

ORIGINAL RESEARCH

A comparative study of injection ondansetron and palonosetron intravenously on haemodynamic parameters and post operative nausea and vomiting

¹Dr. Sagar Duseja, ²Dr. Aditi Dugaya, ³Dr. Sarita Gohiya, ⁴Dr. Anshumann Dutta

^{1,2,3,4}Department of Anaesthesia, Sri Aurobindo Institute of Medical Sciences, Indore, Madhya Pradesh, India

Corresponding Author

Dr. Sagar Duseja

Department of Anaesthesia, Sri Aurobindo Institute of Medical Sciences, Indore, Madhya Pradesh, India

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Abstract

Background: Comparison of the effect of injection ondansetron and palonosetron intravenously on haemodynamic parameters and post operative nausea and vomiting. **Materials & methods:** A total of 120 patients aged between 18-60 years scheduled for emergency and elective minor surgeries were selected randomly. Patients were divided into two groups: GROUP O – Ondansetron group – 4- 8 mg, and GROUP P – Palonosetron group -0.0075 mg . All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. **Results:** Mean age of the patients of the Group O and Group P was 31.5 years and 30.1 years respectively. Mean height among the patients of the Group O and group P was 160.8 cm and 162.7 cm respectively. Mean weight among the patients of the Group O and group P was 69.7 Kg and 71.3 Kg respectively. Both the groups were comparable in terms of age and anthropometric variables. Incidence of postoperative nausea and vomiting was significantly higher among Group O in comparison to group P. While comparing the hemodynamic response in between the two study groups at different time intervals, non-significant results were obtained. **Conclusion:** Palonosetron is more effective than ondansetron in patients undergoing surgery under spinal anesthesia. However, considering the small sample size and homogenous nature of surgery and anesthesia, the authors believe that further studies with larger sample size need to be undertaken.

Key words: Palonosetron, Ondansetron, Anesthesia

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INTRODUCTION

Nausea and vomiting are common complaints seen by emergency department physicians and primary care clinicians daily. Ondansetron is on the World Health Organization's (WHO) List of Essential Medicines, a list of medications considered effective and safe in meeting the essential needs of a health care system. Other antiemetics that appear on this list with ondansetron include dexamethasone and metoclopramide. Ondansetron has widespread utility as an antiemetic drug and is effective against nausea and vomiting of various etiologies.^{1- 3} Ye et al., demonstrated that ondansetron, a specific 5-HT antagonist, blocks Na channels in rat brain neurons. They also found that ondansetron is 15 times more potent than lidocaine in causing numbness when injected under the skin. Ondansetron has been showed

to be an effective alternative. Recently, some studies demonstrated that ondansetron is a well-established agent for prevention of postoperative nausea and vomiting.^{4- 6}

Palonosetron, the newest agent in the 5-HT₃RA class of drugs, has a strong binding affinity to 5-HT₃ receptors and thus selectively blocks serotonin from binding to these receptors peripherally and centrally. It has little or no affinity for other receptors. Palonosetron is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderate to highly emetogenic cancer chemotherapy. Compared with earlier 5-HT₃ RAs, palonosetron has unique pharmacokinetic properties. After administration in healthy subjects and cancer patients, slow elimination from the body occurs after an initial decline in plasma

levels.⁷Hence; the present study was conducted for comparing the effect of injection ondansetron and palonosetron intravenously on haemodynamic parameters and post operative nausea and vomiting.

MATERIALS & METHODS

The present study was conducted for comparing the effect of injection ondansetron and palonosetron intravenously on haemodynamic parameters and post operative nausea and vomiting. This study was carried out at the Department of Anaesthesiology and Critical Care, Sri Aurobindo Institute Of Medical Sciences Hospital, Indore (M.P). After Ethical committee clearance, a total of 120 patients aged between 18-60 years scheduled for emergency and elective minor surgeries were selected randomly. An informed written consent was taken from all the patients relatives in groups after the approval of institutional ethical committee and as per inclusion and exclusion criteria. Routine investigations were done. Written informed consent was obtained. Patients were advised Nil Orally for a period of 6-8 hours prior to surgery. Patients were divided into two groups: GROUP O – Ondansetron group – 4- 8 mg, and GROUP P – Palonosetron group -0.0075 mg . In group A, opiate free general anaesthesia was induced using Multimodal drug regime including- Dexmedetomidine, MgSO₄, Lidocaine with cis-

atracuronium as the muscle relaxant maintained with O₂ and N₂O . Drug dosing was done so as to maintain a BIS between 40-60. In group B, opiate free general anaesthesia was induced using Multimodal drug regime including- Dexmedetomidine, MgSO₄, Lidocaine with cis-atracuronium as the muscle relaxant maintained with O₂ and N₂O drug dosing was done following the clinical signs such as loss of eyelash reflex and verbal response during induction and heart rate, BP and spo₂ during maintenance. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software.

RESULTS

Mean age of the patients of the Group O and Group P was 31.5 years and 30.1 years respectively. Mean height among the patients of the Group O and group P was 160.8 cm and 162.7 cm respectively. Mean weight among the patients of the Group O and group P was 69.7 Kg and 71.3 Kg respectively. Both the groups were comparable in terms of age and anthropometric variables. Incidence of postoperative nausea and vomiting was significantly higher among Group O in comparison to group P. While comparing the hemodynamic response in between the two study groups at different time intervals, non-significant results were obtained.

Table 1: Demographic data

Variable	Group P	Group O	p- value
Mean age (years)	30.1	31.5	0.12
Height (cm)	162.7	160.8	0.28
Weight (Kg)	71.3	69.7	0.34

Table 2: Postoperative nausea and vomiting

Variable	Group P		Group O	
	Number	Percentage	Number	Percentage
Postoperative nausea	3	5	10	16.67
p- value	0.00 (Significant)			
Postoperative vomiting	4	6.67	12	20
p- value	0.00 (Significant)			

Table 3: Comparison of heart rate at different time intervals

Heart rate	Group P	Group O	p-value
Baseline	79.2	78.4	0.42
Before induction	80.7	77.6	0.25
After induction	82.4	79.2	0.45
10 mins after induction	81.6	80.7	0.38
After extubation	80.3	79.3	0.81

Table 4: Comparison of SBP at different time intervals

SBP	Group P	Group O	p-value
Baseline	118.3	120.7	0.65
Before induction	120.7	122.3	0.88
After induction	122.3	121.7	0.16
10 mins after induction	121.8	120.3	0.23
After extubation	119.4	122.9	0.75

Table 5: Comparison of DBP at different time intervals

DBP	Group P	Group O	p-value
Baseline	78.3	80.3	0.46
Before induction	80.7	82.7	0.36
After induction	82.3	81.3	0.91
10 mins after induction	81.4	80.9	0.28
After extubation	79.3	52.9	0.34

Table 6: Comparison of SpO₂ at different time intervals

SpO ₂	Group P	Group O	p-value
Baseline	99.2	99.1	0.74
Before induction	98.6	99.5	0.38
After induction	99.4	98.3	0.16
10 mins after induction	98.4	99.3	0.38
After extubation	99.3	98.7	0.28

DISCUSSION

Palonosetron is a pharmacologically unique 5-HT₃RA approved by the US Food and Drug Administration and European Medicines Agency for the prevention of nausea and vomiting associated with moderately and highly emetogenic chemotherapy (CINV) as a single intravenous dose given before chemotherapy. Palonosetron can provide protection from emesis and nausea during both the acute and the delayed phases of CINV. It has a chemical structure that does not resemble the older 5-HT₃RAs and exhibits distinct binding properties and a unique interaction with the 5-HT₃ receptor. Ondansetron, a first-generation 5-HT₃ receptor antagonist, is widely used as an antiemetic, in varied post-operative settings and clinical situations.⁸ Hence; the present study was conducted for comparing the effect of injection ondansetron and palonosetron intravenously on haemodynamic parameters and post operative nausea and vomiting.

Mean age of the patients of the Group O and Group P was 31.5 years and 30.1 years respectively. Mean height among the patients of the Group O and group P was 160.8 cm and 162.7 cm respectively. Mean weight among the patients of the Group O and group P was 69.7 Kg and 71.3 Kg respectively. Both the groups were comparable in terms of age and anthropometric variables. In a previous study conducted by Sharma MK et al, authors reported that mean age, mean weight and mean height of the patients of group P was 28.1 years, 161.9 cm and 68.7 Kg respectively. In their study, mean weight and mean height of the patients of group P was 28.5 years, 162.4 cm and 67.3 Kg respectively.¹⁰

In the present study, incidence of postoperative nausea and vomiting was significantly higher among Group O in comparison to group P. While comparing the hemodynamic response in between the two study groups at different time intervals, non-significant results were obtained. Choudhary, J., et al evaluated the effects of two 5-HT₃ serotonin receptor antagonists; granisetron and palonosetron on hemodynamics, sensory, and motor blockade induced by intrathecal bupivacaine in patients undergoing abdominal hysterectomy. In total, 126 female patients

(ASA I and II physical status) undergoing abdominal hysterectomy under spinal anesthesia with intrathecal bupivacaine were randomly divided into three groups out of which 40 patients in each group were evaluated for final outcome. Group G received intravenous 1 mg granisetron, group P received intravenous palonosetron 0.075 mg, and group C received intravenous normal saline. The systolic blood pressure, diastolic blood pressure, mean arterial pressure, and heart rate showed no significant differences among the three groups. Time to reach peak sensory block and modified Bromage 3 motor block, time to two segmental regression of sensory block, and motor regression to modified Bromage score of 0 were not statistically different among the three groups. Although statistically significant early regression of sensory block to segment S1 was seen in group G as compared to group P and group C, it was of no clinical significance. The incidence of nausea and vomiting was significantly lower in group G and P.¹¹ Fonseca NM et al assessed the effect of the 5-HT₃ antagonist in postanesthetic antiemetic management of patients submitted to laparoscopic cholecystectomy with total intravenous anesthesia. Sixty individuals who underwent video cholecystectomy were randomized into three groups of 20 individuals according to the treatment administered: 0.125 mg of palonosetron (Group 1); 4 mg of ondansetron associated with 4 mg of dexamethasone (Group 2); 4 mg of dexamethasone (Group 3). Group 1 presented a lower incidence of PONV and required less rescue medication in the first postoperative hour. There was no significant difference among the three groups regarding PONV incidence in the first 12 postoperative hours. Groups 1 and 2 were superior to Group 3 regarding the control of PONV from 12 to 24 hours, and after rescue medication from 12 to 24 hours. Group 1 showed significantly superior nausea control in the first 12 postoperative hours. The study showed evidence that palonosetron is superior to the drugs compared regarding a protracted antiemetic effect and less requirement of rescue drugs, mainly related to its ability to completely inhibit the uncomfortable symptom of nausea.¹²

CONCLUSION

Palonosetron is more effective than ondansetron in patients undergoing surgery under spinal anesthesia. However, considering the small sample size and homogenous nature of surgery and anesthesia, the authors believe that further studies with larger sample size need to be undertaken.

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