ORIGINAL ARTICLE

Haemodynamic Variability in Obstetric Patients Receiving Spinal Anaesthesia for Caesarean Section: A Comparative Analysis of the Effect of Prophylactic Administration of Ondansetron and Placebo.

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ABSTRACT **Background:** Ondansetron suppresses the Bezold Jarisch reflex and has been postulated to be a therapeutic strategy for spinal-induced hypotension in obstetric patients for Caesarean section. The study is aimed at evaluating the effect of prophylactic ondansetron on spinal-induced hypotension in pregnant women scheduled for Caesarean section.

Methodology: Eligible patients were randomized to receive 4mg Ondansetron diluted to 5ml (Group O, n=39) and 5ml of normal saline (Group C, (n=39) 5mins before spinal anaesthesia respectively. The arterial blood pressure, intraoperative vasopressor consumed, incidence of spinal-induced hypotension, bradycardia, side effects like nausea, vomiting, shivering were assessed and recorded. Data was collected and analysed using SPSS 25 for Windows. Numerical data was analysed using an unpaired student t-test, while Categorical data was analysed using the chi-squared test. A p-value < 0.05 was considered significant.

Results: There was a significant decrease in mean HR between group O (99.8±14.7) and group C (91.0±14.5) within 5 minutes of SAB. The reduction in mean MAP was significant (p=0.04) at the 20th minute between the groups. Total ephedrine and glycopyrrolate consumed were significantly lower in group O (0.8±3.6; 0.07±0.1)mg than in group C (12.6±10.2; 0.14±0.1)mg, respectively. The incidence of nausea, vomiting, and shivering was significantly lower in group O (15.8%; 2.6%; 10.5%) than in group C (41.0%; 20.5%; 51.3%) respectively.

Conclusion: Prophylactic ondansetron significantly reduced haemodynamic depression, incidence of nausea, vomiting, and shivering as well as total vasopressor consumption in obstetric patients undergoing Caesarean section under SAB.

Keywords: Haemodynamic Variability, Ondansetron, Obstetric patients, Caesarean section.

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INTRODUCTION

Regional anaesthesia, specifically spinal anesthesia, has been documented by a study in developed countries, to reduce maternal mortality to about 80% when used for Caesarean section.[1] This explains why spinal anaesthesia is the technique of choice for Caesarean section.[2]

Spinal anaesthesia, is however, associated with unwanted effects commonly hypotension, bradycardia. It has been observed that incidence of spinal induced hypotension in obstetric and non-obstetric patients is about 80% and 40% respectively,[2] while incidence of bradycardia during spinal anaesthesia was observed to be up to 30% in non-obstetric patients.[3] This indicates that up to 80% of women who undergo spinal anaesthesia are at risk of hypotension, which is a huge number.[3,4]

A study conducted in Ethiopia[5] showed that the incidence of spinal induced hypotension in women who had Caesarean section was 80% while another study done in South Africa[6] revealed that 79% of anesthesia

related deaths were caused by spinal anaesthesia and two- third of the deaths were directly related to spinal induced hypotension. Another meta-analytical study conducted by Heesen et al [7] reported that the incidence of spinal induced hypotension was approximately 50% of obstetric population. These indicates that spinal induced hypotension is a global issue. Hypotension caused by spinal anaesthesia when associated with bradycardia without adequate treatment can lead to deleterious complications like loss of consciousness, cardiovascular collapse in the mother and acidosis, neurological injury in neonates.[2,3,8] Uterine displacement, preloading and co-loading with crystalloids, use of Crawford wedge are some strategies employed to mitigate the incidence of hypotension following spinal anaesthesia, with each method alone showing no clinical satisfactory result.[1,9,10]

In a study conducted by Rashad et al,[9] intravenous ondansetron 4mg administered prior to spinal anaesthesia in parturient undergoing elective Caesarean section was found to significantly reduce hypotension and the use of vasopressors. However, some controversies still exist in terms of the effect of ondansetron on the hemodynamic variables in obstetric patient under subarachnoid block.[11]

Oofuvong et al[12] evaluated the minimum effective weight – based dosing of ondansetron in reducing hypotension in Caesarean section under subarachnoid block and they observed that the findings were comparable irrespective of the dose used. In another study conducted by Trabelsi et al[13] they showed that ondansetron significantly reduced the incidence of hypotension following spinal anaesthesia in Caesarean section.

Ondansetron's antiemetic activity involves the selective inhibition of the 5-HT_3 receptors.[12] These receptors are located peripherally as cardiac chemoreceptors on the cardiac vagal afferent and centrally in the chemoreceptor trigger zone. On the other hand, the Bezold–Jarisch reflex (BJR) is one of the mechanisms, which explain the occurrence of hypotension after spinal anaesthesia through serotonin with decreased blood volume.[12] Stimulation of cardiac chemoreceptors in the heart by decreased venous return increases the parasympathetic activity, while it decreases the sympathetic activity resulting in vasodilatation and bradycardia.[2,3,9] As a result, ondansetron can suppress the BJ reflex, and it has been postulated as a therapeutic strategy to prevent hypotension in patients undergoing spinal anaesthesia.[12]

Ondansetron when used prophylactically in spinal anaesthesia can also reduce the risk of shivering and post operative nausea and vomiting that may be associated with subarachnoid block.[3a] However, there is dearth of local studies analysing the effect of prophylactic ondansetron on the haemodynamic variability in pregnant women coming for Caesarean section under spinal anaesthesia.

The aim of this study was to comparatively evaluate the effect of prophylactic administration of intravenous ondansetron and placebo on the spinal anaesthesia induced hypotension and bradycardia in pregnant women coming for Caesarean section under spinal anaesthesia.

PATIENTS AND METHODS

This was a prospective, randomized, double-blind comparative study. Ethical clearance for this study was obtained from the Health Research and Ethics Committee of the Federal Teaching Hospital Owerri, Imo state with reference number FUTH/OW/HREC/VOL.1/033; as well as a written informed consent from the patients before they were enrolled into the study.

The sample size was calculated using the formula of comparison of mean[14] from a similar study performed by Mohamed et al [3] with a reported MAP of 67.58 ± 14.48 in ondansetron group and 74.89 ± 11.74 in saline group, with a power of 90%, confidence interval of 95%, alpha error of 0.05, an estimated 36 patients was recruited into each group. Considering dropout and non – response (10% contingency), a total of 39 patients per group were included in this study.

All female parturients aged 20 – 40years with ASA class II and III scheduled to undergo elective Caesarean section under spinal anaesthesia were recruited for this study.

Parturients with hypersensitivity to ondansetron, history of hypertensive disorders, anaemia, heart disease, diabetes, placenta previa, patient receiving selective serotonin reuptake inhibitor or migraine medication, patients with BMI>35 kg/m2 and non-consenting patient refusal were excluded from the study.

Pre-operative evaluation was done at least a day before the surgery, to establish rapport with the patient, clinically ascertain patient's fitness for anaesthesia and surgery, develop pre-operative and post-operative plans and obtain informed written consent.

The recruited and eligible patients were randomized into Group O (n= 39) and Group C (n= 39) in a balanced manner with a computer- generated number allotment concealed in an opaque envelope, to receive i.v ondansetron 4mg (2ml) diluted to 5ml in a 5cc syringe and 5ml of normal saline in a 5cc syringe respectively. The patients and anaesthesiologist administering the drug and assessing the outcomes were blinded to the group randomization. All participants received oral ranitidine 150mg the night before surgery and was fasted overnight. Clear liquids were allowed till 2 h before surgery. Before the spinal block the baseline non-invasive blood pressure (BP), pulse rate and pulse oximetry (SPO2) readings were recorded, and a peripheral 16-gauge intravenous cannula also inserted. All the patients received i.v. ranitidine (1 mg/kg) and preloaded with lactated Ringer's solution 15 mL/ kg given over 30 min. Patients in Group O received 4 mg ondansetron diluted to 5 ml with normal saline

intravenously and group C received intravenous 5 ml normal saline injected over 1 min, 5 min before starting the subarachnoid block. The spinal anaesthesia was instituted for the patients in the sitting position at the level of L3–4 or L4–5 by injection of 2 ml 0.5% hyperbaric bupivacaine (Marcaine, AstraZeneca) intrathecally using a 27-gauge Quincke needle after cerebrospinal fluid free flow, and then, patients were placed in the supine position with left lateral uterine displacement using a Crawford wedge. Intravenous lactated Ringer's solution was used for fluid maintenance at 1-3 ml/ kg/h till the end of surgery. A resident anaesthesiologist blinded to the study drug solutions measured and recorded the haemodynamics, presence of nausea, vomiting, shivering. Presence of shivering was assessed using Crossley and Mahajan scale.[15] Mean Arterial Pressure (MAP), heart rate (HR), and oxygen saturation (SPO_2) were recorded from the start of spinal anaesthesia at 2-min interval for 15 min then every 5 min till the end of operation. The sensory level was judged by hypoesthesia to pinprick after positioning and every 2minutes till a minimum level of T_6 was achieved. Also, motor block was assessed using the modified Bromage scale till there was complete motor block.

Hypotension was defined as a decrease in MAP >20% from baseline.[3] Bradycardia also was defined as a HR < 50 beats per minute [3] and post spinal hypotension as hypotension occurring immediately after administration of local anaesthetics.[3] These were treated with 5mg of ephedrine given intermittently and intravenous Atropine 0.6mg respectively. Failed spinal was regarded as no block after attempting Spinal anaesthesia for the proposed surgery within 10-15 min.[3]

The primary objective of this study was to compare the arterial blood pressure between the groups. The secondary objectives included the total intraoperative vasopressor consumed, incidence of bradycardia between the groups, incidence of spinal induced hypotension among the groups, and incidence of side effects of the spinal anaesthesia like nausea, vomiting and shivering.

Data was manually collected and entered into a data collection form and analyses was done with the statistical package for social sciences (SPSS) 25 for windows. Categorical variables were expressed as proportions and percentages and was analysed using Chi-square test. Continuous data were expressed as mean and standard deviation for normally distributed data. The normally distributed data was analysed using unpaired student's t-test. A p-value of <0.05 was considered significant. Tables were used to present the result.

RESULTS

A total of 78 patients were recruited but 77 patients with 38 patients in ondansetron group and 39 patients in control group completed the study.

Table I shows the demographic characteristics and baseline vital signs of Group O and Group C. The mean age, BMI, baseline heart rate (HR) and baseline mean arterial blood pressure (MAP) in Group O and Group C were comparable with p values (p=0.87; p=0.49; p=0.23; p=0.51) respectively.

A comparison of the mean heart rate between group O and group C at specific times over sixty minutes is shown in Table II. There was a significant difference (p,0.05) in the decrease in the mean HR between Group O (99.8±14.7) and Group C (91.0±14.5) within 5mins of the SAB, however it remained comparable subsequently between the groups over the next 1hr.

Table III compared the mean HR at specific times within Group O and Group C independently. Here, the mean HR transiently decreased significantly between 5mins and 10mins after the SAB in group O. However, there was a consistent decrease in mean HR within group C and it remained comparable over the period of assessment.

A comparison of the mean MAP at specific times over 60mins between group O and Group C shows that the mean MAP was comparable amongst the groups until 20mins from SAB, when the difference in mean MAP became significant (p=0.04) amongst the groups but remained comparable subsequently [Table IV].

Table V shows the comparison of the mean MAP at specific times within Groups O and C independently. There was a sharp significant decrease of mean MAP following SAB within Group O up to 10mins and subsequently became comparable, however Group C maintained a significant decrease in mean MAP following SAB up to 20mins except between 10mins and 15mins(p=0.291). Subsequently it became comparable.

A comparison of the total ephedrine and glycopyrrolate consumption, and incidence of side effects amongst Group O and Group C shows a significant decrease (p=0.000; p=0.003) in the mean total ephedrine and glycopyrrolate consumption in group O when compared with group C for ephedrine and glycopyrrolate respectively. Nausea, Vomiting, and Shivering were found to be significantly lower in group O (15.8%; 2.6%; 10.5) than in group C (41.0%; 20.5%; 51.3%), P = 0.013; 0.016; and 0.000 respectively. However, the incidence of hypotension (2.6%) and bradycardia (2.6%) in group O were comparable with that of group C (7.7%; 2.6%). P = 0.31 and 0.74 respectively [Table VI].

DISCUSSION

The index study revealed that there is a significant difference in reduction in mean HR, MAP, amount of ephedrine and glycopyrolate consumed as well as the incidence of side effects including nausea, vomiting and shivering between the groups, however with regards to incidence of hypotension and bradycardia they are comparable.

Table I: Comparisons of the Demographic data and Base line vital signs between the groups

Variables	Group O(n=38)	Group C(n=39)	t	p value
Age (yrs)	30.9±4.5	32.9±4.2	-	0.87
BMI (kg/m^2)	30.8±4.3	30.5±4.6	-	0.49
Baseline HR (b/m)	96.0±17.8	92.0±11.2	1.199	0.23
Baseline MAP (mmHg)	92.0±13.0	93.8±13.4	-.614	0.51

Table II: Comparison of mean HR between Groups O and C at specific times

Variables	Group O(n=38)	Group C(n=39)	T	p value
5min	99.8±14.7	91.0±14.5	2.623	0.011
10min	94.9±15.7	89.3±13.8	1.694	0.09
15min	94.8±16.1	90.5±16.6	1.174	0.24
20min	94.0±14.2	87.6±14.1	1.975	0.05
30min	94.4±13.7	90.0±17.9	1.206	0.23
40min	92.8±15.2	92.8±15.4	0.009	0.99
50min	92.8±16.1	94.6±11.6	-.580	0.58
60min	90.1±14.4	91.5±11.3	-.477	0.63

Table III: Comparison of mean HR within groups O and C respectively over 30minutes

Variables	Group O		Group C	
	Heart rate	p value	Heart rate	p value
Baseline	96.0±17.8		92.0±11.2	
5min	99.8±14.7	0.082	91.0±14.5	0.535
5min	99.8±14.7		91.0±14.5	
10min	94.9±15.7	0.016	89.3±13.8	0.481
10min	94.9±15.7		89.3±13.8	
15min	94.8±16.1	0.954	90.5±16.6	0.531
15min	94.8±16.1		90.5±16.6	
20mins	94.0±14.2	0.575	87.6±14.1	0.233
20min	94.0±14.2		87.6±14.1	
30min	94.4±13.7	0.822	90.0±17.9	0.364

Table IV. Comparison of the mean MAP between Group O and Group C

Variables	Group O(n=38)	Group C(n=39)	t	p value
5min	87.6±13.7	89.2±14.7	-.494	0.623
10min	80.4±14.3	82.7±17.2	-.636	0.53
15min	82.1±13.5	80.1±17.0	-.564	0.56
20min	79.8±13.1	73.5±14.8	2.044	0.04
30min	79.7±13.1	77.6±15.6	.636	0.52
40min	80.7±10.4	81.9±13.9	-.443	0.65
50min	82.7±11.1	85.4±12.1	-1.004	0.32
60min	83.7±13.9	88.9±13.3	-1.596	0.115

The result of this study showed that the baseline hemodynamic parameters (HR, MAP) are comparable in both groups (p<0.194) (p<0.592) respectively. However, there was a significant difference (p<0.008) in mean HR(99.76±14.712) for those that received ondansetron when compared with those that did not receive ondansetron (90.75±14.436) after 5mins from SAB. Subsequently the HR remained comparable (p<0.08) (p<0.211) (p<0.065) (p<0.284) at 10mins, 15mins, 20mins and 30mins between the groups.

Table V: Comparisons of mean MAP within groups O and group C respectively at specific times

Variables	Group O		Group C	
	MAP	p value	MAP	p value
Baseline	92.0±13.0		128.4±15.7	
5min	87.6±13.7	0.002	89.2±14.7	0.048
5min	87.6±13.7		89.2±14.7	
10min	80.4±14.3	0.000	82.7±17.2	0.005
10min	80.4±14.3		82.7±17.2	
15min	82.1±13.5	0.313	80.1±17.0	0.291
15min	82.1±13.5		80.1±17.0	
20min	79.8±13.1	0.201	73.5±14.8	0.001
20min	79.8±13.1		73.5±14.8	
30min	79.8±13.1	0.597	77.6±15.6	0.061

Table VI: Comparison of the total ephedrine and glycopyrrolate consumption, and the incidence of side effects between Group O and Group C

Variables	Group O(n=38)	Group C(n=39)	χ^2 / t	p value
Ephedrine(mg)	0.8±3.6	12.6±10.2	6.729	0.000
Glycopyrrolate(mg)	0.07±0.10	0.14±0.1	3.020	0.003
Incidence of bradycardia	1(2.6%)	1(2.6%)	0.000	0.74
Incidence of hypotension	1 (2.6%)	3(7.7%)	1.001	0.31
Nausea	6(15.8%)	16(41.0%)	6.006	0.013
Vomiting	1(2.6%)	8(20.5%)	5.962	0.016
Shivering	4(10.5%)	20(51.3%)	14.901	0.000

This is similar to the study conducted by Samarah et al[16] which reported that prophylactic use of ondansetron in obstetric patients undergoing SAB for surgery reduced the HR significantly (p<0.03) within 4mins following SAB but remained comparable among the groups subsequently. Conversely, Kaur et al[17] reported that prophylactic ondansetron in obstetric patients following SAB reduced the HR significantly (p<0.016) (p<0.038) (p<0.030) (p<0.035)(p<0.001)(p<0.012) at 6mins, 8mins, 10mins, 12mins, 14mins, 16mins respectively between the groups. Trabelsi et al[13] however, reported that there was no difference in HR amongst the groups in their study. The similarity observed with Samarah et al[16] and the index study could be attributed to the dose of ondansetron and 0.5% hyperbaric bupivacaine used. Both studies used 4mg of ondansetron and 2ml of 0.5% hyperbaric bupivacaine. Subedi et al[18] showed that the maximal cephalad spread of heavy marcaine following SAB is significantly higher with higher dose of heavy marcaine, hence with attendant increase in the risk of hemodynamic instability. In contrast, Kaur et al[17] used ondansetron dose of 0.1mg/kg and 15mg of 0.5%

hyperbaric bupivacaine, which could account for the sustained significant reduction over 10 minutes (6th mins- 16th mins). However, some studies[16] have shown that ondansetron has a peak onset time of 30mins.

This study also revealed that there was a significant difference (p<0.026)(p<0.044) in the reduction in mean MAP at the 20th minutes between group O (64.39±12.94)(79.82±13.06) and group C (57.82±12.42)(73.46±14.18) respectively. This is corroborated by the study conducted by Kaur et al[17] who reported a significant difference in reduction in MAP at 20th min after SAB between ondansetron group receiving 4mg and control group, however this reduction was sustained from 4th mins till 20th mins and thereafter became comparable between the groups. This can be alluded to the dose of local anaesthetics used for spinal anaesthesia, dose of ondansetron and the amount of fluid used for preloading in these studies. Kaur et al[17] used 3ml of 0.5% hyperbaric bupivacaine, 0.1mg/kg of ondansetron, and 10ml/kg of normal saline for preloading. In comparison, the index study used 2ml of 0.5% hyperbaric bupivacaine, a fixed dose of 4mg ondansetron, and 15ml/kg of normal saline respectively. However, Marcinaiak et al[19] reported that the difference in reduction in SBP, DBP, and MAP between the ondansetron and the control groups in their study was comparable. The difference in these findings with the index study can be attributed to the difference in the methodology; Marciniak et al[19] used a height-adjusted dose of 0.5% hyperbaric bupivacaine and hydroxyethyl starch (a colloid) for preloading. Some studies[20-23] have documented that the use of height-adjusted hyperbaric bupivacaine resulted in reduced cephalic spread of anaesthesia and decreased incidence and severity of maternal hypotension, as well as the use of colloids has better hemodynamic stability in obstetric patients.

The result of the index study within the groups independently showed an immediate significant reduction in MAP in Group O after the SAB lasting about 10mins after which it became comparable all through the period of assessment, however in Group C the significant decrease in mean MAP after the SAB lasted up to 20mins. This can be explained by the onset of action of ondansetron, which may have bridged the reduction after 10 minutes of SAB in Group O. Studies[16,24] have documented that the onset of ondansetron is between 15mins to 30mins for its antiemetic effect to occur.

The present study also reported that the quantity of ephedrine and glycopyrrolate consumed was significantly lower (P<0.000)(P<0.003) in group O (0.7895±3.5880 and 0.0737±0.0978) compared to group C (12.5641±10.1872 and 0.1487±0.1189), respectively. However, there was no significant difference (P<0.747 and P<0.317) in the incidence of bradycardia and hypotension in the ondansetron group (2.6%)(2.6%) when compared with the control group(2.6%)(7.7%), respectively. Sigh et al [25] reported an incidence of hypotension (34.3%) and bradycardia (2.9%) in the ondansetron group among obstetric patients compared with hypotension (54.3%) and bradycardia (0%) in the control group, which were not significant. However, there was a significant difference (P< 0.007) in the total ephedrine consumption between the ondansetron group (12mg) and the control group (21.79mg) in their study. Samarah et al[16] in their study showed that the amount of ephedrine consumed was significantly lower (P<0.001) in the ondansetron group (17.8±14.9) compared with the control group (27.2±20.5). However, incidence of hypotension was comparable (P<0.96) between their ondansetron group 43(84.3%) and control group 42(84%). The studies similarly reported a significant reduction in the quantity of ephedrine consumed amongst the ondansetron group in the respective studies, however, the difference in the amount of ephedrine consumed between the ondansetron group in the index study and the other studies can be alluded to the dose of rescue ephedrine given. While the index study used 5mg of ephedrine intermittently, Sigh et al[25] used 6mg of ephedrine and Samarah et al[16] used 9mg - 15mg of ephedrine respectively for treatment of hypotension. Although the three studies similarly reported that there is no significant difference in the incidence of hypotension amongst the ondansetron and control groups in their respective studies, however the difference in the incidence of hypotension among the ondansetron group between the index study and Sigh et al[25] with Samarah et al[16] can be attributed to other methodological measures to prevent hypotension. While the index study preloaded with 15ml/kg of Ringer's lactate, Sigh et al[25] and Samarah et al[16] used 6ml/kg of Ringer's lactate and a fixed dose of 500ml of Ringer's lactate, respectively. Also, while the index study defined hypotension as a reduction of > 20% of baseline MAP, Sigh et al[24] defined hypotension as ≤ 90 mmHg, and Samarah et al[16] defined hypotension as SBP ≥20% baseline or ≤ 100 mmHg. Studies[19,26] have documented that the differences in the criteria for the definition of hypotension by various authors markedly hinder the comparison of study results.

The index study showed that the incidence of nausea, vomiting, and shivering is statistically significant (P< 0.013)(P<0.016)(P<0.000) between group O and group C, respectively. Similarly, Abbas et al[27] reported a significant difference (P<0.002)(P<0.005) in the incidence of nausea (20%)(60%) and vomiting(6.7%)(36.7%) in the ondansetron group compared with the control group respectively. However, Terkawi et al[28] documented that there is no significant difference in the incidence of nausea and vomiting between the ondansetron group and the control group in their study. This variation can be explained by the differential effects of ondansetron in their respective studies. Abbas et al[27] recorded a significant difference in the incidence of hypotension between the ondansetron and control groups, however the index study reported a comparable incidence of hypotension amongst the group with significant incidence of nausea and vomiting. This may stem from the fact that Abbas et al[27] did not define hypotension in their study. Terkawi et al[28] reported that

the incidence of hypotension in both groups was comparable (P=1). Some studies[28,29] have documented that nausea and vomiting following SAB for Caesarean section in obstetric patients is multifactorial but commonly related to hypotension, uterine exteriorization, and vagal reaction. This can be explained by the inhibitory effect of prophylactic ondansetron on the BJR, which in part blocks the hemodynamic depression of SAB, thereby augmenting venous return to the heart. This invariably results in less reduction in cerebral hypo perfusion.[28] Cerebral hypo perfusion is a well-documented factor that can activate the vomiting centre in the medulla.

CONCLUSION

This study showed that prophylactic ondansetron significantly reduced hemodynamic depression, incidence of nausea, vomiting, and shivering as well as total vasopressor consumption in obstetric patients undergoing Caesarean section under SAB.

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