of the Ondansetron patients suffered hypotension (0%), compared to 17% of the placebo participants [9]. Based on this, a total of 90 cases (45 in each group) were required, considering a possible dropout rate of 6 patients.

Inclusion criteria were parturient women aged between 18 and 35 years who were scheduled for Cesarean Section, fasting for a minimum of 8 hours prior to the procedure, and having an American Society of Anesthesia (ASA) physical status of either I or II.

Exclusion criteria were individuals who refused to undergo the procedure or participate in the study, had a physical status of ASA III or above, had contraindications to spinal anesthesia, had psychiatric illness, experienced pre-eclampsia, had central nervous system diseases or neurological diseases affecting the lower limbs, presented a history or evidence of coagulopathy, exhibited allergies to drugs used (specifically ondansetron), experienced a sensory block below the dermatomal level T4 following spinal anesthesia, or were morbidly obese patients with a body mass index (BMI) less than 40.

Patients were divided equally into two groups: Group O (n = 45): Received 8 mg of ondansetron diluted in 10 cm^3 of normal saline administered intravenously 5 minutes prior to spinal anesthesia and **Group P (n = 45):** Received 10 cm^3 of normal saline intravenously 5 minutes before spinal anesthesia as a placebo.

All patients were subjected to the following:

Preoperative Preparation: Routine preoperative assessments, including detailed history taking, examination, and investigations, were conducted for all patients. Data such as age, height, weight, and duration of the surgical procedure were recorded. Patients were instructed to fast for 8 hours before surgery and avoid taking any medications aside from the study assignments.

Intraoperative Settings: After admission to the operating room (OR) and securing peripheral venous access, standard monitoring, including non-invasive blood pressure (NIBP), pulse oximetry, and ECG, was performed. Baseline values for oxygen saturation, heart rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean arterial blood pressure (MAP) were recorded with patients in the supine position with a left lateral tilt of 15°. Hydration with 15 ml/kg Before spinal anaesthesia was provided, Hartmann's solution was administered. The temperature in the operation room was kept between 24 and 26 ° C. Anesthesia was induced according to the assigned groups. The drugs were prepared by an anesthesia nurse, ensuring blinding of the assigned anesthetist. At the L3/4 or L4/5 interspace, a 27-gauge spinal needle with a pencil tip was used to provide spinal anaesthetic.

Intraoperative Monitoring: During the procedure, conscious level, sensory block level, motor block level, blood pressure, heart rate, oxygen saturation, and adverse effects were assessed and recorded. Any complications such as persistent pain or unsuccessful spinal anesthesia were documented. The group assignment was concealed from the attending anesthesiologist and perioperative data collectors.

Postoperative Period: In the postoperative period, patients were assessed for hemodynamic parameters (mean arterial blood pressure, heart rate, and oxygen saturation) before leaving the post-anesthesia care unit (PACU). Medications were administered according to the occurrence of complications such as vomiting, shivering, bradycardia, or hypotension.

Statistical analysis

This study's data were submitted to several statistical analyses using version 23 of the Statistical Package for the Social Sciences (IBM SPSS). The Kolmogorov-Smirnov test was used to evaluate the normality of quantitative data distribution. Quantitative variables were represented as numbers and percentages, whereas quantitative variables were provided as means, standard deviations, and ranges. Chi-square test was used to compare qualitative data across groups, and Fisher's exact test was used when anticipated counts in any cell were less than 5. To compare two independent groups with quantitative data and a parametric distribution, independent t-tests were used. The significance threshold was established using a 95 percent confidence interval and a 5 percent margin of error. Therefore, p-values less than the specified significance level were considered statistically significant.

3. Results

No statistically substantial changes were present between studied groups concerning demographic data, anthropometric measures, ASA score and total surgery time with p-value > 0.05.

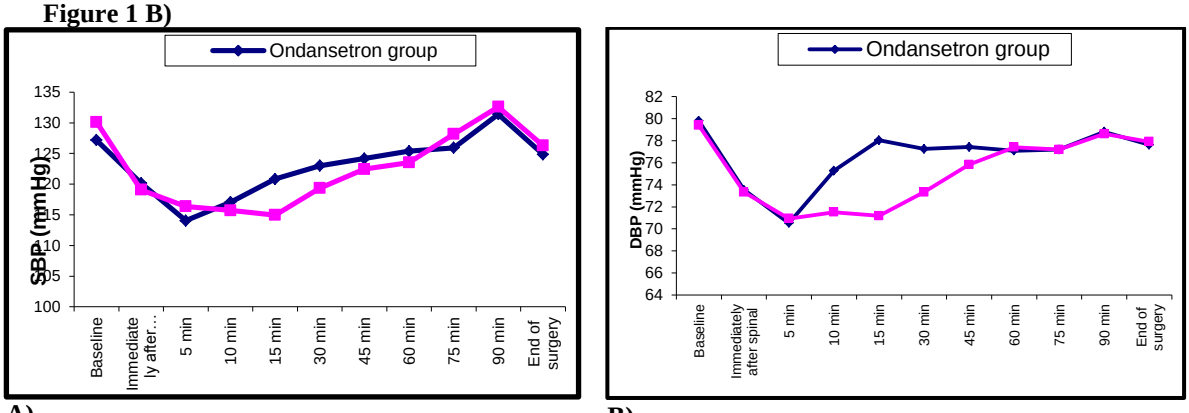
Table (1) Comparison between ondansetron group and placebo group regarding demographic data, anthropometric measures, ASA score and total time of surgery

		Ondansetron group	Placebo group	Test value	P-value
		No. = 45	**No. = 45**		
Age	Mean ± SD	29.82 ± 5.06	30.04 ± 5.01	-0.209•	0.835
	Range	21 – 39	21 – 39		
Gender	Female	18 (40.0%)	25 (55.6%)	2.182*	0.140
	Male	27 (60.0%)	20 (44.4%)		
Weight	Mean ± SD	72.04 ± 7.24	71.89 ± 7.4	0.101•	0.920
	Range	60 – 90	60 – 90		
Height	Mean ± SD	169.18 ± 6.99	169.64 ± 6.91	-0.318•	0.751
	Range	157 – 188	157 – 188		
Body Mass Index (BMI)	Mean ± SD	25.15 ± 1.71	24.95 ± 1.67	0.574•	0.567
	Range	22 – 29.4	22 – 29.4		
ASA	1	29 (64.4%)	34 (75.6%)	1.323*	0.250
	2	16 (35.6%)	11 (24.4%)		
Total time of surgery	Mean ± SD	76.13 ± 9.77	76.16 ± 9.74	-0.011•	0.991
	Range	60 – 90	60 – 90		

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant, *: Chi-square test; •: Independent t-test

No statistically substantial changes were present between studied groups concerning SBP at different time of measurement except at 15 min, 30 min, 45 min and 60 min there was statistically significant decrease in SBP in placebo group than ondansetron group with p-value < 0.001, < 0.001, 0.035 and 0.040 respectively. **Figure 1 A)**

No statistically substantial changes were present between studied groups regarding DBP at different time of measurement except at 10 min, 15 min and 30 min there was statistically significant reduction in DBP in placebo group than ondansetron group with p-value < 0.001, < 0.001 and 0.001 respectively. **Figure 1 B)**

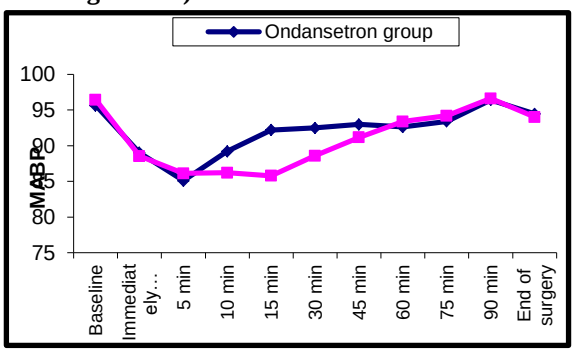


A) **B)**

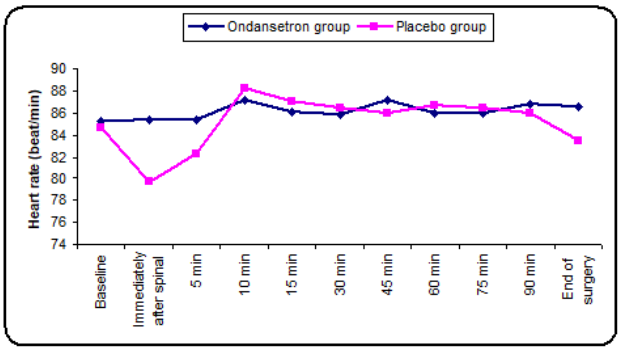
Fig. (1) A) Mean systolic blood pressure in the two studied groups at different time of measurements and B) Mean diastolic blood pressure in the two studied groups at different time of measurement.

No statistically substantial changes were present between studied groups regarding MABP at different time of measurement except at 10 min, 15 min, 30 min and 45 min. there was statistically significant decrease in MABP in placebo group than ondansetron group with p-value < 0.001, < 0.001, <0.001 and 0.046 respectively. **Figure 2 A)**

No statistically substantial changes were present between studied groups regarding heart rate at different time of measurement except immediately after spinal and at end of surgery showed decrease in heart rate in placebo group than ondansetron group with p-value = 0.025 and 0.014 respectively. **Figure 2 B)**



A)



B)

Fig. (2) A) Mean arterial blood pressure in the two studied groups at different time of measurement and B) Heart rate (beat/min) in the two studied groups at different time of measurement.

There was no statistically significant difference found between the two studied groups regarding SaO2 at different time of measurement with p-value > 0.05. **Figure 3**

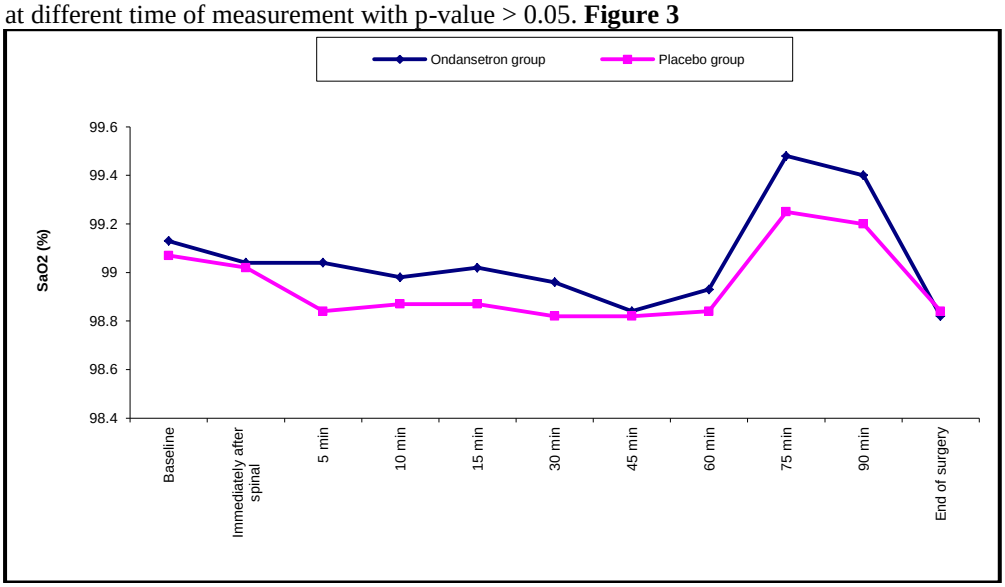


Figure (3) SaO2 (%) in the two studied groups at different time of measurement.

The frequency of hypotension was significantly higher in the placebo group immediately after spinal anaesthesia and 5 minutes later compared to the ondansetron group, according to statistical analysis with p-value = 0.026 and 0.014 respectively. **Table 2**

Table (2) Comparison between ondansetron group and placebo group regarding incidence of hypotension at different time of measurement

Hypotension		Ondansetron group No. = 45	Placebo group No. = 45	Test value	P-value	Sig.
Immediately after spinal	No	44 (97.8%)	38 (84.4%)	4.939*	0.026	S
	Yes	1 (2.2%)	7 (15.6%)			
5 min	No	44 (97.8%)	37 (82.2%)	6.049*	0.014	S
	Yes	1 (2.2%)	8 (17.8%)			
10 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			

15 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
30 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
45 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
60 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
75 min	No	29 (100.0%)	27 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
90 min	No	5 (100.0%)	5 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
End of surgery	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			

P-value > 0.05: Non-significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant, *: Chi-square test

There was no statistically substantial change in bradycardia incidence between two studied groups at different times of measurements. **Table 3**

Table (3) Comparison between ondansetron group and placebo group regarding incidence of bradycardia at different time of measurement

Bradycardia		**Ondansetron group**	**Placebo group**	**Test value**	**P-value**	**Sig.**
		No. = 45	**No. = 45**			
Immediately after spinal	No	44 (97.8%)	41 (91.1%)	1.906*	0.167	NS
	Yes	1 (2.2%)	4 (8.9%)			
5 min	No	44 (97.8%)	40 (88.9%)	2.857*	0.091	NS
	Yes	1 (2.2%)	5 (11.1%)			
10 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
15 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
30 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
45 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
60 min	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
75 min	No	28 (100.0%)	27 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
90 min	No	5 (100.0%)	5 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			
End of surgery	No	45 (100.0%)	45 (100.0%)	–	–	–
	Yes	0 (0.0%)	0 (0.0%)			

P-value > 0.05: Non significant; P-value < 0.05: Significant; P-value < 0.01: Highly significant, *: Chi-square test

There was statistically significant increase in the incidence of shivering in placebo group than ondansetron group at 5 min post spinal with p-value = 0.024 while no statistically substantial change was found between the two studied groups at any other time. **Figure 4**

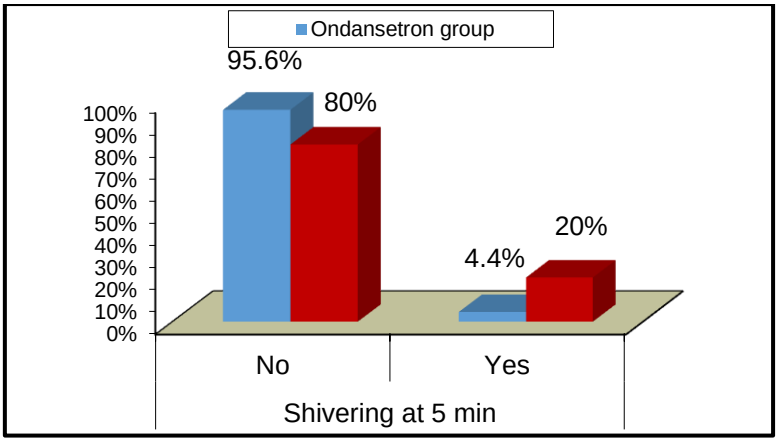


Fig. (4) Incidence of shivering at 5 min in the two studied groups.

There was statistically significant increase in the incidence of nausea and vomiting in placebo group than ondansetron group with p-value < 0.001 and 0.011 respectively while no statistically significant difference found between the two studied groups regarding ECG changes or pruritis. **Figure 5**

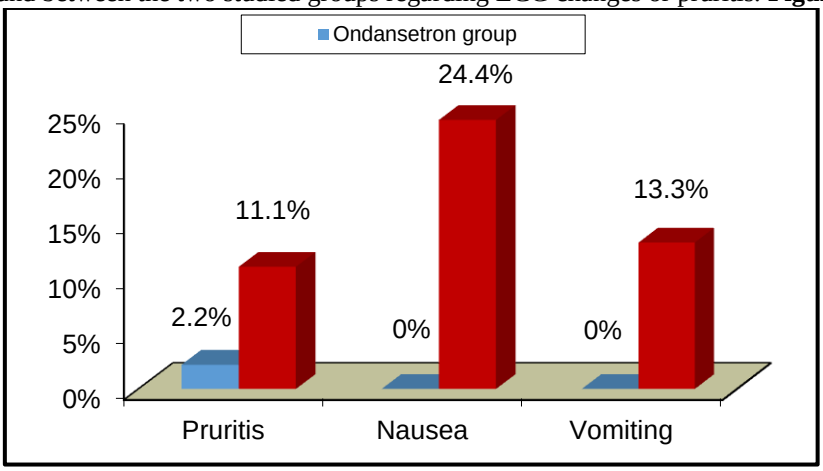


Fig. (5) Incidence of pruritis, nausea and vomiting in the two studied groups.

4. Discussion

In our study, comparison was done between two groups which were Group A (ondansetron) 8 mg iv administered 5 mins before spinal anaesthesia and Group B (placebo) as regard their effects on blood pressure changes, heart rate changes, SaO2 changes, incidence of hypotension and bradycardia, also Shivering, ECG changes, nausea and vomiting.

Ondansetron has been studied previously for use in spinal anaesthesia, by Sahoo et al., Trabelsi et al., Owczuk R et al., and Rashad and Faramawy, These studies demonstrated that intravenous ondansetron attenuated spinal anaesthesia induced hypotension when administered prior to spinal anaesthesia, In addition to decreasing the dosages of vasopressors needed by patients, the outcomes of this trial were consistent with these earlier findings [10-13].

In Group A (ondansetron), 2 out of 45 patients (4.4%) experienced SBP < 90mmHg and MABP < 20% of baseline. They were treated with 6 mg ephedrine and maintained SBP > 90mmHg throughout the surgery. In Group B (placebo), 15 out of 45 patients (33.3%) had similar blood pressure drops and received ephedrine treatment. Decreased DBP accompanied the drop in SBP and MABP in each patient.

Our study found a statistically significant increase in the incidence of hypotension immediately and 5 minutes after spinal anesthesia in the Placebo group (33.3% out of 45 cases) compared to the Ondansetron group (4.4% out of 45 cases), with p-values of 0.026 and 0.014, respectively. Additionally, there was a significant decrease in the amount of vasopressor (ephedrine) required in the Ondansetron group compared to the Placebo group. These findings align with a meta-analysis by Gao et al. (2015), which showed that prophylactic administration of intravenous ondansetron reduces the incidence of spinal anesthesia-induced hypotension and vasopressor consumption [14]. Similar outcomes were also oseen in studies by Owczuk et al. (2008) and Sahoo et al. (2012) in different patient populations [10, 12]. Another study by Marashi et al. (2014) demonstrated that intravenous ondansetron at various doses attenuates spinal-induced

hypotension, bradycardia, and shivering. However, it should be noted that in our study, a higher dose of 8mg ondansetron was administered, and bradycardia did not show a statistically significant difference in the ondansetron group [9].

In contrast to our study, Ortiz-Gómez et al. (2014) found minimal effects of prophylactic ondansetron on hypotension incidence in healthy parturient undergoing spinal anesthesia [15]. The present study focused on surgeries below the umbilicus, excluding obstetric cases, making direct comparison difficult due to unique factors in pregnancy. In Group A (ondansetron), 2 patients (4.4%) experienced bradycardia associated with hypotension and received 0.5 mg atropine. In Group B (placebo), 9 patients (20%) had bradycardia, and all received 0.5 mg atropine. Although there was no significant difference in bradycardia incidence, Group A required less atropine compared to Group B. Regarding SaO2 level, in our study there was no statistically significant difference found between the two studied groups at different time of measurement.

In our study, the incidence of shivering in Group A (ondansetron) was 2 out of 45 patients (4.4%), which was significantly lower than in Group B (placebo) with 9 out of 45 patients (20%) experiencing shivering. Shivering was categorized into different grades based on severity. Shaking is a typical side effect of spinal anaesthesia, although its specific cause is unknown. One study suggested that hypothalamus-secreted neurotransmitter serotonin (5-HT) has a function in thermoregulation.

Kelsaka et al. (2006) investigated the effectiveness of ondansetron and meperidine in decreasing spinal anesthesia-induced trembling. They discovered that ondansetron exhibited effects comparable to meperidine. Our study, however, only compared ondansetron to saline, not meperidine [16].

In another study by Marashi et al. (2014) involving 210 patients, they compared six and twelve milligrammes of ondansetron to a placebo group. The incidence of shivering did not vary significantly between the two ondansetron groups, but the control group had a higher incidence of shivering (45%). These findings align with our study [9].

In our study, the ondansetron group showed a significant reduction in the incidence of intraoperative nausea and vomiting compared to the placebo group (p-value < 0.001 and 0.011, respectively). None of the patients in the ondansetron group had nausea or vomiting during surgery, while 11 out of 45 cases (24.4%) reported nausea and 6 out of 45 cases (13.3%) reported vomiting in the placebo group. These patients were given metoclopramide to alleviate their symptoms. These findings align with previous studies by Sahoo et al. (2012), Owczuk et al. (2008), Rashad and Farmawy (2013), and Wang et al. (2014), that also proved the usefulness of ondansetron in decreasing nausea and vomiting during surgery [10, 12, 13, 17].

Ghazi and Mostafa (2005) found ondansetron to be more effective than propofol in preventing emetic symptoms after spinal anesthesia, supporting our study's findings despite our comparison being with a saline group [18]. Additionally, Goda and Amin (2012) demonstrated that consistent with our research, prophylactic intravenous ondansetron preloaded with lactated Ringer's solution prior spinal anaesthesia decreased the occurrence of hypotension, bradycardia, nausea, vomiting, and shivering [19].

Ondansetron, which is chemically identical to 5-HT3, specifically blocks 5-HT3 receptor-induced vagal activation and decreases 5-HT release in the fourth ventricle, so successfully reducing vomiting. Multiple studies have demonstrated that ondansetron lowers greatly the occurrence of intraoperative and postoperative nausea and vomiting [20].

Although only one case in the ondansetron group and five cases in the placebo group reported symptoms of pruritus, the difference was not statistically significant. The use of ondansetron for preventing pruritus and shivering remains a topic of debate. Pruritus may be initiated by opioids spreading via cerebrospinal fluid to the head, where they act on medulla oblongata and spinal L or 5-HT3 receptors. Ondansetron, a selective 5-HT3 receptor antagonist commonly used to prevent or treat nausea and vomiting, has been shown in clinical studies to effectively control pruritus resulting from intrathecal opioid injections, such as fentanyl [6].

5. Conclusion

Prophylactic intravenous ondansetron 8mg iv. 5 minutes prior to spinal anaesthesia decreased spinal anesthesia-induced hypotension, reductions in SBP, MABP, and heart rate in patients undergoing elective Caesarean section under spinal anaesthesia with bupivacaine. Ondansetron did not have a significant impact on DBP or vasopressor usage; however, doses were decreased. The incidence of intraoperative nausea & vomiting and shivering was reduced after ondansetron administration.

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