



EFFECT OF INTRAVENOUS ONDANSETRON PREMEDICATION ON SPINAL ANESTHESIA INDUCED HYPOTENSION IN CESAREAN SECTION - A RANDOMIZED CONTROLLED STUDY.

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ABSTRACT **Background:-** Spinal anesthesia is the most common anaesthesia technique for cesarean section. In this technique injection of a local anesthetic agent is injected into the subarachnoid space. The most common complication of spinal anesthesia is hypotension which is due to sympathetic blockade and activation of the Bezold Jarisch reflex which leads to the utilization of higher doses of vasopressors for the maintenance of blood pressure. The present study was conducted to compare the effect of intravenous ondansetron premedication on spinal anesthesia-induced hypotension with normal saline. **methodology:-**An observational study was conducted in 180 term parturients of ASA - II, scheduled for elective LSCS under spinal anesthesia. The patients were divided into two equal age groups: ondansetron 4mg (group O, n=90) and saline group (group S, n=90). Ondansetron 4mg (2ml) was given 10 min before the procedure in group O and group S received 2ml normal saline. Under all aseptic precautions, subarachnoid space was accessed through L3-L4 or L4-L5 intervertebral space using 25G Quincke's spinal needle. After confirmation of the free flow of CSF, a 2ml hyperbaric injection of bupivacaine 0.5% (Heavy) was administered in the subarachnoid space. Mean arterial pressure less than 65mmHg was considered as hypotension and treated with iv mephentermine 6mg bolus. **Result-** The Occurrence of hypotension in Group O (22.22%) was significantly lower than in group S (61.11%) (p<0.001). The MAP was significantly higher in Group O at 2,4,6,8,10,12,14,16,20 and 25 minutes (p<0.005). 18 (20%) patients required one dose of mephentermine 6mg, and 2(2.22%) patients required two doses in group O. In group S 40 patients ((44.44%) required one dose of mephentermine 10 patients ((11.11%)) required two doses and 5 patients (5.55%) required 3 doses. In group O 3 patients (3.33%) and in group S, 12 patients (13.33%) had nausea which was statistically significant with a P value of 0.01. In group S 12 patients (13.33%) and 4 patients (4.44%) in group O had shivering. Which was statistically significant with a P value of 0.03. **Conclusion –** Ondansetron is effective in preventing spinal-induced hypotension in elective cesarean section.

KEYWORDS : Ondansetron , Bezold Jarisch reflex , Hypotension, LSCS,

INTRODUCTION-

Spinal anesthesia is one of the most common regional anesthetic techniques used for cesarean section because it has an easy, fast, and reliable onset of anesthesia, minimum failure rates, minimum drug dose, and very good muscle relaxation during surgery. In parturients, spinal anesthesia has the added advantage of minimum blood loss, clinically insignificant neonatal drug transfer, circumvents the risks of airway manipulation during general anesthesia, and the mother remains awake to experience childbirth the most memorable moment in her life. Hypotension during spinal anesthesia results due to sympathetic blockade leading to reduced preload and afterload, causing lower maternal mean arterial blood pressure, as well as due to activation of Bezold Jarisch reflex (BJR). Studies found that 5-HT₃ antagonists block BJR, and Ondansetron, a 5-HT₃ receptor antagonist is effective in attenuating the hypotension in parturients undergoing cesarean deliveries followed by spinal anesthesia. This study was conducted to evaluate the effect of ondansetron in preventing hypotension induced by spinal anesthesia in parturients undergoing elective cesarean deliveries.

Methodology

The present study "Effect of intravenous ondansetron premedication on spinal anesthesia induced hypotension in cesarean section – A randomized controlled study" was conducted in the department of anaesthesiology and pain management, Pt. J.N.M. Medical College and Dr. B.R.A.M. Hospital, Raipur (C. G.) after approval from Institutional Scientific & Ethics Committee registration in Clinical Trials Registry of India (CTRI/2022/04/041661).

A total of 180 parturients, 18- 40 years of ASA physical status –II, having term pregnancy were included in this study. All the parturients were informed about the anesthesia technique and study design & then written informed consent was taken. All the selected parturients were randomized into two groups O and S by using a random no. table.

As per the protocol of our institute, all parturients fasted for 6 hours

before surgery. On arrival at the operation theatre, the parturient was taken in a supine position. Routine multipara monitors were attached & baseline HR, NIBP, pulse oximetry & ECG were recorded. Ondansetron 4mg (2ml) was given 10 min before the procedure in group O and group S received 2ml normal saline.

The parturient was placed in left lateral decubitus and under all aseptic precautions subarachnoid space was accessed through L3-L4 or L4- L5 intervertebral space using 25G/26 G Quincke's spinal needle. After confirmation of the free flow of CSF, a 2ml hyperbaric injection of bupivacaine 0.5% (w/v) was administered in the subarachnoid space. Surgery was started once the T6 level of sensory block was achieved. Assessment of neonate was performed by the Apgar score at 1 min and 5 min. Bolus intravenous injection of mephentermine (6mg) was given on the development of hypotension, (i.e. decrease MAP less than 65 mmHg). Bradycardia, a fall in heart rate below 50 per minute was treated with IV atropine 0.6mg & these parturients were excluded from the study

Statistical Analysis

After completion of the study all the recorded datas were collected and presented as a percentage, proportion, mean, and standard deviation(SD). Datas were analyzed using paired /unpaired "t" tests, chi-square test was used to assess the statistical difference between the two groups.

In the present study p value <0.05 at a 95% confidence interval was considered significant.

OBSERVATION AND RESULT

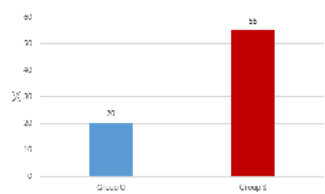
TABLE -1

	Group O	Group S
Age (Mean ± SD)	25.8±1.89	25.62±1.74
Weight(kg)	58.02±6.41	57.66±6.15
Height(cm)	156.08±5.86	156.19±5.58

TABLE -2 CONSUMPTION OF NO. OF BOLUSES OF VASOPRESSOR (Mephentermine)

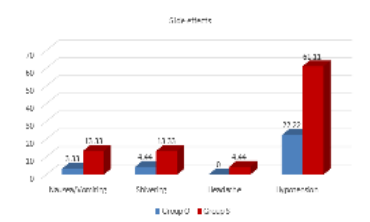
Doses of Mephentermine (No. of Bolus)	Group O	% Of Patients	No. of boluses of Mephentermine	Group S	% Of Patients Requiring boluses	No. of boluses of Mephentermine	P value
0	70	77.77%	0	35	38.8%	0	0.001
1	18	21.11%	18	40	44.44%	40	0.004
2	2	2.22%	4	10	11.11%	20	0.016
3	0	0	0	5	5.55%	15	0.023
Total	90	100%	22	90	100%	75	

GRAPH -1



Graph-1 Incidence of hypotension.

GRAPH -2 INCIDENCE OF SIDE EFFECTS AND COMPLICATIONS



The demographic data of this two group are comparable. There was no significant difference in age, height, and weight between the two groups (Table 1). The incidence of hypotension in the ondansetron group was 22.22% as compared to 61.11% in the normal saline group (Graph- 1). The SBP, DBP, and MAP were significantly higher in the ondansetron group as compared to the normal saline group (at 2, 4, 6, 8, 10, 14, 16, 18, 20, and 25 minutes) after the administration of spinal anesthesia. No statistically significant difference was found between the heart rates in the ondansetron group and the normal saline group. No episodes of bradycardia were observed in either group. 20 patients in the ondansetron group and 55 patients in the normal saline groups required boluses of intravenous mephentermine for correction of hypotension. 18 (20%) patients required one dose of mephentermine 6mg, and 2(2.22%) patients required two supplemental doses in group O. In group S 40(44.44%) patients required one dose of mephentermine, 10(11.11%) patients required two doses and 5(5.55%) patients required 3 doses. A total of 20(22.22%) and 55(61.11%) patients required mephentermine in Group O and Group S respectively with a significant P value of <0.001. 3 patients complained of nausea in the Ondansetron group compared to 12 patients in the Normal saline group. The difference in nausea between the two groups was statistically significant (p-value 0.015) (Graph-2) In group S 12 (13.33%) patients and 4(4.44%) patients in group O had shivering. Which was statistically significant with a P value of 0.03. In both, study groups none of the patients had any episodes of vomiting. The mean APGAR Score at 1-minute and 5 minutes interval in the ondansetron group were 7.59 ± 0.49 and 8.98 ± 0.15 and the normal saline group was 7.58 ± 0.50 and 8.97 ± 0.18.

DISCUSSION

Hypotension is the most common complication after spinal anaesthesia. Parturients are more prone to develop hypotension after spinal anesthesia. Hypotension occurs mostly due to sympathetic blockade, compression of the great vessel by the gravid uterus, decrease venous return, and activation of the bezold-jarisch reflex. To prevent hypotension following spinal anesthesia different techniques are used like preloading and co-loading with ringer lactate. Ondansetron is a 5 HT₃(5-Hydroxytryptamine) receptor antagonist. It

prevents activation of BJR and attenuates the hypotension in parturients undergoing cesarean deliveries followed by spinal anesthesia. In our study, we found that prophylactic administration of 4 mg of ondansetron was effective in preventing hypotension in parturients undergoing elective cesarean section under spinal anesthesia. Hypotension for this study was defined as the MAP less than 65 mm of Hg. Sahoo et al⁹, and Wang Q et al¹⁵ also observed a decreased incidence of hypotension after prophylactic administration of intravenous ondansetron in a patient undergoing surgery under spinal anesthesia. The incidence of hypotension in the ondansetron group was less as compared to the saline group in those reported above studies.

Owczuk et al⁸ observed that prophylactic use of intravenous ondansetron 8mg is effective in attenuating the drop of systolic and mean blood pressure after spinal anesthesia but does not show an effect on diastolic blood pressure or heart rate. Meng Wang et al¹ evaluate 4 different dosages of intravenous ondansetron, (2, 4, 6, and 8 mg), and found 4 mg intravenous ondansetron was the optimal dose to prevent hypotension in parturients who were undergoing cesarean section under spinal anesthesia. Potdar et al⁷ compared two different doses of ondansetron 4mg and 8 mg with normal saline and found that ondansetron reduced the incidence of spinal anesthesia-induced hypotension but the duration of effect lasted for up to 10 min. they also observed that increasing the dose of ondansetron 4mg to 8 mg does not benefit in terms of reduced incidence of hypotension.

In our study, the consumption of mephentermine was significantly lesser in the parturients who received prophylactic ondansetron compared to the normal saline group. T.Sahoo et al⁹, Tatikonda et al¹², Walid Trabelsi et al¹³, Potdar et. al⁷, and Bhiwal et al(2021)² also observed that requirement of vasopressor consumption was significantly less in the patients who received prophylactic ondansetron compared to the normal saline group. The reduced incidence of hypotension is the primary cause of less requirement of vasopressor for correction of hypotension. Bradycardia was not observed in any of the participants in our study.

In our study incidence of nausea in the ondansetron group was 3.33%, compared to 13.33%, in the normal saline group (p= 0.01), T.Sahoo et al⁹, Tatikonda et al¹², Walid Trabelsi et al¹³ also observed reduced incidence of nausea in a patient who received ondansetron compared to normal saline. None of the patients in either of the study groups vomited. In group S 12 (13.33%) patients and 4(4.44%) patients in group O had shivering (p-value -0.03).

In our study, there is no significant difference in the APGAR scores of the newborn at 1 minute and 5 minutes respectively in the ondansetron group and the normal saline group. Trabelsi et al¹³ found that ondansetron can be helpful to improve the metabolic and vital parameters of the newborn. Pasternak B et al⁶ observed that exposure to ondansetron in pregnancy was not associated with a significantly increased risk of spontaneous abortion, stillbirth, any major birth defect, preterm delivery, or infant born with low birth weight.

CONCLUSION

In our study, we concluded that premedication with intravenous ondansetron effectively decreases the incidence of hypotension amongst the parturients undergoing elective cesarean section under spinal anesthesia. The requirement of vasopressor i.e. intravenous mephentermine was also fewer amongst the parturients and was not associated with any neonatal side effects too as per the APGAR score.

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