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EFFICACY OF PRE-OPERATIVE ONDANSETRON AGAINST NORMAL SALINE TO PREVENT SPINAL ANAESTHESIA INDUCED HYPOTENSION IN NON-OBSTETRICAL SURGICAL PROCEDURES - A COMPARATIVE STUDY

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Abstract

Background: One of the most frequent side effects is acute and often profound hypotension that increases the risk of perioperative neurological & cardiovascular events especially in elder. The different studies on animal have suggested that serotonin may be an important factor inducing BJR. This is having a significant impact on decreasing the blood volume and helps to change the mechanism that triggering the activation of 5-HT3 receptors that is located in intracardiac vagal nerve endings by serotonin.

Aim: The aim of the present study is to evaluate the efficacy of intravenous Ondansetron in preventing the incidence of hypotension in non-obstetrical surgical procedures in AGMC & GBP Hospital.

Methods: Patients of both sexes physical status grade l and ll, age between 20 to 60 years, scheduled for any elective lower abdominal and lower limb surgeries (non-obstetric population) under spinal anaesthesia. The data were collected for both the groups as per the study tools and is depicted in comparative charts. Mean ± SD (Standard Deviation) was calculated for quantitative variables like age, weight, BMI, and MAP.

Results: The proportion of males/ females in both the groups was almost similar with no statistically significant difference. However a statistically significant difference was marked in the body weight of the two groups. Comparison of the development of nausea after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the proportion of patients that developed hypotension was higher in the normal saline group (2.8%) compared to the ondansetron group (0.7%) and the difference between the proportions was not statistically significant.

Conclusion: The study concluded that ondansetron 4 mg intravenously is an effective prophylactic means of prevention of post spinal anaesthesia induced hypotension within and after 30minutes, maintaining statistically significantly better hemodynamic profiles following spinal anaesthesia and also beneficial to reduce the incidence of postoperative nausea, vomiting and shivering compared to normal saline.

Keywords: *Hypotension, bradycardia, Bezold-Jarisch reflex and Ondansetron*

Introduction

Spinal anesthesia is a common procedure performed for both inpatient and outpatient surgical interventions. Despite the popularity and ease of its use, the procedure is frequently associated with hemodynamic instability. One of the most frequent side effects is acute and often profound hypotension that increases the risk of perioperative neurological & cardiovascular events especially in elder[i].

According to analysis, both groups involved the receptors in the causation of hypotension and bradycardia that lead to spinal blockage. However, it was identified that mechanoreceptors is present in all chambers which is very sensitive. The different studies on animal have suggested that serotonin may be an important factor inducing BJR. This is having a significant impact on decreasing the blood volume and helps to change the mechanism that triggering the activation of 5-HT3 receptors that is located in intracardiac vagal nerve endings by serotonin[ii]. Apart from this, some of the studies on human and animals have also suggested that the BJR can be decreased by 5-HT3 antagonists.

Ondansetron, is a serotonin 5-HT3 receptor antagonist and it is useful for preventing the spinal induced in recent time. There are many studies that have analyzed and presented the fact that Bezold Jarish Reflex (BJR) is playing a critical role in suppressing venodilatation and augmenting venous return[iii]. Moreover, it has been considered that implementation of BJR blunt is helpful for less bradycardia[iv]. There are two factors that have significant impact on the sensitivity nerves involve the fibers in local anesthesia and diameter myyelination[v]. This is safe and effective form of performing the anesthesia which can be used as general anesthesia for common surgeries for lower body. In the current scenario, pencil point needles are also available for injecting the anesthesia.

This is allowing the surgical procedures to perform the activities without painful sensation to the person. Apart from this, there are some sedation are also available and used by the care professionals to make the patient feel relax after the spinal surgery. In addition to this, the sensory blockage above T4 are more complicated and having the serious impact on the cardiac output in systematic vascular resistance and have the impact on the spinal hypotension. However, the overall cardiac performance is less affected and resulting from blockage of T1 through T5 sympathetic fibers. In addition to this, rapid decrease in left ventricular volume has been causing severe bradycaridia and asystole[vi].

Aim

The aim of the present study is to evaluate the efficacy of intravenous Ondansetron in preventing the incidence of hypotension in non-obstetrical surgical procedures in AGMC & GBP Hospital.

Method and material

It was a comparative study cross sectional study performed at the operation theatre under the Dept. of Anaesthesiology, AGMC & GBP Hospital for 1½ years (December 2018 to May 2020). Patients of both sexes with American Society of Anaesthesiologists (ASA) physical status grade I and II, aged between 20 to 60 years, scheduled for any elective lower abdominal and lower limb surgeries (non-obstetric population) under spinal anaesthesia. A total of 280 patients were recruited based on the following inclusion and exclusion criteria.

Inclusion Criteria

1. Patient giving consent for the study.
2. Patients with ASA physical status I and II.
3. Patient of either gender between 20 to 60 years.
4. Non-obstetrical (elective lower abdominal, orthopaedic, or gynaecologic) surgical procedure.

Exclusion Criteria

1. Patients with ASA grade > II and age < 20years, > 60 years.
2. Patient with a history of allergy to or side effects from ondansetron or local anaesthetics.
3. Patients with body mass index (BMI) i.e, weight in kg / height in meter² ≥35).
4. Preoperative fever (temp > 38*c).
5. Comorbid conditions like moderate to severe hypertension, coronary artery disease or other cardiovascular disease, diabetes mellitus, pulmonary, hepatic or renal diseases.
6. Failed spinal block.

Data management: The data were collected for both the groups as per the study tools and is depicted in comparative charts. Mean ± SD (Standard Deviation) was calculated for quantitative variables like age, weight, BMI, and MAP (mean arterial pressure). Statistical Analysis of data was carried out for all comparison by SPSS (IBM SPSS, version 20). P value less than 0.05 was to be considered as significant.

Results

Comparison of baseline characteristics between patients in the Ondansetron and Normal Saline groups, show that there was no significant differences in the mean age or mean BMI in patients in the two groups. The proportion of males/ females in both the groups was almost similar with no statistically significant difference. However a statistically significant difference was marked in the body weight of the two groups.

Table 1: Comparison of proportion of patients

Hypotension		**Ondansetron Group I (n=136)**	**Normal Saline Group II (n=144)**	**Chi square test**	P-value
Within 30 minutes of spinal anaesthesia	Yes	14 (10.3%)	46 (31.9%)	19.47	0.000*
	No	122 (89.7%)	98 (68.1%)		
30 minutes or more after spinal anaesthesia	Yes	8 (5.9%)	17 (11.8%)	3.018	0.082
	No	128 (94.1%)	127 (88.2%)		

Comparison of the development of hypotension within 30 minutes after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the proportion of patients that developed hypotension was higher in the normal saline group (31.9%) compared to the ondansetron group (10.3%) and the difference between the proportions was statistically significant. Similarly, comparison of the development of hypotension following 30 minutes after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the proportion of patients that developed hypotension was higher in the normal saline group (11.8%) compared to the ondansetron group (5.9%) and the difference between the proportions was statistically significant.

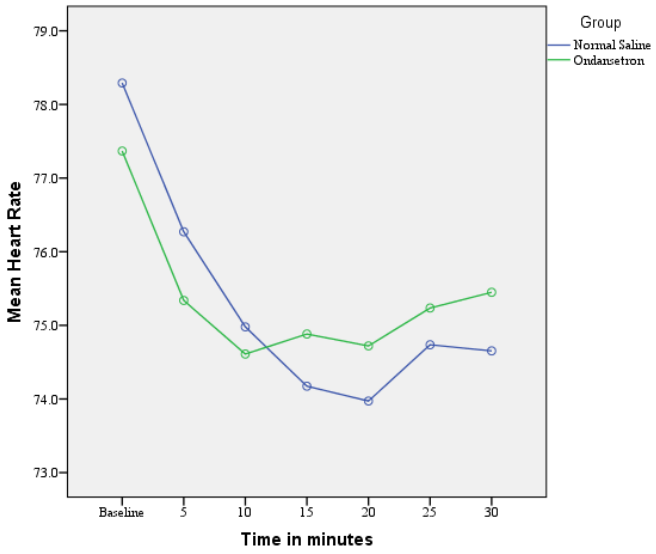

Figure 1: Heart Rate

The comparison between the mean heart rate (HR) between Ondansetron and Normal Saline groups over time. The two groups showed no statistically significant differences in the mean heart rate (HR) throughout the period of observation of the patient.

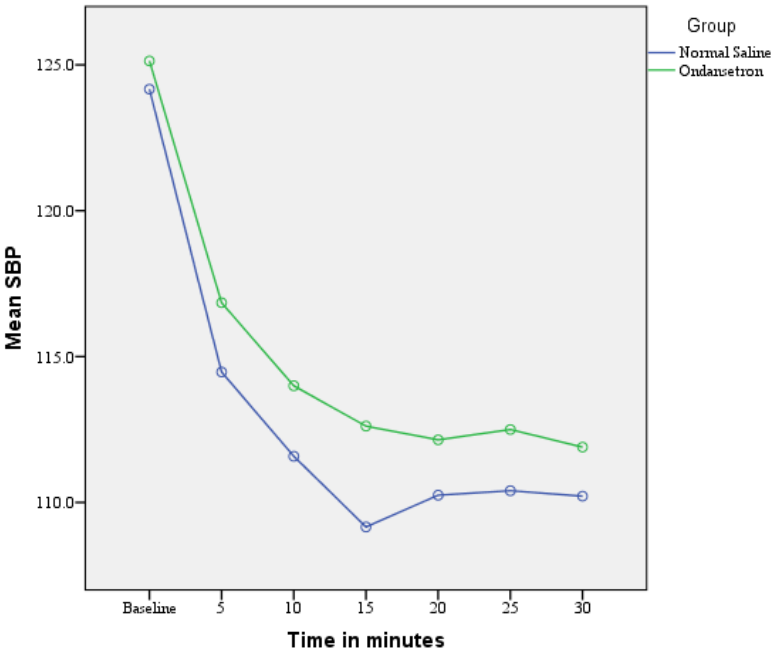

Figure 2: Systolic Blood Pressure

The comparison between the mean systolic blood pressure (SBP) between Ondansetron and Normal Saline groups over time. The two groups showed no statistically significant differences at baseline. However the mean systolic blood pressure (SBP) was significantly different in the two groups between 5 and 25 minutes.

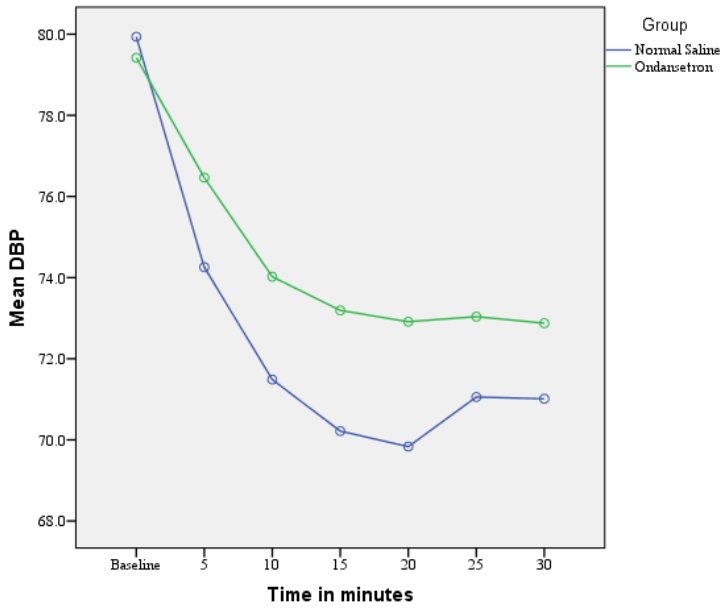

Figure 3: Diastolic Blood Pressure

The comparison between the mean diastolic blood pressure (DBP) between Ondansetron and Normal Saline groups over time. The two groups showed no statistically significant differences at baseline. However the mean diastolic blood pressure (DBP) was significantly different in the two groups between 5 and 30 minutes.

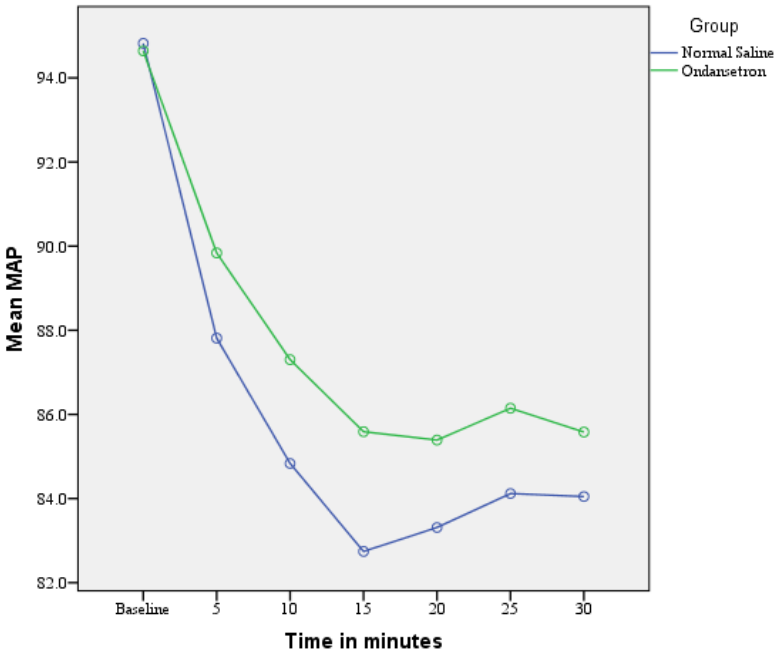

Figure 4: Mean Arterial Pressure

The comparison between the mean arterial pressure (MAP) between Ondansetron and Normal Saline groups over time. The two groups showed no statistically significant differences at baseline. However the MAP scores were significantly different in the two groups between 5 and 30 minutes.

Table 2: Comparison between total vasopressor consumption in Ondansetron and Normal Saline groups over time

Variable	Ondansetron Group I (n=136)	Normal Saline Group II (n=144)	Independent group t test#	p value
Mean vasopressor consumption (in mg)	0.46 ± 1.46	1.60 ± 2.53	-4.59	0.000

Comparison of mean vasopressor consumption after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the mean vasopressor use (in mg) in the group of patients receiving normal saline was significantly higher than in the group of patients receiving ondansetron.

Table 3:

Outcome		Ondansetron Group I (n=136)	Normal Saline Group II (n=144)	Chi square test#	P-value
Nausea	Yes	1 (0.7%)	4 (2.8%)	1.664	.197
	No	135 (99.3%)	140 (97.2%)		
Shivering	Yes	4 (2.9%)	9 (6.3%)	1.730	.188
	No	132 (97.1%)	135 (93.8%)		
Vomiting	Yes	0 (0%)	2 (1.4%)	1.902	.168
	No	136 (100%)	142 (%)		
Bradycardia	Yes	0 (0%)	2 (1.4%)	1.902	.168
	No	136 (100%)	142 (%)		

Comparison of the development of nausea after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the proportion of patients that developed hypotension was higher in the normal saline group (2.8%) compared to the ondansetron group (0.7%) and the difference between the proportions was not statistically significant.

In addition to this, Comparison of the development of shivering after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the proportion of patients that developed shivering was higher in the normal saline group (6.3%) compared to the ondansetron group (2.9%) and the difference between the proportions was not statistically significant.

Apart from this, Comparison of the development of vomiting after spinal anesthesia between patients in the Ondansetron and Normal Saline groups show that the proportion of patients that developed vomiting was higher in the normal saline group (1.4%) compared to the ondansetron group (0 %) and the difference between the proportions was not statistically significant.

Discussion

Ondansetron and Normal Saline groups, show that there was no significant differences in the mean age or mean BMI in patients in the two groups. The proportion of males/ females in both the groups was almost similar with no statistically significant difference.

Study has done comparison between the mean heart rate (HR) between Ondansetron and Normal Saline groups over time. The two groups showed no statistically significant differences in the mean heart rate (HR) throughout the period of observation of the patient.

The two groups showed no statistically significant differences at baseline. However the mean systolic blood

pressure (SBP) was significantly different in the two groups between 5 and 25 minutes. The comparison between the mean diastolic blood pressure (DBP) between Ondansetron and Normal Saline groups over time. However the MAP scores were significantly different in the two groups between 5 and 30 minutes. Moreover, as per the views of **Owczuk R et al**,[vii] the diminished venous return of blood is observed in the spinal blocks and includes the deformation of cardiac wall. This is having a significant impact on the irritation of mechanoreceptors and activation of the Bezold-Jarisch reflex (BJR)[viii ix].

The study has analyzed the hypotension and found that it was higher in the normal saline group (2.8%) compared to the ondansetron group (0.7%) and the difference between the proportions was not statistically significant. Additionally, shivering was higher in the normal saline group (6.3%) compared to the ondansetron group (2.9%) and the difference between the proportions was not statistically significant. Moreover the outcome of the study has suggested that vomiting was higher in the normal saline group (1.4%) compared to the ondansetron group (0 %) and the difference between the proportions was not statistically significant. As per the studies of **Marashi et al,**[x] and others 33% of patients having issues related to hypotension and 13% were having bradycardia in non-obstetric group. In addition to this, the percentage of hypotension in obstetric group with non-laboring is high which was estimated between 50-60%. It is common after onset of labor[xi xii].

Conclusion

Ondansetron, a potent $5HT_3$ receptor antagonist, has shown promising results in preventing spinal induced hypotension and associated adverse events in non obstetrical population. On the basis of the findings of the present study, we concluded that ondansetron 4 mg intravenously is an effective prophylactic means of prevention of post spinal anaesthesia induced hypotension within and after 30minutes, maintaining statistically significantly better hemodynamic profiles following spinal anaesthesia and also beneficial to reduce the incidence of postoperative nausea, vomiting and shivering compared to normal saline.

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