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The role of prophylactic ondansetron in counteracting hypotension due to spinal anesthesia in obstetric subjects

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Abstract

Background: Hypotension following spinal anaesthesia is the most common side effect with increased incidence in obstrectics patients and may affect both mother and fetus if not promptly corrected. Amongst the various methods for controlling this hypotension, the role of 5-hydroxytryptamine (5-HT3) receptor antagonist ondansetron has been highlighted in some recent studies.

Methods: The study was a randomized, placebo-controlled, double blinded one in which 89 obstrectics patients, aged 18-40 years, undergoing elective caesarean section under spinal anaesthesia were randomized to receive equal volume of 8 mg inj. Ondansetron (Group O) and normal saline (Group NS). The haemodynamic parameter such as systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP), heart rate (HR) was recorded every 2 minutes till 20 minutes and thereafter every 5 minutes till the end of the surgery. The number of hypotension episodes, rescue inj phenylepinephrine doses, nausea, sensory block level, APGAR score and other side effects were recorded.

Results: The SBP showed significant decrease at 2, 8 and 14 minutes in the NS group when compared with group O, $P<0.05$. The DBP, MAP and HR recorded no significant differences between the two groups. However, the incidence of hypotension, hypotension episodes, nausea and rescue vasopressor requirements were significantly more in the NS group than group O.

Conclusion: Intravenous prophylactic ondansetron attenuatees the fall in blood pressure caused by spinal anesthesia in parturient undergoing elective caesarean section with decrease in incidence and severity of hypotension, and additional benefit of decreaseing the incidence of nausea.

Keywords: Spinal anaesthesia, hypotension, ondansetron, caesarean section

INTRODUCTION

Spinal anaesthesia is the most common and preferred anaesthetic technique for caeserian section due to its ability to give rapid and reliable onset of anaesthesia from the mid-thoracic level to the sacrum with a failure rate of less than one percentage.[1] Studies show infants born by caesarean section with spinal anaesthisia are in better condition than those born under general anaesthesia.[2] Spinal induced Hypotension (SIH) is common, the incidence being 52.6% in parturient patients.[3] The main cause of hypotension is the rapid blockade of sympathetic nerves and aortocaval compression. SIH has detrimental effects on mother causing severe nausea and vomiting, unconsciousness and cardiovascular

collapse, if not treated promptly. In fetus, hypotension of less than two minutes can cause fetal acidemia along with compromised placental blood flow.[4] Various methods for the prevention of SIH has been studied of which ondansetron is believed to have a role in countering the hemodynamic changes occurring after subarachnoid block.[5] This action of ondansetron is attributed to its antagonistic action on peripheral serotonin receptors 5-hydroxytryptamine (5-HT3 type) which inhibits the Bezold-Jarisch Reflex (BJR).

5-HT3 receptors are G-protein coupled, ligand-gated fast-ion channels. In response to hypovolemia serotonin, released from activated thrombocytes, triggers the peripheral 5-HT3 receptors which increases the efferent vagal nerve activity.[6] Study by Yamano et al[7] showed induction of BJR by administration of serotonin in rats was blocked by 5-HT3 receptor antagonist which is the principle on which ondansetron is being studied for its role in counteracting hypotension.

Ondansetron is a highly specific and selective serotonin 5-HT3 receptor antagonist. It is a relatively safe drug and used traditionally for the treatment and prevention of post-operative nausea and vomiting (PONV). Study by Pastenak B[8] et al has shown ondansetron to be safe in pregnancy and not associated with significant risk of adverse fetal outcomes. With regard to these advantages and with various studies suggesting the additional role of ondansetron in suppressing the effects of SIH[9-17], the current study was done to identify the effectiveness of ondansetron in counteracting hypotension among obstetrics patients undergoing elective caesarean section.

Material and methods

The study was a randomized, placebo-controlled, double-blinded one conducted in the department of Anaesthesiology, at a Tertiary care centre, Imphal, Manipur for a period of two years starting from October 2018 to August 2020. After Institutional ethical committee clearance and written informed consent from 90 patients with American Society of Anaesthesiologists (ASA) physical status I or II, aged 18-40 years who underwent elective caesarean delivery under subarachnoid block were enrolled for the study. Patients with history of allergy to local anaesthetic agent and/or study drugs, bleeding tendency, local injection site infection, patient who were uncooperative, cardiac, respiratory diseases and kidney disorder, neurological deficit, spinal deformity, on selective serotonin reuptake inhibitors or serotonin-related migraine medication, and obese subjects were excluded from the study.

Preoperative assessment was done a day prior to the scheduled day of surgery and tablet ranitidine 300 mg and injection metoclopramide were given, 2 hours before the operative procedure. All ninety patients were randomised to one of the 2 groups using a computer-generated random table: Group O received 8 mg of ondansetron intravenously diluted in 10 ml saline, 5 minutes before lumbar puncture for spinal anaesthesia. Group S (control group) received 10 ml of normal saline in the same way and same timing.

On arrival to the operation theatre, intravenous (i.v) access was established with an 18 guage peripheral intravenous cannula and prehydrated with 500 ml lactated ringer solution in all the patients. Before spinal anaesthesia, routine monitoring- heart rate (HR), non-invasive blood pressure (NIBP), pulse oximetry (SPO_2) and electro-cardiogram (ECG) were applied and the pre-operative values of the above-mentioned parameters were recorded.

The study drug or saline was prepared by an anaesthesiologist blinded to the group allocation and marked only with a coded label. The syringes containing the study drugs were identical with each other and were made to contain same volume of 10 ml. Lumbar puncture for spinal anaesthesia was performed with patient in the sitting position with a 25 guage spinal needle through L3-4 or L4-5 intervertebral space under strict sterile conditions. 2 ml (10 mg) of hyperbaric bupivacaine (0.5%) was injected into the subarachnoid space in both groups when free flowing cerebrospinal fluid was observed. Thereafter all patients were placed in supine position with a left lateral tilt by placing a pillow under the right hip. 2-3 litres per minute oxygen was administered via venturi mask until the delivery of baby.

Level of sensory block was assessed according to loss of pin prick sensation (25 guage hypodermic needle) by an anaesthesiologist who was blinded to the study groups, once every 3 minutes until the same dermatome level is recorded on three consecutive occasions. This dermatome level was regarded as the highest sensory block height. After obtaining a sensory block higher than T6 dermatome, surgical procedure commenced/ proceeded. Systolic blood

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pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR) were recorded every 2 minutes upto 20 minutes then every 5 minutes until skin closure.

Hypotension, defined as fall in the systolic blood pressure (SBP) less than 80 mmHg or less than 80% of baseline was treated by infusion of 100 ml of crystalloids and with intravenous phenylephrine 50 micrograms bolus as and when required. A heart rate lower than 60 beats per minute was defined as bradycardia and was treated with injection atropine 0.5 mg intravenously. The incidence of hypotension, cumulative episodes of hypotension (the mean number of cumulative hypotension episodes), total phenylephrine consumption and adverse effects such as hypertension, nausea, vomiting and incidence of bradycardia was recorded throughout the study. Demographic data (age, weight, height, duration of surgery) and obstetric data (parity, indication of caesarean section) of all the patients were noted. Apgar score at 1, 3, 5 and 10- minutes and new born weight were recorded. At the end of surgery all patients were shifted to post-anesthetic care unit for routine follow up care.

Sample size was calculated based on the study conducted by Owczuk R et al[10] where with a power of 80% and a significance level of 5%, we recruited 45 patients were recruited for each group. Considering 5% dropouts. Collected data is kept password protected and only the investigators have access to the data. The data collected was summarized using descriptive statistics like percentage, mean. Statistical analysis of the data obtained was done using Windows based statistical package for social sciences [SPSS] Version 21.0 (Armonk, NY: IBM Corp) by using student's t test for continuous data, chi square test for categorical data, etc whichever was appropriate and $P<0.05$ was considered as statistically significant.

Results and observation

The study protocol was completed in 89 patients and the demographic parameter and duration of surgery, as shown in table 1, in the two groups were comparable, statistically not significant and will not affect the study outcome.

Table 1: Patient's characteristics and duration of surgery among the 2 study groups

Characteristics	*Group NS N=45(Mean±SD)*	*Group O N=44(Mean±SD)*	*p-value*
Age (yrs)	30.13±5.52	28.55±3.97	0.12
Weight (kgs)	67.20±15.37	67.48±6.29	0.91
Height (cms)	155.40±3.76	156.73±3.26	0.07
Duration of surgery(mins)	38.44±5.82	39.32±6.25	0.49

$P<0.05$ is significant

The changes in the systolic blood pressure, as shown in Table 2, showed maximum fall in the two groups from its baseline value till the 8th minutes and thereafter rose to attain its baseline value around 50 minutes. However, the fall is more in the NS group and the difference is statistically significant at 2nd, 8th and 14th minutes intraoperatively.

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Table 2: Comparison and distribution of Systolic blood pressure recordings (SBP) in the two groups

Time points	*Group NS N=45(Mean±SD)*	*Group O N=45(Mean±SD)*	*p-value*
Baseline	124.82±6.35	122.02±9.43	0.10
2 minutes	111.36±14.23	116.95±12.03	**0.04**
4 minutes	109.71±12.31	109.57±13.89	0.95
6 minutes	107.60±13.32	109.05±12.84	0.60
8 minutes	107.71±11.37	112.39±11.48	**0.05**
10 minutes	113.22±9.57	111.52±9.38	0.40
12 minutes	113.36±10.75	112.07±9.83	0.55
14 minutes	109.78±8.12	113.55±7.84	**0.02**
16 minutes	111.13±9.01	111.09±11.59	0.98
18 minutes	110.29±9.51	111.91±8.98	0.41
20 minutes	109.16±10.19	111.59±10.10	0.26
25 minutes	111.09±11.37	113.27±8.82	0.31
30 minutes	112.20±10.13	113.28±9.22	0.32
35 minutes	113.21±8.18	114.89±9.79	0.61
40 minutes	111.21±9.36	114.89±11.25	0.21
45 minutes	115.00±9.68	113.46±10.60	0.70
50 minutes	115.00±3.10	123.40±10.43	0.19

P<0.05 is significant

The diastolic blood pressure in both the groups, as shown in chart 1, fall from the baseline value to a maximum at around the 16th minutes and thereafter rose slowly. However, the changes in both the groups are comparable and statistically not significant.

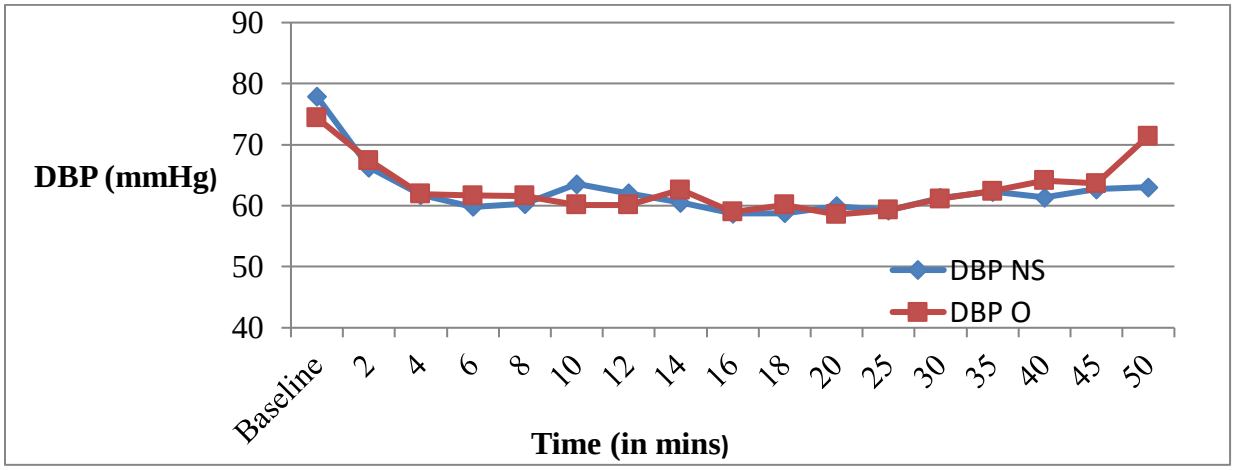

Chart 1: showing variation of mean DBP readings.

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The heart rate changes, as shown in chart 2, show maximum rise at around 2 to 4 minutes in both the groups and thereafter decreases to attain its baseline value, and this changes in the two groups are comparable and statistically not significant.

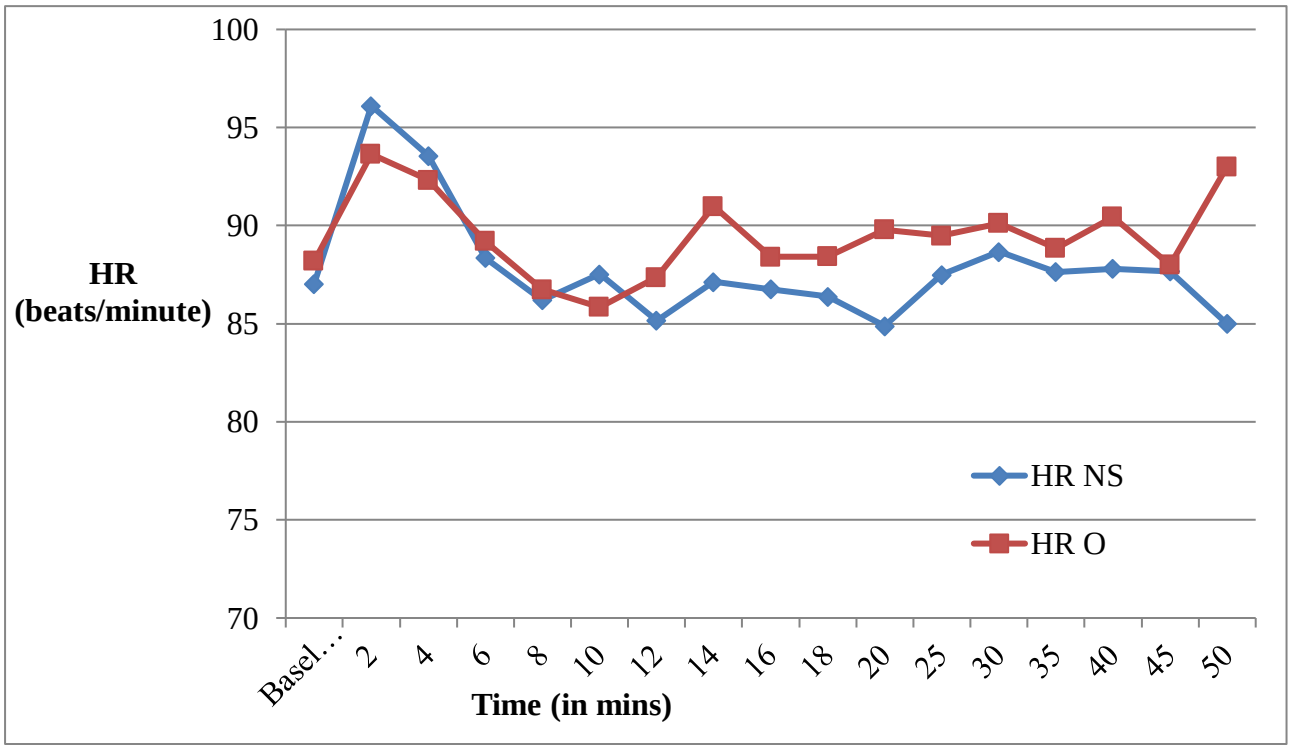

Chart 2: showing variation of mean heart rate readings.

The incidence of hypotension and nausea, as shown in table 2, was significantly more in the NS group as compared with the O group.

Table 2: Incidence of hypotension and nausea

Parameter		*NS (%)*	*O (%)*	*TOTAL (%)*	*p-value*
Incidence of hypotension	YES	28 (62)	15 (34)	43 (48)	0.00
	NO	17 (37)	29 (65)	46 (52)	
Incidence of Nausea	YES	12 (26)	2 (4)	14 (15)	0.00
	NO	33 (73)	42 (95)	75 (84)	

P<0.05 is significant

The hypotension episode and rescue phenylepinephrine dose requirements were significantly lesser in the O group as compared with the NS group.

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Table 3: Comparison of hypotension episode and rescue doses

Parameter	*Study group*	*Mean ±SD*	*p-value*
Hypotensive events per patient	NS (n=45)	1.47±1.54	**0.00**
	O (n=44)	0.55±0.84	
Rescue dose in micrograms	NS (n=45)	82.22±91.17	**0.00**
	O (n=44)	27.27±42.39	

P<0.05 is significant

The sensory block distribution was comparable in both the groups and statistically not significant. Moreover, the adverse effects, apart from nausea which was more in NS group, are comparable in both the groups. There were no incidence of bradycardia and neonatal APGAR score were within normal limits and comparable in both the groups.

DISCUSSION

Regional anaesthesia in caesarean section in the form of spinal anaesthesia has increased from 84.9% in 2010 to 93.3% in 2017.[18] One of the most important drawback of spinal anaesthesia is Spinal-induced hypotension (SIH) causing maternal nausea and vomiting, fetal acidosis and even cardiovascular collapse if not managed quickly and effectively.[4] The incidence of SIH varied as 33% in non-obstetric cases and as high as 90% in obstetrics cases.[19] In caesarean delivery, rapid onset of sympatholysis due to increased sensitivity of nerve fibres to local anaesthetics along with gravid uterus compression on aortacaval vessels are the main reasons for increased incidence of hypotension in obstetric patients.[20] Techniques to decrease the incidence of hypotension includes- uterine displacement, lower legs compression, administration of crystalloids and/or colloids, patient's position and use of vasopressors or ondansetron.[5] Ondansetron, a highly effective and specific 5-HT3 receptor antagonist, was used for its proposed role in counteracting SIH by alleviating the Bezold-Jarish Reflex (BJR) and averting the reflex response of peripheral vasodilation, hypotension and bradycardia.

The incidence of SIH was 28(62%) patients in group NS and 15(34%) patients in group O, p=0.00, in our study. The systolic blood pressure (SBP) recordings showed a significant decrease in group NS at 2, 8 and 14 minutes, p-value<0.05 when compared with group O. The diastolic blood pressure (DBP), mean arterial pressure (MAP) and heart rate (HR) showed no significant differences among the groups. The incidence of hypotension and dose requirement of phenylephrine was significantly reduced in group O (p<0.05). Nausea was significantly increased in group NS (p=0.00).

Owczuk R et al[10] compared 8 mg intravenous ondansetron dose and normal saline in attenuating hypotension post spinal anaesthesia in 71 patients undergoing surgery under spinal anaesthesia and demonstrated that ondansetron attenuated the fall of systolic and mean arterial pressure but does not have an influence on diastolic blood pressure or heart rate which have similar observations with our study with attenuation of fall of SBP at 2, 8 and 14 minutes time points in group O with no effect on DBP and HR. In another study of Owczuk R et al[11] in the elderly population aged above 70 years showed similar findings such as the significant increase in SBP in group O, fewer incidence of hypotension in ondansetron group than saline group and less phenylephrine requirement in ondansetron group than saline group.

Marashi SM et al[12] compared two different doses of intravenous ondansetron, 6mg or 12 mg with placebo group and observed significant hypotension requiring treatment, p=0.04 in the NS group which is similar to our present study findings. Rashad MM et al[13] studied in 60 pregnant women the effects of intravenous ondansetron 4 mg (group O), granisetron 1 mg (group G) against a control group (group S) who received normal saline and found significant decrease in MAP in groups S and G at 5, 10, 15, 20 and 25 minutes when

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compared with group O with no significant difference in heart rate among the 3 groups were observed. There was significant increase in the incidence of nausea and significant increase in use of ephedrine in group S and group G than group O (35% and 25% vs 5% respectively, p=0.05). Our present study also showed ondansetron group having lesser incidence of hypotension (34% vs 64% respectively, p=0.00) and nausea (4% vs 26% respectively, p=0.00) when compared to control group.

Ortiz-Gomez JR et al[14] in their study comparing 8 mg ondansetron to placebo group in a study population of 130 healthy pregnant women found no difference in the number of patients with hypotension even though the number of hypotensive events per patient and ephedrine requirements significantly increased in placebo group than ondansetron group which is almost similar with our study.

Trabelsi W et al[15] in their randomized control study of 4 mg ondansetron (group O) against group S receiving normal saline found SBP, DAP and MAP values higher in Group O between the 4th to 10th minute, p<0.001 when compared to group S with increased incidence of hypotension, nausea and more ephedrine consumption in the S group. Their findings concur with our present study findings.

Khalifa OSM[16] in their study, had significant less vasopressor requirements and lower incidence of nausea in the odansetron group than the control group, p<0.05. Wang Q et al[17] also reported that maternal hypotension (p=0.01) and nausea (p=0.004) were significantly lower in ondansetron-treated patients with lesser requirement for phenylephrine administration and their findings were corroborative with our study. Similar findings were also recorded in the different studies by El Khouly NI and Meligy AM[21] , Ahmed Z and Haidy S[22] and Shabana AA et al[23] which supported our study findings.

The effective dose of ondansetron in preventing this SIH is not well established [24] . Sahoo T et al[9] and many other studies have found 4 mg as optimal dose in attenuating SIH.[13,15-17,21-24] Potkar MP et al[25] however found no difference of effect of 4 mg or 8 mg ondansetron on incidence of SIH. Studies by Owczuk R et al[10, 11] and Ortiz-Gomez JR et al[14], like our study used 8 mg ondansetron and found its beneficial effect in maintaining hemodynamic stability.

Ondansetron is conventionally used for prevention of post-operative nausea and vomiting (PONV) but not for its role as an anti-hypotensive drug which is challenged by studies which failed to confirm its efficacy in reducing incidence of hypotension. [18-26] The limitation in our study was a small sample size and further studies are needed to determine its exact dose response effect for controlling SIH.

The above findings clearly point out that prophylactic ondansetron 8 mg does have an effect in attenuating the fall in blood pressure caused by spinal anesthesia in parturient undergoing elective caesarean section with decrease in incidence and severity of hypotension. It had the additional benefit to decrease the incidence of nausea.

CONCLUSION

The prophylactic use of 8 mg intravenous ondansetron attenuated the fall in blood pressure following spinal anaesthesia and also reduced the incidence of hypotensive events and vasopressor consumption.

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