



## Assessment of Efficacy and Safety of Granisetron in Preventing Hypotension Following Spinal Anaesthesia in Patients Undergoing Elective Caesarean Section in a Tertiary Care Hospital of Bihar

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### ABSTRACT

**Background:** Subarachnoid block (SAB) or spinal anaesthesia is the most commonly used anaesthesia technique for conducting caesarean section. Although subarachnoid block is considered safe, it is associated with high risk of hypotension specially in elective caesarean section. The selective 5-hydroxytryptamine-3 (5-HT<sub>3</sub>) receptors are also present peripherally in the form of cardiac chemoreceptors on sensory component of vagal nerve endings and also in the wall of right and left ventricles. So, action of serotonin on these 5-HT<sub>3</sub> receptors results in decrease in blood pressure and heart rate.

**Aim/Objective:** To assess the efficacy and safety of intravenous granisetron in prevention of hypotension and bradycardia following spinal anaesthesia in parturients undergoing lower segment caesarean section (LSCS).

**Materials and method:** Parturients were randomized into two groups using a web generated random number. Granisetron group patients received IV Granisetron 1mg and Saline group patients received IV 5ml of 0.9% normal saline. Both the groups received the allocated drug solution intravenously 10 minutes before administration of SAB. A fall in the systolic blood pressure below 100mmHg or a fall in mean arterial blood pressure of more than 20% from baseline was considered as hypotension and managed with 6mg bolus of intravenous mephenteramine.

**Results:** More events of hypotension were observed in saline group (74%) than granisetron group (34%) with statistically significant difference ( $p < 0.05$ ). Mephentermine was used more frequently than in saline group as compared to granisetron group. Atropine was not required in either patient. No significant difference between two groups was recorded with respect to height of sensory block ( $p > 0.05$ ). Similarly, both groups were comparable with respect to duration of surgery, intra-operative and post-operative complications.

**Conclusion:** Our study results showed that granisetron is effective in decreasing incidence of hypotension in parturients undergoing elective caesarean section under spinal anaesthesia in addition to its anti-emetic effect which is its main indication without any risk of significant intra-operative or post-operative negative outcomes.

**Keywords:** Granisetron, Hypotension, Spinal Anaesthesia, Caesarian Section, Heart Rate.

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like Bezold-Jarisch reflex (BJR) gets stimulated, then the cardiac autonomic balance gets shifted towards the parasympathetic nervous system leading to bradycardia, which precipitates hypotension further.<sup>3</sup> The Bezold-Jarisch reflex (BJR) is one of the mechanisms, which can explain the incidence of hypotension after spinal anaesthesia through serotonin with decreased blood volume.<sup>4</sup>

The selective 5-hydroxytryptamine-3 (5-HT<sub>3</sub>) receptors are also present peripherally in the form of cardiac chemoreceptors on sensory component of vagal nerve endings and also in the wall of right and left ventricles. These receptors are also located in the chemoreceptor trigger zone of the medulla oblongata. Serotonin activates these receptors and cause rise in parasympathetic vagal output. So, action of serotonin on these 5-HT<sub>3</sub> receptors results in decrease in blood pressure and heart rate.<sup>5,6</sup>

### INTRODUCTION

Subarachnoid block (SAB) or spinal anaesthesia is the most commonly used anaesthesia technique for conducting caesarean section. Although subarachnoid block is considered safe, it is associated with high risk of hypotension specially in elective caesarean section.<sup>1</sup> Similarly, risk of bradycardia is also high and reported in some studies.<sup>2</sup> Increased heart rates physiologically compensate for hypotension due to SAB. However, if vagus nerve mediated cardio-depressor reflex



Some animal studies have proved the effectiveness of granisetron in reducing the incidence of hypotension and bradycardia.<sup>7</sup> In a study that has investigated the effect of 5-HT<sub>3</sub> antagonist granisetron on heart rate and blood pressure during head-up tilt table test, the effectiveness of granisetron in reducing incidence of hypotension and bradycardia was observed that also associated its anti-hypotensive action to BJR.<sup>8</sup> In addition to anti-hypotensive effect, various studies have also shown faster regression of sensory level when granisetron and ondansetron were given before subarachnoid block.<sup>9-11</sup> However, number of studies that have evaluated the efficacy and safety of granisetron and other 5-HT<sub>3</sub> antagonists on subarachnoid block in other surgeries are limited.<sup>9</sup>

Studies carried out with Granisetron by Khalifa, Eldaba et al., Mohammedi et al., and Megahed et al. found that it was effective in prevention of hypotension following SAB.<sup>12-15</sup> However, contrary to the above findings, Shrestha et al., Lamichhane et al., and Saberi et al. found Granisetron was not effective in prevention of hypotension following SAB.<sup>16-18</sup>

This study was carried out with primary objective to assess the effectiveness of 1mg intravenous granisetron in prevention of hypotension and the secondary objective to assess the effect of granisetron in preventing bradycardia following spinal anaesthesia in parturients undergoing lower segment caesarean section (LSCS).

## MATERIALS AND METHODS

This was a prospective double-blind randomized controlled study. A total of 100 healthy term parturients of age between 20 to 35 years who were undergoing elective caesarean section under spinal anaesthesia were included in this study. They were divided into two groups with 50 patients in each. Parturients not willing to participate in this study, presence of any contraindication for spinal anaesthesia, patients on serotonin agonists or antagonists, history of allergy to study drug, and presence of any co-existing diseases were excluded from the study.

Parturients were randomized into two groups using a web generated random number. The study drugs prepared in a volume of 5ml and presented as coded syringes to the anaesthesiologist. Granisetron group patients received IV Granisetron 1mg and Saline group patients received IV 5ml of 0.9% normal saline. Both the groups received the allocated drug solution intravenously 10 minutes before administration of SAB. All parturients were kept fasting for eight hours and they were uniformly pre-medicated with inj pantocid 40mg and inj. metoclopramide 10mg on the morning of surgery.

In the operating room, IV line was secured with 18-G intravenous cannula and infusion of ringer lactate solution started. Baseline vital parameters of parturients including heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure (MAP), oxygen saturation (SpO<sub>2</sub>) and ECG were recorded in the operating room. A fall in the systolic blood pressure below

100mmHg or a fall in mean arterial blood pressure of more than 20% from baseline was considered as hypotension and managed with 6mg bolus of intravenous mephenteramine.

Subarachnoid block was given in a sitting position in midline approach with a 25-gauge Quincke spinal needle. After confirming free flow of cerebrospinal fluid, 2.2ml of 0.5% hyperbaric bupivacaine was given in the subarachnoid space at the rate of 1ml/10 seconds. Parturients were made supine after putting a sterile gauze over the skin at the lumbar puncture site. Time of intrathecal drug deposition noted and the haemodynamic parameters were recorded. All the parameters were observed and recorded at baseline then at every two minutes ten time then after 20 minutes, recording was made every 5 minutes during intra-operative period.<sup>19</sup> Same haemodynamic parameters were also assessed after surgery.<sup>19</sup> Other parameters were also recorded like height of sensory block (by pin-prick with blunt needle from below upwards) after five minutes of SAB, duration of surgery, amount of intra operative blood loss, total requirement of IV mephenteramine, need of IV atropine to treat bradycardia, and Apgar score (Appearance, Pulse, Grimace, Activity, and Respiration) of the neonate (at birth, at one minute, and at five minutes).

## Statistical Analysis

Data collected were recorded in tabular form using Microsoft excel 365. Descriptive analysis was done to analyse the data. Unpaired t test was used to test the significance of difference among continuous data and chi-square test was used to test significance of difference between categorical data. P-value less than 0.05 was taken as significant.

## RESULTS

More events of hypotension were observed in saline group (74%) than granisetron group (34%) with statistically significant difference (p<0.001).

**Table 1:** Incidence of hypotension

	Saline Group (%, n=50)	Granisetron Group (%, n=50)	P- value (chi- square)
	Number of patients with no event of hypotension	13 (26%)	33 (66%)
Number of patients with event of hypotension	37 (74%)	17 (34%)	
Total	50	50	

Mephentermine was used more frequently than in saline group as compared to granisetron group. Atropine was not required in either patient.



**Table 2:** Use of mephenteramine and atropine

	Saline Group (mean ± SD)	Granisetron Group (mean ± SD)	P – value (Chi-square)
Total Mephenteramine used in milligram /number of patients	13.37 ± 7.21	8.29 ± 3.07	
Total atropine used in milligram /number of patients	Not used	Not used	--

**Table 3:** Comparison of systolic blood pressure between the two study groups

	Saline Group (mean ± SD)	Granisetron Group (mean ± SD)	P Value (unpaired t test)
T0	127.40±5.308	128.13±7.82	0.447
T1	122.80±5.18	125.60±9.83	0.330
T2	118.20±5.88	120.73±9.05	0.485
T3	115.46±6.078	116.53±8.64	0.002
T4	112.70±5.22	113.46±8.05	0.035
T5	110.73±5.023	110.66±12.63	0.120
T6	112.40±4.76	111.20±12.60	0.002
T7	117.20±6.35	112.13±11.63	0.101
T8	117.33±6.48	116.40±10.6	0.119
T9	120.80±8.49	117.13±9.493	0.105
T10	117.21±6.48	116.39±10.8	0.001
T11	118.21±6.41	117.31±10.20	0.193
T12	119.25±6.45	118.35±10.15	0.114
T13	120.70±8.39	117.02±9.483	0.127
T14	120.80±8.49	117.13±9.493	0.105
T15	122.46±7.137	116.00±9.82	0.061
T16	120.80±8.49	115.13±9.493	0.065
T17	121.46±8.01	116.93±8.30	0.072

T0 - Baseline / Pre-spinal values, T1-T10 - Values at every 2 minutes interval after spinal anesthesia for 20 minutes, T11-T17 - values at every 5 minutes interval from 20 minutes onwards after spinal anesthesia

**Table 4:** Comparison of diastolic blood pressure between the two study groups

	Saline Group (mean ± SD)	Granisetron Group (mean ± SD)	P Value (unpaired t test)
T0	81.80±3.12	81.46±6.51	0.048
T1	81.80±3.12	78.53±7.314	0.028
T2	80.33±3.11	76.26±8.415	0.111
T3	76.80±3.34	72.53±8.06	0.080
T4	72.66±2.98	72.00±8.18	0.677
T5	71.60±5.10	68.33±12.36	10.00
T6	70.46±3.98	70.13± 7.62	0.385
T7	73.00±6.09	70.46±6.31	0.066
T8	73.20±5.39	72.33±12.09	0.721
T9	73.33±5.73	72.86±10.52	0.832
T10	74.40±5.96	73.23±11.90	0.627
T11	75.66±4.95	73.63±12.40	0.408
T12	75.93±6.180	74.86±13.65	0.004
T13	73.33±5.73	72.86±10.52	0.832
T14	73.20±5.39	72.33±12.09	0.721
T15	73.00±6.09	68.33±12.36	0.086
T16	73.33±5.73	72.86±10.52	0.832
T17	74.40±5.96	73.23±11.90	0.627

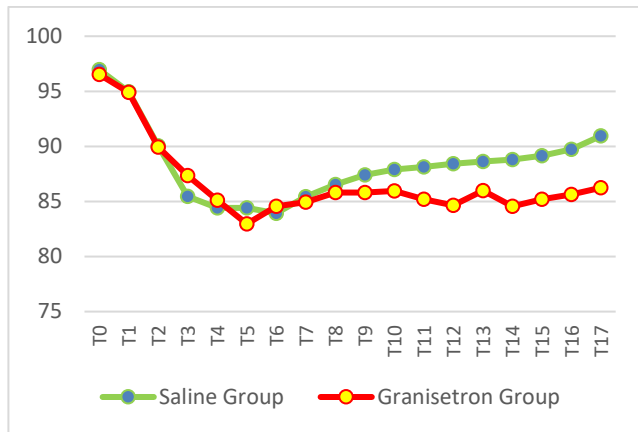
T0 - Baseline / Pre-spinal values, T1-T10 - Values at every 2 minutes interval after spinal anesthesia for 20 minutes, T11-T17 - values at every 5 minutes interval from 20 minutes onwards after spinal anesthesia

**Table 5:** Comparison of Mean arterial pressure between the two study groups

	Saline Group (mean ± SD)	Granisetron Group (mean ± SD)	P Value (unpaired t test)
T0	96.96±4.97	96.53±8.43	0.838
T1	94.96±4.95	94.89±6.37	0.946
T2	90.06±6.38	89.93±4.96	0.928
T3	85.46±4.52	87.36±7.76	0.251
T4	84.40±4.87	82.96±6.93	0.908
T5	84.42±3.86	85.10±7.70	<b>0.003</b>
T6	83.93±4.60	84.56±6.11	0.043
T7	85.42±3.86	84.93±11.0	0.274
T8	86.53±3.94	85.80±9.46	0.180
T9	87.90±3.90	85.94±7.06	<b>0.001</b>
T10	87.40±3.85	85.80±9.46	0.081
T11	88.12±3.96	85.20±8.64	0.093
T12	89.14±4.94	85.20±8.82	0.081
T13	88.62±4.82	85.98±8.60	0.112
T14	88.79±4.92	84.56±6.11	0.115
T15	88.43±4.86	84.63±8.97	<b>0.001</b>
T16	89.73±5.53	85.63±8.97	0.081
T17	90.96±4.97	86.24±8.60	0.083



T0 - Baseline / Pre-spinal values, T1-T10 - Values at every 2 minutes interval after spinal anaesthesia for 20 minutes, T11-T17 - values at every 5 minutes interval from 20 minutes onwards after spinal anaesthesia



**Figure 1:** Comparison of Mean arterial Blood pressure between the two study groups

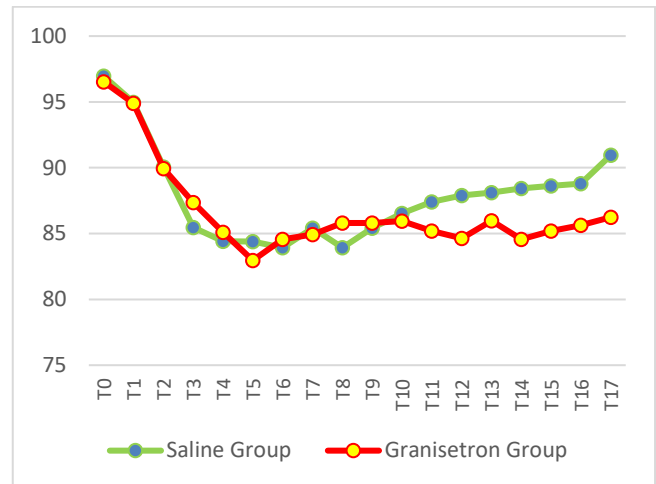
On comparing mean arterial pressure between two groups, we found statistically significant difference at T5, T9 and T15 (P<0.05). Overall, better control was observed in saline group with regard to mean arterial pressure.

**Table 6:** Comparison of Heart Rate between the two study groups

	Saline Group (mean ± SD)	Granisetron Group (mean ± SD)	P Value (unpaired t test)
T0	96.96±4.97	96.53±8.43	0.838
T1	94.96±4.95	94.89±6.37	0.946
T2	90.06±6.38	89.93±4.96	0.928
T3	85.46±4.52	87.36±7.76	0.251
T4	84.42±3.86	85.10±7.70	<b>0.003</b>
T5	84.40±4.87	82.96±6.93	0.908
T6	83.93±4.60	84.56±6.11	0.043
T7	85.42±3.86	84.93±11.0	0.274
T8	86.53±3.94	85.80±9.46	0.180
T9	87.40±3.85	85.80±9.46	0.081
T10	87.90±3.90	85.94±7.06	<b>0.001</b>
T11	88.12±3.96	85.20±8.64	0.093
T12	88.43±4.86	84.63±8.97	<b>0.001</b>
T13	88.62±4.82	85.98±8.60	0.112
T14	88.79±4.92	84.56±6.11	0.115
T15	89.14±4.94	85.20±8.82	0.081
T16	89.73±5.53	85.63±8.97	0.081
T17	90.96±4.97	86.24±8.60	0.083

T0 - Baseline / Pre-spinal values, T1-T10 - Values at every 2 minutes interval after spinal anaesthesia for 20 minutes,

T11-T17 - values at every 5 minutes interval from 20 minutes onwards after spinal anaesthesia



**Figure 2:** Comparison of Heart Rate between the two study groups

On comparing mean arterial pressure between two groups, we found statistically significant difference at T4, T10 and T12 (P<0.05). Overall, better control was observed in saline group with regard to mean arterial pressure.

No significant difference between two groups was recorded with respect to height of sensory block (p>005). Similarly, both groups were comparable with respect to duration of surgery, intra-operative and post-operative complications.

We also compared Apgar score to compare neonatal outcome between two groups and found no significant differences.

**DISCUSSION**

Regional anaesthesia remains the preferred choice and safe method for caesarean delivery across the world. However, it has its own set of complication including hypotension and bradycardia. Hypotension is the physiological impact of spinal anaesthesia and can have potential harmful maternal and foetal effect. Several methods such as preloading with IV fluids, physical methods like positioning and pharmacological agents are being used to prevent and treat this adverse effect of SAB. Different Pharmacological agents such as mephenteramine, phenylephrine and ephedrine apart from crystalloid preloading is being used over past years. Numerous studies have been done to show the efficacy of each of these pharmacological agents in treating hypotension post SAB.

Prevention of post spinal hypotension and its adverse effect in parturients remains a concern for the anaesthesia practitioner and an effective and safe prophylactic pharmacological agent will be ideal for this purpose. With the introduction of 5-HT3 receptor antagonist in clinical practice, several studies are being conducted over past few years to explore these agents as an option for treating post spinal hypotension. Various articles have been published



showing the efficacy of both ondansetron and Granisetron for management of post-spinal hypotension. However, some studies have found that Granisetron is not much effective for this very purpose. In our study we have tried to address this issue. We have conducted a prospective, randomized, double-blind study with the aim to study the effectiveness of intravenous Granisetron (1mg) in prevention of hypotension in parturients undergoing elective caesarean under spinal anaesthesia.

In our study we observed that 74% of parturients of saline group developed hypotension after spinal anaesthesia whereas only 34% of parturients had hypotension in Granisetron group and this difference was statistically significant with a p-value <0.01 (table 1).

In a similar study, Eldaba et al. also reported a statistically significant difference with 3% occurrence of hypotension in the Granisetron group whereas it was 64% in the normal saline group.<sup>13</sup> Megahed et al. and Sayed et al. also observed significantly less incidence of hypotension when patients were given Granisetron or ondansetron as compared to normal saline.<sup>15,20</sup>

In the present study mean dose of intravenous mephenteramine for the treatment of hypotension was significantly low in Granisetron group compared to Saline group (Table 2). Mohammedi et al. reported that there was no any significant difference between the two study groups in relation to the need for vasopressor for management of post-spinal hypotension, however they utilized a higher dose of Granisetron (3mg) in their study. Mohammedi et al. did not take factors like level of sensory block and type of intravenous fluids used into consideration, which could have affected the pathophysiology of hypotensive episodes in the perioperative period.<sup>14</sup>

Baseline systolic blood pressure between the two study groups was similar in this study. After administration of spinal anaesthesia, systolic blood pressure at different time points was comparable between the two groups except for measurements at 6 minutes, 8 minutes, 12 minutes, 20 minutes, and 30 minutes. Various authors have studied the onset and duration of post-spinal hypotension and have observed hypotension occurring after three minutes of SAB and this hypotension persisting throughout the intra-operative period.<sup>21,22</sup> Comparing the above two findings, this study showed that the decrease in SBP was greater in the saline-treated group up to 30 minutes after SAB, and Granisetron had a beneficial effect against the decrease in SBP after SAB. Diastolic blood pressure between the two groups was comparable throughout the study except at minute 30, which showed that granisetron had a negligible effect on diastolic blood pressure compared to systolic blood pressure. Saberi et al. observed similar results for diastolic blood pressure.<sup>18</sup>

In this study, baseline mean arterial blood pressure was comparable between granisetron group and saline group. After SAB administration, the difference in mean arterial

blood pressure between the two groups was significantly different at 8, 12, 20, and 30 minutes, which was similar to the change in systolic blood pressure between the two groups at the same time interval. Mean arterial blood pressure takes into account both systolic blood pressure and diastolic blood pressure. Because diastolic blood pressure did not show a significant difference between the two groups, the changes that occurred in systolic blood pressure appeared in a similar manner, and we observed similar significant changes in mean arterial blood pressure. Eldaba et al. also concluded that granisetron significantly reduced the fall in mean arterial blood pressure when used as premedication before spinal anaesthesia for caesarean section and observed a prolonged mean time to onset of hypotension in the granisetron group (16 minutes) in compared to the saline group (seven minutes).<sup>13</sup>

In our study, the baseline heart rate was comparable in both groups. After SAB, the heart rate trend showed a non-significant difference between granisetron group and saline group throughout the study period. Our findings of heart rate change were similar to those of Lamichhane et al. although they used higher doses of granisetron in their studies, they did not see significant changes in heart rate.<sup>17</sup>

In our study, we found no episode of significant bradycardia in any of the groups, and therefore intravenous atropine was not necessary. However, Eldaba et al. found a significant difference in the incidence of bradycardia, i.e., more parturient in the saline group had bradycardia compared to the granisetron group and concluded that granisetron given before spinal anaesthesia reduced the incidence of bradycardia, probably due to inhibition of the Bezold-Jarisch reflex.<sup>13</sup>

There is high prevalence of hypotension after spinal anaesthesia. This risk is even greater during caesarean section surgery as compared to other surgeries with some study reporting it to be as high as 50-60% in obstetric surgeries.<sup>1,2</sup> This risk can be affected by many determinants before the surgery. For better analysis of this issue, total duration of surgery, blood loss during surgery, height of sensory block and other possible intra-operative procedure were also assessed and compared in our study.

The frequency of hypotension is greater specially in obstetric surgery when sensory block at level T4 or higher is achieved with spinal anaesthesia. At the block at this level, there is greater block in sympathetic outflow which is major determinant of haemodynamic parameters in subarachnoid block.<sup>21</sup> Therefore, monitoring of level of sensory block is essential in intraoperative period after spinal anaesthesia.

Haemodynamic parameters are also affected by intra-operative blood loss which can lead to hypotension and tachycardia. Therefore, association of blood loss during surgery and events of hypotension was also analysed in our study. However, no significant findings were observed in both groups.

We also compared Apgar score to compare neonatal outcome between two groups and found no significant differences. The Apgar score is used in the assessment of condition of neonates soon after birth and is frequently used tool for standard examination.<sup>23</sup> Similar findings were reported in study conducted by eldaba et al. where no significant impact of granisetron on Apgar score was confirmed.<sup>13</sup>

Our study had certain limitation also. One of limitations of our study was limited number of patients (50 in each group), need more extensive study with large number of patients. The carry-over effects of previous medication, comorbidities and drug interactions between concurrent medications were not taken into consideration. Exhaustive study designs are needed to analyse these relations effectively.

## CONCLUSIONS

Hypotension is major limiting factor for most commonly used anaesthesia technique for lower segment caesarean section which is subarachnoid block or spinal anaesthesia. Our study results showed that granisetron is effective in decreasing incidence of hypotension in parturients undergoing elective caesarean section under spinal anaesthesia in addition to its anti-emetic effect which is its main indication without any risk of significant intra-operative or post-operative negative outcomes.

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