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EFFECT OF PROPHYLACTIC ONDANSETRON ON SPINAL ANAESTHESIA - INDUCED HYPOTENSION DURING CAESAREAN SECTION AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

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ABSTRACT

Objective: **To determine the effect of prophylactic ondansetron on the incidence of spinal anaesthesia- induced hypotension during caesarean section at Moi Teaching and Referral Hospital (MTRH), Kenya.**

Materials and Methods: **A randomized, double-blind, control trial was conducted at MTRH involving 194 parturients at term gestation who underwent elective caesarean sections under spinal anaesthesia. Block randomization and consecutive sampling were employed. Participants were divided into two groups of 97: Group O received 4 mg intravenous ondansetron, and Group S received an equivalent volume of saline, both administered 15 minutes before spinal anaesthesia. Data on demographics, clinical, anaesthesia and surgical outcomes, vasopressor usage, and neonatal results were collected using a structured questionnaire and analyzed using STATA version 16. Statistical tests included the two proportions z-test, t-test, fisher's exact and Mann-Whitney U test, with significance set at $P < 0.05$.**

Results: **Both groups exhibited comparable baseline demographic and clinical characteristics. The mean age of participants was comparable between Group S (29.9 ± 4.8 years) and Group O (30.3 ± 4.7 years; P=0.56). A majority in both groups were under 35 years of age (Group S: 80.4%, Group O: 77.3%), with no statistically significant difference (P=0.598). The incidence proportion of spinal anaesthesia-induced hypotension (SAIH) was 85.6%. Group O had lower SAIH occurrence (77.3%, n=75) compared to group S (93.8%, n=91), P=0.001. Mean systolic blood**

pressure variations across time intervals did not differ significantly between Group S and Group O (P>0.05).
***Conclusion*: Prophylactic 4mg intravenous ondansetron is effective in reducing the incidence of SAIH.**

INTRODUCTION

Caesarean section (CS) is among the most commonly performed surgeries on women globally, with spinal anaesthesia (SA) preferred over general anaesthesia due to its safety profile and maternal-fetal benefits [1]. At Moi Teaching and Referral Hospital (MTRH), Eldoret, Kenya, SA is used in over 70% of CS cases. Although SA has contributed to reduced anaesthesia-related maternal mortality, it remains associated with complications—most notably spinal anaesthesia-induced hypotension (SAIH), which affects 50–80% of parturients globally and poses risks to both maternal and fetal outcomes [2,3].

SAIH results from sympathetic blockade leading to vasodilation, reduced systemic vascular resistance, and compromised uteroplacental perfusion. Bradycardia may also occur due to high spinal levels and activation of the Bezold–Jarisch reflex (BJR), a serotonin- mediated cardioinhibitory response. Various mitigation strategies exist, including fluid loading, lower-leg compression, and vasopressors, but none are universally effective.

Recent evidence suggests ondansetron, a 5-HT3 receptor antagonist commonly used as an antiemetic, may attenuate SAIH and bradycardia by inhibiting serotonin-mediated BJR activation. However, its prophylactic use in this context remains underexplored, particularly in East Africa. This study aims to evaluate the impact of prophylactic intravenous ondansetron on the incidence of SAIH during CS at MTRH.

METHODS

Approval to conduct the study was sought from the institution's research and ethics committee (IREC), approval number 0004102, and from the Chief Executive Officer of MTRH, under reference number ELD/MTRH/R&P/10/2/V.2/210.

This study was a randomized, double-blind, control trial, conducted at Moi Teaching and Referral Hospital (MTRH) obstetric theatres and antenatal wards between August 2022 and September 2023. The study population included all pregnant women who were 37 weeks gestation or more, classified as ASA class II, aged 18 years and above, and scheduled for an elective cesarean section under spinal anaesthesia. The exclusion criteria included pregnant women with pre-anaesthetic hypotension (systolic BP < 100 mmHg), parturients with hypersensitivity to ondansetron, all hypertensive (systolic BP > 140mmHg) patients, and parturients with any cardiac disease.

In this study, the sample size was calculated using the formula for comparing two proportions as described by Fleiss in 1981 [4]. Based on prior data from Kenyatta National Hospital, the incidence of spinal anaesthesia–induced hypotension was reported at 64% [5]. This value was used as the expected proportion in the control group for the sample size estimation. A sample size of 194 participants was obtained, with 97 allocated to

each study arm: Group S (saline) and Group O (ondansetron). A consecutive sampling technique was employed.

Randomization for the study was performed using block randomization with computer-generated numbers. Allocation to study arms (1:1 ratio) was determined by a biostatistician using random numbers, which were secured in Sequentially Numbered Opaque Sealed Envelopes (SNOSE).

Eligible parturients were enrolled a day before elective caesarean section, after preoperative review and informed consent. Baseline demographics were collected, and on arrival to theatre, vital signs were recorded. Participants were then randomized into study arms using block randomization and received the assigned study drug. Each participant was connected to a cardiac monitor and preloaded with 500 mls of normal saline. Spinal anaesthesia was then administered 15 minutes later from the time the study drug was administered. Thereafter, the participant was positioned lying supine and a wedge was placed under the right hip to provide a left lateral tilt so as to prevent aortocaval compression. Vital signs including non-invasive blood pressure, mean arterial pressure, heart rate, and peripheral oxygen saturation were monitored at regular intervals. Hypotension (Systolic Blood Pressure <100 mmHg) was managed with 6 mg IV ephedrine or 50–200 mcg IV phenylephrine boluses, repeated every 3 minutes until resolution. Maternal outcomes (incidence of spinal anaesthesia–induced hypotension, bradycardia, vasopressor use, estimated blood loss) and neonatal outcome (APGAR score) were recorded in a structured questionnaire.

After data collection was completed, the electronic dataset was imported into STATA version 16 for management and statistical analysis. Categorical variables, including comorbidities, indication for caesarean section, hypotension, and bradycardia, were summarized as frequencies with corresponding percentages. Numerical variables, such as age, weight, height, peripheral oxygen saturation (SpO_2), duration of surgery, estimated blood loss, and total intravenous fluids administered, were summarized as means with corresponding standard deviations when normally distributed, or as medians with corresponding interquartile ranges when not. The primary outcome was the incidence proportion of spinal anaesthesia – induced hypotension (SAIH). A two-proportion z-test was employed to compare the incidence proportion of SAIH between the saline group and the ondansetron group. All the test results were considered statistically significant if P - value was less than 0.05.

RESULTS

A total of 194 participants were enrolled in the study. Participants were randomized into two groups: the intervention group (Group O), which received 4 mg (2 ml) of intravenous ondansetron 15 minutes before spinal anaesthesia, and the control group (Group S), which received an equivalent volume of normal saline at the same interval. Each group comprised 97 participants. There were no statistically significant differences in the demographic or clinical characteristics between the two groups. The ages of participants ranged from 19 to 42 years. There was no significant difference in mean maternal age between the two groups: 29.9 ± 4.8 years in Group S (saline) and 30.3 ± 4.7 years in Group O (ondansetron) (P = 0.56). The majority of women were younger than 35 years, comprising 80.4% (n = 78) in Group S and

77.3% (n = 75) in Group O, with no significant difference (P = 0.598). Women of advanced maternal age (≥35 years) accounted for 19.6% (n = 19) in Group S and 22.7% (n = 22) in Group O, also without significant difference (P = 0.598). Table 1 presents the demographic and clinical characteristics of the study participants.

Table 1

Patient Demographics and Clinical Characteristics

	Group S	**Group O**	**P-value**
	N=97	N=97	
Patient age (years)			
< 35 years	78 (80.4%)	75 (77.3%)	0.598[1]
≥ 35 years	19 (19.6%)	22 (22.7%)	
BMI (Kg/m²)			
Underweight (< 18.5)	1 (1.0%)	1 (1.0%)	0.951[2]
Normal (18.5 – 24.9)	29 (29.9%)	26 (26.8%)	
Over weight (25.0 – 29.9)	35 (36.1%)	36 (37.1%)	
Obese (≥ 30)	32 (33.0%)	34 (35.1%)	
Indication for caesarean section			
Maternal cause			0.248[1]
No	8 (8.2%)	13 (13.4%)	
Yes	89 (91.8%)	84 (86.6%)	
Fetal cause			0.314[1]
No	85 (87.6%)	80 (82.5%)	
Yes	12 (12.4%)	17 (17.5%)	
Parity			>0.99[2]
Nulliparous (0)	5 (5.2%)	5 (5.2%)	
Multiparous (1 – 4)	90 (92.8%)	89 (91.8%)	
Grand Multiparous (≥ 5)	2 (2.1%)	3 (3.1%)	
Comorbidities			0.516[1]
Absent	91 (93.8%)	93 (95.9%)	
Present	6 (6.2%)	4 (4.1%)	

[1] *Chi Square test*

[2] *Fisher's exact test*

BMI – Body Mass Index

Kg/m² - Kilogram per Square Meter

Table 2 and Figure 1 illustrate the comparison of mean systolic blood pressure trends between Group S and Group O during the perioperative period. The baseline systolic blood pressure in Group S ranged from 101 to 139 mmHg, with a mean of 120.0 ± 10.2 mmHg. In Group O, it ranged from 100 to 138 mmHg, with a mean of 120.3 ± 9.0 mmHg. The difference between the two groups was not statistically significant (P = 0.909). The systolic blood pressure dropped within the first 5 minutes after spinal anaesthesia administration, showing almost identical mean values in both groups. The subsequent systolic blood pressure measurements up to 30 minutes were comparable in both groups, P > 0.05.

Table 2

Comparison of Mean Systolic Blood Pressure trends between Group S and Group O

	Group S	**Group O**	**P-value**
	N=97	N=97	
Baseline Systolic Blood Pressure (BP) (mmHg)			0.909[1]
Mean (SD)	120.0 (10.2)	120.3 (9.0)	
Range	101 – 139	100 – 138	
Systolic BP 5 minutes after SA			0.966[1]
Mean (SD)	109.2 (18.1)	109.1 (18.6)	
Range	66 – 172	47 – 148	
Systolic BP 10 minutes after SA			0.636[1]
Mean (SD)	106.4 (17.8)	107.7 (19.8)	
Range	52 – 158	64 – 158	
Systolic BP 15 minutes after SA			0.191[1]
Mean (SD)	109.2 (18.2)	112.8 (20.5)	
Range	64 – 164	70 – 205	
Systolic BP 20 minutes after SA			0.849[1]
Mean (SD)	108.2 (15.2)	107.8 (19.2)	
Range	76 – 148	70 – 166	
Systolic BP 25 minutes after SA			0.371[1]
Mean (SD)	111.4 (14.8)	113.4 (15.4)	
Range	79 – 154	78 – 153	
Systolic Bp 30 minutes after SA			0.649[1]
Mean (SD)	110.8 (13.7)	111.7 (13.4)	
Range	79 – 146	79 – 142	

[1] *ttest*

Bp – Blood Pressure

SA – Spinal Anaesthesia

mmHg - Millimeters of Mercury

SD- Standard Deviation

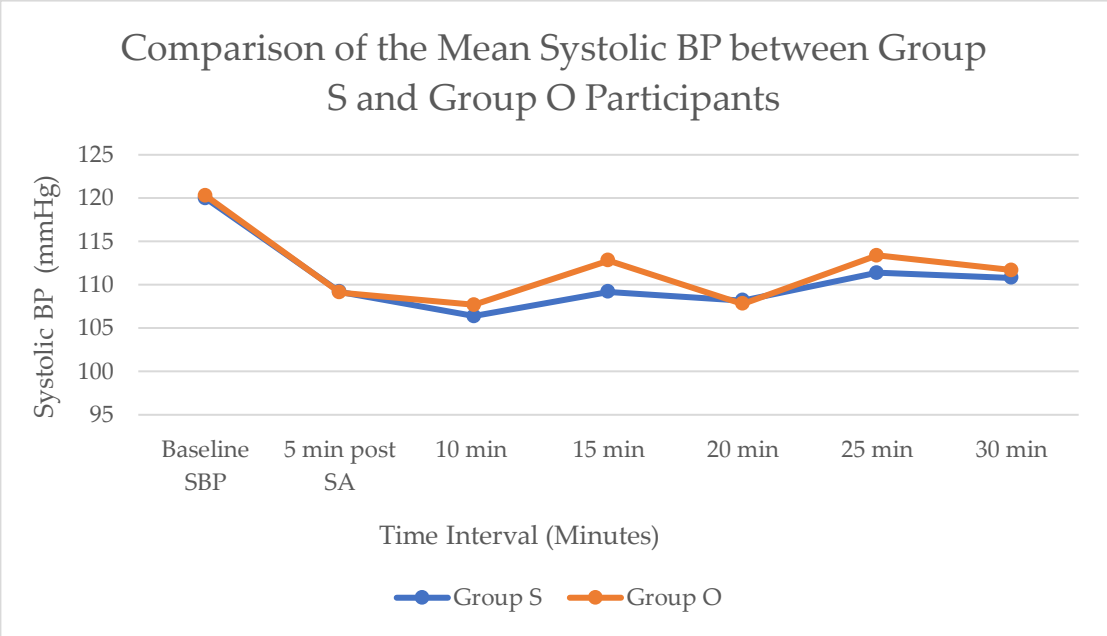

Figure 1: Comparison of Mean Systolic Blood Pressure Between Group S and Group O

The overall incidence proportion of spinal anaesthesia induced hypotension was 85.6% (n= 166). As shown in Table 3, the incidence proportion of spinal anaesthesia-induced hypotension was significantly lower in Group O (77.3%, n=75) compared to Group S (93.8%, n=91), with a P-value of 0.001.

Table 3

Effect of Prophylactic Ondansetron on Spinal anaesthesia Induced Hypotension

	Group S	Group O	P-value
	N=97	N=97	
Hypotension			0.001
No	6 (6.2%)	22 (22.7%)	
Yes	91 (93.8%)	75 (77.3%)	

The bivariate analysis revealed that participants who did not receive ondansetron, those with a baseline systolic blood pressure of less than 120 mmHg, and those who received a 10 IU intravenous bolus of oxytocin were significantly associated with spinal anaesthesia-induced hypotension. These findings are summarized in Table 4 below.

Table 4

Bivariate Analysis of Factors associated with Maternal Hypotension

	Hypotension		
	Absent	**Present**	**p-value**
Variables	**N=28**	**N=166**	
Arm			0.001[1]
Control (Placebo)	6 (6.2%)	91 (93.8%)	
Case (Ondansetron)	22 (22.7%)	75 (77.3%)	
Patient age			0.588[1]
<35years	21 (13.7%)	132 (86.3%)	
≥35years	7 (17.1%)	34 (82.9%)	
Parity			0.568[2]
Nulliparous	2 (20.0%)	8 (80.0%)	
Multiparous	25 (14.0%)	154 (86.0%)	
Grand Multiparous	1 (20.0%)	4 (80.0%)	
Body Mass Index (Kg/m²)			0.447[2]
Underweight	1 (50.0%)	1 (50.0%)	
Normal	8 (14.5%)	47 (85.5%)	
Over weight	11 (15.5%)	60 (84.5%)	
Obese	8 (12.1%)	58 (87.9%)	
Birth weight			>0.99[2]
<4000g	27 (14.5%)	159 (85.5%)	
≥4000g	1 (12.5%)	7 (87.5%)	
Baseline systolic blood pressure (mmHg)			0.013[1]
≥120	20 (20.8%)	76 (79.2%)	
<120	8 (8.2%)	89 (91.8%)	
Anaesthesia to cutting time (minutes)			0.589[3]
Mean (SD)	11.3 (3.9)	10.8 (5.1)	
Range	5 – 20	5 – 35	
Ondansetron to cutting time (minutes)			
Mean (SD)	29.9 (8.0)	28.0 (7.3)	0.222[3]
Range	22 – 58	20 – 65	
Oxytocin (10 IU intravenous bolus)			0.046[2]
No	5 (33.3%)	10 (66.7%)	
Yes	23 (12.8%)	156 (87.2%)	
Tranexamic acid (1g intravenous)			0.918[1]
No	9 (14.1%)	55 (85.9%)	
Yes	19 (14.6%)	111 (85.4%)	
Carbetocin (100mcg intravenous)			0.261[1]
No	15 (17.6%)	70 (82.4%)	
Yes	13 (11.9%)	96 (88.1%)	
Estimated Blood Loss (milliliters)			0.172[4]
Median (IQR)	550 (500-600)	550 (500-650)	
Range	400 – 700	350 – 3600	

Total fluids (milliliters)			0.192[4]
Median (IQR)	2000.0 (2000.0-2250.0)	2000.0 (2000.0-2500.0)	
Range	1500 – 3500	1500 – 6250	
Comorbidities			>0.99[2]
Absent	27 (14.7%)	157 (85.3%)	
Present	1 (10.0%)	9 (90.0%)	

[1] Chi Square test
[2] Fisher's exact test
[3] ttest
[4] Mann Whitney U test
mmHg - Millimeters of Mercury
Kg/m² - Kilogram per Square Meter
IU – International Units
Mcg- micrograms

In the multivariate analysis, detailed in Table 5, logistic regression was utilized to evaluate all variables that demonstrated statistical significance in the bivariate analysis, as shown in Table 4. After adjusting for maternal, anaesthesia-related, surgery-related, and neonatal characteristics, the analysis revealed that patients who did not receive prophylactic ondansetron before spinal anaesthesia were 4.841 times more likely to develop spinal anaesthesia-induced hypotension. Additionally, patients with a baseline systolic blood pressure below 120 mmHg were 3.562 times more likely to develop spinal anaesthesia-induced hypotension. The administration of oxytocin was not associated with spinal anaesthesia-induced hypotension.

Table 5

Multivariate Analysis of Factors Associated with Maternal Hypotension

Hypotension	**AOR**	**P - value**	**95% CI**
Arm			
Case (Ondansetron)	Ref		
Control (Saline)	4.841	0.002	1.782 – 13.149
Baseline systolic Blood Pressure			
≥120	Ref		
<120	3.562	0.008	1.389 – 9.137
Oxytocin			
No	Ref		
Yes	2.546	0.154	0.704 – 9.205

AOR: Adjusted Odds Ratio

DISCUSSION

As shown in this clinical trial, there were no significant differences between the two groups in terms of age, weight, height, BMI, indications for caesarean section, parity, or comorbidities, confirming effective randomization and minimizing selection bias. Comparable findings have been reported in studies from Palestine and India, where no significant demographic differences were observed between study arms [6,7].

Spinal anaesthesia-induced hypotension (SAIH) lacks a universal definition, with thresholds ranging from absolute systolic blood pressure (SBP) <90–100 mmHg to relative reductions from baseline, contributing to wide global incidence estimates of 15.8–91.4% [8,9]. In this study at Moi Teaching and Referral Hospital, the incidence proportion of SAIH was 85.6% using the definition of SBP lower than 100 mmHg. This was comparable to findings from Germany (91%), Turkey (87.9%), and Ethiopia (80–83.7%) [10–12]. The high rate observed locally may be explained by low baseline systolic blood pressure (<120 mmHg), prolonged preoperative fasting leading to dehydration, and the exclusion of hypertensive or emergency cases, which typically present with higher baseline pressures [9,13].

In contrast to the high incidence observed in this study, lower rates of spinal anaesthesia-induced hypotension have been reported elsewhere. At Kenyatta National Hospital, the incidence was 64%, attributed to routine prophylactic administration of 5 mg ephedrine and the use of a different definition of hypotension (SBP <90 mmHg) [5]. Similarly, a 57% incidence was reported at Wad Medani Maternity Teaching Hospital in Sudan, where patients were preloaded with up to 1500 ml crystalloid and given 6 mg ephedrine prophylactically [12]. At Gandhi Memorial Hospital in Addis Ababa, Ethiopia, the incidence was 64%, likely influenced by a larger sample size (n=422) and universal prophylactic administration of ondansetron prior to spinal anaesthesia [13]. By comparison, in the present study only a subset of patients received ondansetron.

In this study, prophylactic ondansetron reduced the incidence of spinal anaesthesia-induced hypotension (SAIH) by 16.5%, with significantly fewer cases in the ondansetron group (77.3%) compared to the normal saline group (93.8%; P=0.001). The protective effect is attributed to ondansetron's blockade of the Bezold–Jarisch reflex, which is triggered by serotonin-mediated cardiac mechanoreceptor activation during sympathetic blockade.

Comparable findings have been reported internationally. At Tribhuvan University Teaching Hospital, Nepal, ondansetron reduced SAIH by 51.2% (20.9% vs 72.1%; P<0.001) [7]. In India, reductions of 18.4% and 21.4% were observed, while studies in Pakistan (20.8%) and Tunisia (40%) also demonstrated significant benefit [14–17].

However, some studies reported no significant effect. At Cukurova University Hospital, Turkey, incidence rates were similar between ondansetron (88.9%) and saline groups (87%; P=0.767), likely due to the use of an 8 mg dose, which is less effective than the optimal 4 mg [10,18]. Similarly, at Dilla University Referral Hospital, Ethiopia, no significant difference was observed (68.4% vs 65.8%; P=0.807), possibly due to the higher 10 mg dose used [19].

Study Limitations

Definition challenge: There is no global consensus on defining spinal anaesthesia-induced hypotension (SAIH), making it difficult to establish a cutoff. The study relied

on textbook guidance, using systolic blood pressure <100 mmHg as the definition [9].
Table tilt estimation: Accurately measuring the recommended 15°–30° tilt to prevent aortocaval compression was difficult. This was standardized by using a 25° wedge placed on the right hip of all parturients after intrathecal injection.

CONCLUSION

This study demonstrates that a prophylactic intravenous dose of 4 mg ondansetron significantly reduces the incidence of spinal anaesthesia-induced hypotension in women undergoing elective caesarean section. These findings support the use of ondansetron as an effective preventive strategy to enhance maternal safety and improve perioperative outcomes.

RECOMMENDATIONS

Anaesthesia providers should consider administering 4 mg of intravenous ondansetron approximately 15 minutes before spinal anaesthesia in elective caesarean sections to reduce the incidence of spinal anaesthesia-induced hypotension.

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